Wednesday
May 12, 1993

Briefings on How To Use the Federal Register
For information on briefings in Washington, DC, and Philadelphia, PA, see announcement on the inside cover of this issue.
THE FEDERAL REGISTER

WHAT IT IS AND HOW TO USE IT


WHO: The Office of the Federal Register.

WHAT: Free public briefings (approximately 3 hours) to present:

1. The regulatory process, with a focus on the Federal Register system and the public's role in the development of regulations.
3. The important elements of typical Federal Register documents.

WHY: To provide the public with access to information necessary to research Federal agency regulations which directly affect them. There will be no discussion of specific agency regulations.

WASHINGTON, DC

WHEN: June 15 at 9:00 am
WHERE: Office of the Federal Register, 7th Floor Conference Room, 800 North Capitol Street NW, Washington, DC (3 blocks north of Union Station Metro)

RESERVATIONS: 202-523-4538

PHILADELPHIA, PA

WHEN: May 25, at 1:00 pm
WHERE: William J. Green, Jr.
Federal Building, Conference Room 6306–10, 600 Arch St.
Philadelphia, PA

RESERVATIONS: Federal Information Center
1-800-347–1997

How To Cite This Publication: Use the volume number and the page number. Example: 58 FR 12345.
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Free Electronic Bulletin Board service for Public Law numbers, Federal Register finding aids, and a list of Clinton Administration officials is available on 202–275–1538 or 275–0920.
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This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are key to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

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

FEDERAL DEPOSIT INSURANCE CORPORATION

12 CFR Part 329

RIN 3064-AA67

Interest on Deposits

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Final rule.

SUMMARY: The Board of Directors of the FDIC is amending its regulations on interest on deposits by removing the section pertaining to advertisements soliciting deposits by state nonmember banks. The section being removed has been superseded by regulations issued by the Board of Governors of the Federal Reserve System on September 21, 1992, to implement the requirements of the Truth in Savings Act.

EFFECTIVE DATE: June 21, 1993.

FOR FURTHER INFORMATION CONTACT: Mark A. Mellon, Attorney, Legal Division, FDIC, 550 17th St., NW., Washington, DC 20429, (202) 898-3854.

SUPPLEMENTARY INFORMATION: Paperwork Reduction Act

No collections of information pursuant to section 3504(b) of the Paperwork Reduction Act (44 U.S.C. 3501 et seq.) are contained in the final rule. Consequently, no information has been submitted to the Office of Management and Budget for review.

Regulatory Flexibility Act

Pursuant to section 605(b) of the Regulatory Flexibility Act (Pub. L. 96-354, 5 U.S.C. 601 et seq.), the final rule would not have a significant impact on a substantial number of small entities. The final rule is a technical amendment which imposes no recordkeeping, reporting or other compliance requirements on small entities.

Discussion

Section 329.3 of the FDIC’s regulations pertains to advertisements of insured state nonmember banks that solicit deposits. It requires that the interest rates listed in such advertisements be stated in terms of simple interest. If a percentage yield achieved by compounding interest over a year is stated in an advertisement, the annual rate of simple interest must also be stated. Percentage yields based on periods in excess of a year may not be used in advertisements. Time and amount requirements must be stated clearly and conspicuously.

Advertisements may not be inaccurate or misleading nor may they use the term “profit”. Persons who solicit deposits on the behalf of insured nonmember banks are bound by the rules of §329.3. If a penalty will be imposed for withdrawal of a deposit prior to its maturity, advertisements for such deposits must clearly and conspicuously state that such withdrawal will result in a substantial penalty.

The Truth in Savings Act (the TISA) (12 U.S.C. 4301 et seq., contained in the Federal Deposit Insurance Corporation Improvement Act of 1991, Public Law 102-242, 105 Stat. 2236) was enacted in December 1991. The TISA requires depository institutions to disclose fees, interest rates and other deposit account terms to consumers. It imposes restrictions on advertisements by depository institutions that solicit deposits. The Board of Governors of the Federal Reserve System (the Board of Governors) is given responsibility under the TISA to prescribe regulations that apply to all depository institutions.

The Board of Governors issued Regulation DD, 12 CFR part 329, to implement the TISA on September 21, 1992. 57 FR 43337, September 21, 1992. Amendments to Regulation DD were subsequently issued to incorporate minor changes to the regulation, to provide guidance on issues raised by depository institutions since publication of the final regulation, and to reflect changes made to the TISA by the Housing and Community Development Act of 1992 (Pub. L. 102-550, 106 Stat. 3672), 58 FR 15077, March 19, 1993. The regulations are effective on June 21, 1993. 12 CFR 230.2(a).

Regulation DD’s general advertising requirements meet or exceed the requirements set forth in §329.3 for advertisements soliciting deposits by state nonmember banks. For example, both regulations bar the use of the term “profit” and misleading or inaccurate statements in advertisements that solicit deposits. Compare id. §230.6(e) with id. §329.3(e) and (f). Both regulations apply the advertising rules to anyone advertising on behalf of depository institutions. Compare id. §230.1(c) with id. §329.3.

Regulation DD goes beyond §329.3 in precisely specifying the terminology and methods of calculation that must be used for the rate of return and other terms of an account in advertisements that solicit deposits. For example, Regulation DD says that accounts may not be advertised as “free” if maintenance or activity fees may be charged, a provision which §329.3 lacks. Id. §230.8(a). Regulation DD requires disclosure of minimum balances and minimum opening deposits, a statement that fees can reduce the earnings on an account, and a statement that rates on variable-rate accounts are subject to change—all matters that §329.3 does not cover. Id. §230.8(c). Regulation DD specifies how a bonus (a premium, gift or award worth more than $10 which is used to attract deposits) must be advertised, a topic which §329.3 does not address. Id. §230.8(d).

In one minor respect, §329.3 appears to establish a more stringent requirement than Regulation DD. Section 329.3 says that, if an institution imposes an early-withdrawal requirement with respect to a time deposit, any advertisement relating to interest paid on the deposit must contain a “clear and conspicuous statement” that a “substantial penalty” will be imposed in the event of early withdrawal. By contrast, Regulation DD only requires “a statement that a penalty will or may be imposed for early withdrawal.” Compare id. §230.8(c)(6)(ii) with id. §329.3(h). The FDIC considers, however, that the statement required under Regulation DD is adequate to protect the public interest in consumer protection, and accordingly that §320.8(b) is no longer needed.

The FDIC has concluded that, once effective, Regulation DD will supersede the FDIC’s regulation concerning the advertisement of deposits at id. §329.3. The FDIC therefore amends part 329 to
remove § 329.3 upon the effective date of Regulation DD (June 21, 1993). Since this is a purely technical amendment to remove a superseded regulation, notice and comment are unnecessary. See section 553(b)(B) of the Administrative Procedure Act, 12 U.S.C. 553(b)(B).

List of Subjects in 12 CFR Part 329
Advertising, Banks, banking, Interest rates.

For the reasons stated above, the Board of Directors of the FDIC amends Part 329, subchapter B, chapter III of title 12 of the Code of Federal Regulations as follows:
1. The authority citation for part 329 continues to read as follows:
Authority: 12 U.S.C. 1819, 1828(i) and 1832a.

§ 329.3 [Removed]
2. Section 329.3 is removed.

By order of the Board of Directors.

Dated at Washington, DC, this 4th day of May, 1993.

Robert E. Feldman,
Deputy Executive Secretary.

[FR Doc. 93-11155 Filed 5-11-93; 8:45 am]
BILLING CODE 8714-01-P

FARM CREDIT ADMINISTRATION
12 CFR Part 620
RIN 3052-AB40
Disclosure to Shareholders

AGENCY: Farm Credit Administration.

ACTION: Final rule.

SUMMARY: The Farm Credit Administration (FCA), by the FCA Board (Board), adopts a final rule amending its regulations to expand the options available to Farm Credit System (FCS) institutions to comply with the requirements of the directors' certification pertaining to quarterly reports. The proposed rule was published for comment on January 12, 1993 (58 FR 3672). The amendments to the regulations require certification by at least one of the following directors of the board of a filing institution on behalf of the entire board of the institution: The chairperson of the board; the chairperson of the audit committee; or a director designated by the chairperson of the board. After formal board action authorizing the designation, other board members of the institution may continue, but are no longer required, to certify quarterly reports or notices that no significant events have occurred since the previous quarter.

EFFECTIVE DATE: The regulation shall become effective upon expiration of 30 days after this publication in the Federal Register during which either or both Houses of Congress are in session. Notice of the effective date will be published in the Federal Register.

FOR FURTHER INFORMATION CONTACT: Tong-Ching Chang, Staff Accountant, Technical and Operations Division, Office of Examination, Farm Credit Administration, McLean, Virginia 22102-5090, (703) 883-4483, TDD (703) 883-4444, or William L. Larsen, Senior Attorney, Regulatory Operations Division, Office of General Counsel, Farm Credit Administration, McLean, Virginia 22102-5090, (703) 883-4020, TDD (703) 883-4444.

SUPPLEMENTARY INFORMATION: In connection with amendments to part 620, Disclosure to Shareholders, undertaken to implement the 1987 amendments (Pub. L. 100-233) to the Farm Credit Act of 1971 (1971 Act), 12 U.S.C. 2127(b)(6), the FCA amended § 620.2(b)(3) to require each member of the board of an FCS institution to certify quarterly reports filed with the FCA within 45 days after the end of each reporting quarter. See 56 FR 29412 (June 27, 1991). After the amended regulations became effective on September 10, 1991, the FCA received letters from several FCS institutions indicating that the requirement of § 620.2(b)(3) that each director certify the quarterly report is burdensome and makes it difficult for them to meet their quarterly report filing date. These institutions stated that due to the frequency and timing of their board meetings and the geographic dispersion of board members, directors do not have enough time to certify quarterly reports and still file the reports by the due dates required by the regulations.

To resolve these logistical and timing problems in the certification of quarterly reports, the FCA proposed to amend § 620.2(b)(3) by expanding the options available to institutions to comply with the quarterly report director certification requirements. The proposed amendment would require quarterly reports filed with the FCA to be certified by, at a minimum, one of the following directors on behalf of the entire board of the filing institution: (1) The chairperson of the board; (2) the chairperson of the audit committee; or (3) a board member designated by the chairperson of the board. Other directors of the filing institution would no longer be required to certify the quarterly reports filed with the FCA.

Under proposed § 620.2(b)(3), individual directors may continue to certify quarterly reports if they so choose, or, by formal board action, they may designate one or more directors to certify quarterly reports on behalf of other nonvoting members of the board. This could eliminate the need for each director to certify quarterly reports.

The comment period for the proposed amendments to § 620.2(b)(3) closed on February 11, 1993. The FCA received four letters commenting on the proposed regulations. Two FCS institutions within the Farm Credit Districts of Omaha and Columbia expressed their strong support for the proposed amendments and urged their adoption as proposed.

The Farm Credit Bank of Baltimore and the Farm Credit Council, on behalf of its membership, also commented in support of the proposed regulations, but suggested that a similar change be made to § 620.10(e)(3), which applies only to FCS banks. Under § 620.10(e)(3), for a given reporting quarter, if a majority of the board of directors of an FCS bank certifies to the FCA that no significant events have occurred that are likely to have a material impact on the bank's related associations that are direct lenders or that no significant events which occurred during the preceding quarters continue to materially affect the related associations, the bank can elect not to distribute its quarterly report to shareholders of the related associations for the quarter. The commenters believe that the considerations applicable to the amendment of § 620.2(b)(3) are equally applicable to § 620.10(e)(3). They suggested that if a single director can certify to the accuracy of an institution's quarterly report (as the proposed revision to § 620.2(b)(3) would allow), he/she should also be able to certify on behalf of the entire board that no significant events have occurred since the previous quarter.

The FCA concurs that considerations applicable to directors' quarterly report certification under §§ 620.2(b)(3) and 620.10(e)(3) are similar and that a corresponding change to § 620.10(e)(3) would alleviate logistical and timing problems currently encountered by the banks and their directors in certifying that no significant events have occurred during the quarter. The FCA also notes that under § 620.10(e)(5), bank quarterly reports will continue to be available on request to shareholders of related associations. Therefore, the FCA finds good cause to include amendments to § 620.10(e) in the final rule corresponding to the amendments to § 620.2(b)(3). Due to the similar nature of these amendments as discussed.
In response to the comments received and based on its consideration of director certification issues, the Board adopts the proposed amendments to §620.2(b)(3) along with amendments to §620.10(e) as described above. The Board believes that report certification helps ensure that directors maintain the level of awareness of the institution's activities and financial condition needed to carry out the board members' fiduciary responsibility as directors. While the board may delegate day-to-day operations to management, it remains responsible for ensuring that the institution operates within the board's prescribed policies, in compliance with applicable laws and regulations, and in a safe and sound manner. The designation permitted by these amendments to §§620.2(b)(3) and 620.10(e)(3) does not relieve directors of the need to be informed about their institution's activities and financial condition or of their accountability for the institution's affairs.

Whether directors certify the institution's periodic reports or not, all directors are responsible, to the best of their knowledge and belief, for ensuring that the reports are true, accurate, complete, and prepared in accordance with applicable laws and regulations. Accordingly, the boards of FCS institutions should have policies in place to ensure timely review by all directors prior to filing periodic reports. Within this framework of director responsibility, these new regulations are intended to alleviate the regulatory burden of FCS institutions and their directors without compromising the regulatory concern regarding directors' accountability embodied in the current requirements of §§620.2(b)(3) and 620.10(e)(3). The FCA notes that the amendment to §620.2(b)(3) does not alter the requirement that all directors certify annual reports.

List of Subjects in 12 CFR Part 620

Accounting, Agriculture, Banks, Banking, Credit, Organization and functions (Government agencies), Reporting and recordkeeping requirements, Rural areas.

For the reasons stated in the preamble, part 620 of chapter VI, title 12 of the Code of Federal Regulations is amended to read as follows:

PART 620—DISCLOSURE TO SHAREHOLDERS

1. The authority citation for part 620 is revised to read as follows:


Subpart A—General

2. Section 620.2 is amended by revising paragraph (b)(3) to read as follows:

§620.2 Preparing and filing the reports.

(b) * * *

(i) For each quarterly report filed under this section, each member of the board or, at a minimum, one of the following board members formally designated by action of the board to certify quarterly reports on behalf of individual board members: The chairperson of the board; the chairperson of the audit committee; or a board member designated by the chairperson of the board.  

(ii) For all other reports, each member of the board.

Subpart C—Quarterly Report to Shareholders

3. Section 620.10 is amended by revising paragraph (e)(3) and the concluding text of paragraph (e) to read as follows:

§620.10 Preparing and distributing the quarterly report.

(a) * * *

(iii) Each member of the board or, at a minimum, one of the following board members formally designated by action of the board to certify on behalf of individual board members: The chairperson of the board; the chairperson of the audit committee; or a board member designated by the chairperson of the board.

(ii) The name and position title of each person signing the certification shall be typed or printed beneath his or her signature. If any officer or any member of the board is unable to or refuses to sign the certification, the bank shall disclose the individual's name and position title and the reasons such individual is unable or refuses to sign the report. If a majority of the board of directors or its designee is unable or refuses to sign the certification, the bank must distribute its quarterly report to shareholders of related direct lender associations.


Curtis M. Anderson,
Secretary, Farm Credit Administration Board.

[FR Doc. 93-11148 Filed 5-11-93; 8:45 am]
BILLING CODE 6705-11-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 92-NM-215-AD; Amendment 39-8563; AD 93-08-15]

Airworthiness Directives; Airbus Industrie Model A320 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to certain Airbus Model A320 series airplanes, that requires modification of the inner rear spar web. This amendment is prompted by reports indicating that cracking was found in the inner rear spar web during fatigue testing. The actions specified by this AD are intended to prevent fatigue cracking, which may lead to reduced structural integrity of the main landing gear.


The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of June 11, 1993.

ADDRESSES: The service information referenced in this AD may be obtained from Airbus Industrie, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France. This information may be examined at the FederalAviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Greg Holt, Aerospace Engineer, Standardization Branch, ANM-113, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055-4056; telephone (206) 227-2140; fax (206) 227-1320.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations to include an airworthiness directive (AD) that is applicable to certain Airbus Model A320 series airplanes was published in the Federal Register on January 6, 1993 (58 FR 515). That action proposed to require modification of the inner rear spar web.
Interested persons have been afforded an opportunity to participate in the making of this amendment. Due consideration has been given to the comments received.

Two commenters support the proposed rule.

One commenter, Airbus Industrie, requests that the applicability be revised to include airplanes having manufacturer's serial numbers (MSN) 009 through 017, inclusive. As proposed, the rule would only be applicable to airplanes having MSN's 003 through 008, and 018 through 021. However, Airbus advises that the eight airplanes not included in the proposed applicability may also be subject to the addressed unsafe condition. The FAA concurs, and has revised the applicability of the final rule to include these additional airplanes. The eight additional airplanes currently are operated by non-U.S. operators under foreign registry; therefore, they are not affected directly by this AD action. However, the FAA considers that the revision to the applicability of the rule is necessary to ensure that the unsafe condition is addressed in the event that these subject airplanes are imported and placed on the U.S. Register in the future.

After careful review of the available data, including the comments noted above, the FAA has determined that air safety and the public interest require the adoption of the rule with the change previously described. The FAA has determined that this change will neither increase the economic burden on any operator nor increase the scope of the AD.

Currently, no airplanes of U.S. registry would be affected by this AD. However, should one of the affected airplanes be imported and placed on the U.S. register, it would take approximately 60 work hours per airplane to accomplish the required actions, and the average labor cost would be $55 per work hour. Based on these figures, the total cost impact of the proposed AD on U.S. operators is estimated to be $3,300 per airplane.

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12291, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this action (1) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it may be obtained from the Rules Docket at the location provided under the caption ADDRESSES.

List of Subjects in 14 CFR Part 39
Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

§ 39.13 [Amended]
2. Section 39.13 is amended by adding the following new airworthiness directive:

93-08-15 Airbus Industrie; Amendment 39-8563; Docket 92-215-AD.
Applicability: Model A320 series airplanes, manufacturer’s serial numbers (MSN) 003 through 008, inclusive, and 010 through 021, inclusive; certificated in any category.
Compliance: Required as indicated, unless accomplished previously.
To prevent fatigue cracking, which may lead to reduced structural integrity of the main landing gear, accomplish the following:
(a) Prior to the accumulation of 12,000 landings, or within 500 landings after the effective date of this AD, whichever occurs later, modify the inner rear spar web in accordance with Airbus Industrie Service Bulletin A320-57-1004, Revision 1, dated September 24, 1992.
(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Standardization Branch, ANM-113.
Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Standardization Branch, ANM-113.

Note: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Standardization Branch, ANM-113.

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

(d) The modification shall be done in accordance with Airbus Industrie Service Bulletin A320-57-1004, Revision 1, dated September 24, 1992, which includes the following list of effective pages:

<table>
<thead>
<tr>
<th>Page No.</th>
<th>Revision level shown on page</th>
<th>Date shown on page</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-3, 5-11, 13, 16, 19, 21-30</td>
<td>Original ...</td>
<td>July 9, 1991.</td>
</tr>
</tbody>
</table>

This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Airbus Industrie, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France.
Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(e) This amendment becomes effective on June 11, 1993.

Issued in Renton, Washington, on April 28, 1993.
Darrell M. Pederson,
Acting Manager, Transport Airplane Certification Service.
[FR Doc. 93-11210 Filed 5-11-93; 8:45 am]
BILLING CODE 4910-13-P

14 CFR Part 39

[Docket No. 93-93-30-AD; Amendment 39-8561; AD 93-08-13]

Airworthiness Directives; Airbus Industrie Model A300 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.
ACTION: Final rule; request for comments.

SUMMARY: This amendment adopts a new airworthiness directive (AD) that is applicable to certain Airbus Industrie Model A300 series airplanes. This action requires inspections of the fuselage skin above the modified lap joint at stringer 43 between frames 37 and 39, and measurement and repair of any damage found. This amendment is prompted by results of an investigation of significant crack damage to the fuselage skin on two Model A300 series airplanes, which were damaged...
Modification No.

involves replacing the skin panels in the installation of Airbus Industrie confirmed that the fuselage skin was nearly opposite each other. It appeared to be similar in nature, ran frames 38 inches) in length on the right-hand side, between frames 38 and 39. If no damage is found as a result of the eddy current inspection, this AD requires repetitive detailed visual inspections from outside the fuselage skin, and repair of any cracks found, until a detailed visual inspection from inside the fuselage skin is accomplished. If damage is found as a result of the eddy current inspection, this AD requires a detailed visual inspection from inside the fuselage skin. If damage is found as a result of any required inspection, that damage must be measured. If the damage does not exceed certain limits, repetitive detailed visual inspections from outside the fuselage skin are required until repair of the damage is accomplished. If the damage exceeds specified limits, this AD requires immediate repair of the affected area. The actions are required to be accomplished in accordance with the AOT described previously.

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

Comments Invited

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

Federal Register / Vol. 58, No. 90 / Wednesday, May 12, 1993 / Rules and Regulations 27925

accidentally during modification of these airplanes. The actions specified in this AD are intended to prevent failure of the fuselage skin, which could result in rapid loss of cabin pressure.


The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of May 27, 1993.

Comments for inclusion in the Rules Docket must be received on or before July 12, 1993.


The service information referenced in this AD may be obtained from Airbus Industrie, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.


SUPPLEMENTARY INFORMATION: The Direction Générale de l’Aviation Civile (DGAC), which is the airworthiness authority for France, recently notified the FAA that an unsafe condition may exist on certain Airbus Industrie Model A300 series airplanes. The DGAC advises that significant crack damage has been found on a Model A300 series airplane. The reported damage was located on the fuselage skin on both sides of the airplane, approximately 120 mm (4.7 inches) above the longitudinal lap joint at stringer 43. Visible cracks were 270 mm (10.6 inches) in length on the right-hand side, between frames 37 and 38, and 170 mm (6.7 inches) in length on the left-hand side, between frames 38 and 38.1. Both cracks, which appeared to be similar in nature, ran straight and horizontal and were located nearly opposite each other.

An investigation of these cracks has confirmed that the fuselage skin was damaged accidentally during the installation of Airbus Industrie Modification No. 6699 in accordance with Airbus Industrie Service Bulletin A300–53–216. That modification involves replacing the skin panels in the keel doubler area of sections 13 and 14. Scratches and notches were found on the skin inner face between frames 37 and 39 (four frame bays), where the internal wing doubler was trimmed to allow the installation of a new lower skin panel. The damage depth was between 0.3 mm (0.0118 inch) and approximately 1 mm (0.039 inch) in the area where the cracks went through the skin. The airplane had accumulated 1,065 hours time-in-service and 351 landings since modification.

Subsequently, Airbus Industrie recommended the inspection of a second airplane from the same operator’s fleet. The second airplane had been modified one month earlier than the airplane discussed previously. The inspection of the second airplane revealed the same type of accidental damage of the internal skin in the same area as that of the first airplane. The scratches and notches were 0.1 mm (0.0039 inch) to 0.75 mm (0.029 inch) deep and 60 mm (2.4 inches) to 210 mm (8.3 inches) long. This damage was located at the cut-line of the internal wing doubler.

Preliminary stress and fatigue calculations have shown that the accidental damage could lead to significant crack development. This condition, if not corrected, could lead to failure of the fuselage skin, which could result in rapid loss of cabin pressure.

Airbus Industrie has issued All Operator Telex (AOT) 53–04, dated January 20, 1993, that describes procedures for a low-frequency eddy current inspection from outside the fuselage skin above the modified lap joint at stringer 43 (left- and right-hand) between four frame bays at frames 37 and 39 to detect damage; repetitive detailed visual inspections from outside the fuselage skin, and repair of any cracks found, until a detailed visual inspection from outside the fuselage skin is accomplished. If damage is found as a result of the eddy current inspection, this AD requires a detailed visual inspection from inside the fuselage skin. If damage is found as a result of any required inspection, that damage must be measured. If the damage does not exceed certain limits, repetitive detailed visual inspections from outside the fuselage skin are required until repair of the damage is accomplished. If the damage exceeds specified limits, this AD requires immediate repair of the affected area. The actions are required to be accomplished in accordance with the AOT described previously.

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

Comments Invited

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

This airplane model is manufactured in France and is type certificated for operation in the United States under the provisions of Section 21.29 of the Federal Aviation Regulations and the applicable bilateral airworthiness agreement. Pursuant to this bilateral airworthiness agreement, the DGAC has kept the FAA informed of the situation described above. The FAA has examined the findings of the DGAC, reviewed all available information, and determined that AD action is necessary for products of this type design that are certificated for operation in the United States. Since an unsafe condition has been identified that is likely to exist or develop on other airplanes of the same type design registered in the United States, this AD is being issued to prevent failure of the fuselage skin, which could result in rapid loss of cabin pressure. This AD requires a low-frequency eddy current inspection from outside the fuselage skin above the modified lap joint at stringer 43 (left- and right-hand) between frames 37 and 39.

Effective May 27, 1993.
action and determining whether additional rulemaking action would be needed.

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

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket Number 93-NM-30-AD." The postcard will be date stamped and returned to the commenter.

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12512, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

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

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

93-06-13 Airbus Industrie: Amendment 39-8561. Docket 93-NM-30-AD.

Applicability: Model A300 series airplanes; MSN 003 through MSN 107, Inclusive; that have been modified in accordance with Airbus Industrie Service Bulletin A300-53-216 (Airbus Industrie Modification No. 6699); certificated in any category.

Compliance: Required as indicated, unless accomplished previously.

To prevent rapid loss of cabin pressure, accomplish the following:

(a) Within 50 landings after the effective date of this AD, perform a low-frequency eddy current inspection from outside the fuselage skin above the modified lap joint at stringer 43 (left- and right-hand) between frames 37 and 39 to detect damage, in accordance with Airbus Industrie All Operator Telex (AOT) 53-04, dated January 20, 1993.

(b) If no damage is found as a result of the inspection required by paragraph (a) of this AD, accomplish paragraphs (b)(1) and (b)(2) of this AD in accordance with Airbus Industrie All Operator Telex (AOT) 53-04, dated January 20, 1993.

(1) Perform a detailed visual inspection from outside the fuselage skin to detect damage in this area thereafter at intervals not to exceed 50 landings until the requirements of paragraph (b)(2) of this AD are accomplished. Prior to further flight, repair any crack that is found.

(2) Within 250 landings after accomplishing the initial (external eddy current) inspection, perform a detailed visual inspection from inside the fuselage skin to detect damage in this area. If no damage is found, no further action is required by this AD. If any damage is found, prior to further flight, measure the length and depth of the damage, and accomplish paragraph (b)(2)(i) or (b)(2)(ii) of this AD, as applicable.

(i) If the damage found is less than or equal to 0.7 mm in depth or 130 mm in length, and if no damage is found in adjacent frame bays, perform a detailed visual inspection from outside the fuselage skin thereafter at intervals not to exceed 50 landings. Prior to the accumulation of 250 landings after accomplishing the internal visual inspection, repair the damaged area in accordance with the AOT. Repair of the damaged area constitutes terminating action for the repetitive inspections required by this paragraph.

(ii) If the damage found is greater than 0.7 mm in depth or 130 mm in length, or if damage is found in the adjacent frame bays, prior to further flight, repair the damaged area in accordance with the AOT.

(c) If any damage is found as a result of the initial (external eddy current) inspection required by paragraph (a) of this AD, prior to further flight, perform a detailed visual inspection from inside the fuselage skin above the modified lap joint at stringer 43 (left- and right-hand) between frames 37 and 39 to detect damage, and measure the damage found in accordance with Airbus Industrie All Operator Telex (AOT) 53-04, dated January 20, 1993.

(1) If the damage found is less than or equal to 0.7 mm in depth and 130 mm in length, and if no damage is found in adjacent frame bays, perform a detailed visual inspection from outside the fuselage skin in this area thereafter at intervals not to exceed 50 landings. Prior to the accumulation of 250 landings after accomplishing the initial (external eddy current) inspection required by paragraph (a) of this AD, repair the damaged area in accordance with the AOT. Repair of the damaged area constitutes terminating action for the repetitive inspections required by this paragraph.

(2) If the damage found is greater than 0.7 mm in depth or 130 mm in length, or if damage is found in the adjacent frame bays, prior to further flight, repair the damaged area in accordance with the AOT.

(d) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Standardization Branch, ANM-113, FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Standardization Branch, ANM-113. Note: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Standardization Branch, ANM-113.

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

(f) The inspections, measurement, and repair shall be done in accordance with Airbus Industrie All Operator Telex 53-04, dated January 20, 1993. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. Copies may be obtained from Airbus Industrie, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(g) This amendment becomes effective on May 27, 1993.
14 CFR Part 39

[Docket No. 92–NM–36–AD; Amendment 39–8559; AD 93–08–12]

Airworthiness Directives; Boeing Model 747 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to certain Boeing Model 747 series airplanes, that requires repetitive inspections to detect cracks in various areas of the fuselage internal structure, and repair, if necessary. This amendment is prompted by results of fatigue tests that identified areas of the fuselage internal structure where fatigue cracks have occurred. The actions specified by this AD are intended to prevent loss of the structural integrity of the fuselage.


The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of June 11, 1993.

ADDRESSES: The service information referenced in this AD may be obtained from Boeing Commercial Airplane Group, P.O. Box 3707, Seattle, Washington 98124–2207. This information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Aircraft Certification Service, Dept. 356-35, 800 North Capitol St. NW., suite 740, Washington, DC 20591; or at the Office of the Federal Register, 21st Street and Constitution Avenue NW., Washington, DC 20410.

FOR FURTHER INFORMATION CONTACT: Mr. Steven C. Fox, Aerospace Engineer, Mail Branch, ANM–1205, Seattle Aircraft Certification Office, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (206) 227–2777; fax (206) 227–1181.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations to include an airworthiness directive (AD) that is applicable to certain Boeing Model 747 series airplanes was published in the Federal Register on April 10, 1992 (57 FR 12467). That action proposed to require repetitive inspections to detect cracks in various areas of the fuselage internal structure, and repair, if necessary. Interested persons have been afforded an opportunity to participate in the making of this amendment. Due consideration has been given to the comments received.

One commenter supports the proposed rule.

Three commenters request that the FAA withdraw the proposed rule. The commenters assert that the proposed requirements of the AD are being accomplished already under existing maintenance programs or inspection programs such as the Structural Inspection Document (SID) program or the Corrosion Prevention and Control Program (CPCP).

The FAA does not concur with the request to withdraw the proposal. The FAA notes that the proposed inspections do not duplicate those addressed in the programs discussed by the commenters. The SID program and the requirements of this AD action differ significantly in certain respects. The SID program is not a self-contained method for addressing aging fleet problems; it serves as a sampling and monitoring tool to provide the FAA with information needed to issue additional AD’s defining corrective action when problems are discovered. The AD that addresses the SID program, AD 93–06–01, Amendment 39–8526 (58 FR 19571, April 15, 1993), is applicable only to a candidate group of Model 747 series airplanes, whereas this AD is applicable to all Model 747–100, 747–200, 747–300, 747SP and 747SR series airplanes. In addition, while AD 93–06–01 requires inspections of certain fuselage frame areas of the airplane in order to detect potential sources of cracking, this AD would require inspections of all frames of the fuselage in order to detect existing cracks. Further, the inspection intervals specified in AD 93–06–01 are less conservative than the intervals proposed in this AD.

Significant differences also exist between the CPCP and this proposed AD. The inspections identified in the CPCP are intended to detect corrosion in these airplanes; however, the inspections that would be required by this AD are intended to detect cracks. Additionally, since corrosion is a time-related phenomenon, the inspection intervals in the CPCP are specified in calendar time. This AD addresses the propagation of fatigue cracks in the fuselage frame area, which is exacerbated by flight cycles. For that reason, the FAA has specified the inspection intervals in this AD in terms of flight cycles, which the FAA considers to be more conservative for the purpose of this AD.

One commenter requests that the proposed compliance time of 22,000 flight cycles for the initial inspection be extended beyond 30,000 or 40,000 flight cycles. The commenter indicates that cracks in the fuselage frames remain in the fail-safe chord until 40,000 flight cycles, and that no catastrophic failure of the fatigue test airplane occurred prior to 40,000 flight cycles for unrepai red cracks.

The FAA does not concur with the commenter’s request to extend the compliance time. While the FAA acknowledges that no catastrophic failure occurred during the fatigue test of the fuselage, that fatigue test was based solely on pressurization loads and contained no effects of flight loads. Therefore, the FAA notes that those test results do not constitute complete fuselage life data. The FAA also notes that although cracks initiating in the outer chord of the fuselage frame dwell in the fail-safe chord of the frame, cracks occurring in the middle chord have grown past both the fail-safe chord and the outer chord during the proposed inspection interval. The FAA concludes that the proposed threshold for accomplishment of the initial inspection is appropriate in order to assure that cracking will be detected in a timely manner.

One commenter requests that the repetitive inspection interval be increased from the proposed 3,000 to 4,000 flight cycles. The commenter estimates that it would take approximately 2,500 work hours to accomplish the actions proposed in the notice, and that an inspection program of this magnitude could be accomplished only during a major (“D” check) maintenance hold. The commenter notes that the repetitive inspection interval specified in the proposal is more consistent with a “C” check interval.

The FAA does not concur with the commenter’s request to increase the repetitive inspection interval. Crack growth rates demonstrated by fuselage pressurization fatigue tests for these airplanes demonstrate that, within 3,000 flight cycles, a crack in the inner chord can propagate to the point where a complete frame failure could occur. Therefore, extending the repetitive inspection interval to 4,000 flight cycles could result in the occurrence of complete failure of one frame, followed by an unacceptable increased crack growth rate in adjacent frames due to increased stress levels from the load transferred by the failed frame. The FAA

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recognizes that the proposed inspection interval of 3,000 flight cycles may not match normally scheduled heavy maintenance inspections so that the impact on operators would be diminished. However, the proposed interval represents what the FAA determined to be the maximum interval of time allowable wherein the inspections could reasonably be accomplished and an acceptable level of safety could be maintained. Paragraph (c) of the final rule provides affected operators the opportunity to apply for an adjustment of the compliance time if data is presented to justify such an adjustment.

After careful review of the available data, including the comments noted above, the FAA has determined that air safety and the public interest require the adoption of the rule as proposed.

There are approximately 610 Boeing Model 747 series airplanes of the affected design in the worldwide fleet. The FAA estimates that 181 airplanes of U.S. registry will be affected by this AD, that it will take approximately 1,746 work hours per airplane to accomplish the required actions, and that the average labor rate is $55 per work hour. Based on these figures, the total cost impact of the AD on U.S. operators is estimated to be $17,381,450, or $96,030 per airplane. This total cost figure assumes that no operator has yet accomplished the required actions, and that the data is presented to justify such an adjustment.

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

For the reasons discussed above, I certify that this action (1) is not a "major rule" under Executive Order 12291; (2) is not a "significant rule" under DOT Regulatory Policies and Procedure (44 FR 11034, February 26, 1979); and (3) will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it may be obtained from the Rules Docket at the location provided under the caption "ADDRESSES."

List of Subjects in 14 CFR Part 39
- Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.
- Adoption of the Amendment
  Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends 14 CFR part 39 of the Federal Aviation Regulations as follows:

PART 39-AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

93–08–12 Boeing; Amendment 39–8559.

Docket 93–NM–38–AD.


Compliance: Required as indicated, unless accomplished previously.

To prevent loss of the structural integrity of the fuselage, accomplish the following:

(a) Prior to the accumulation of 22,000 total flight cycles, or within 1,000 flight cycles after the effective date of this AD, whichever occurs later, unless previously accomplished within the last 2,000 flight cycles; and thereafter at intervals not to exceed 3,000 flight cycles: Perform a detailed visual internal inspection to detect cracks in the areas of the fuselage internal structure noted below, in accordance with Boeing Service Bulletin 747–53–2349, dated June 27, 1991; and prior to further flight, repair any cracks detected, in accordance with FAA-approved procedures.

(1) Sections 41 and 42 upper deck floor beams.
(2) Section 42 upper lobe frames.
(3) Section 46 lower lobe frames.
(4) Section 42 lower lobe frames.
(5) Main entry door cutouts.
(6) Section 41 body station 260, 340, and 400 bulkheads.
(7) Main entry doors.

(b) Prior to the accumulation of 25,000 total flight cycles, or within 1,000 flight cycles after the effective date of this AD, whichever occurs later, unless previously accomplished within the last 2,000 flight cycles; and thereafter at intervals not to exceed 3,000 flight cycles: Perform a detailed visual internal inspection to detect cracks in the Section 46 upper lobe frames, in accordance with Boeing Service Bulletin 747–53–2349, dated June 27, 1991; and prior to further flight, repair any cracks detected, in accordance with FAA-approved procedures.

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

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

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

(e) The inspections shall be done in accordance with Boeing Service Bulletin 747–53–2349, dated June 27, 1991. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. Copies may be obtained from Boeing Commercial Airplane Group, P.O. Box 3707, Seattle, Washington 98124–2207. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(f) This amendment becomes effective on June 11, 1993.

Issued in Renton, Washington, on April 22, 1993.

Darrell M. Pederson,
Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

AIRWORTHINESS DIRECTIVES; SHORT BROTHERS, PLC, MODEL SD3–30, SD3–60, AND SD3–SHERPA SERIES AIRPLANES

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; request for comments.

SUMMARY: This amendment adopts a new airworthiness directive (AD) that is applicable to certain Short Brothers, PLC, Model SD3–30, SD3–60, and SD3–SHERPA series airplanes. This action requires a one-time visual inspection to detect corrosion on the distance piece associated with the wing strut pick up on the stub wing, and repair of corroded parts. This amendment is prompted by reports of corrosion on the distance piece associated with the wing strut pick up on the stub wing. The actions specified in this AD are intended to prevent failure of the distance piece, which could result in reduced strength of the wing strut attachment to the stub
wing on the fuselage and, subsequently, reduced structural strength of the main wing.


'The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of May 27, 1993.

Comments for inclusion in the Rules Docket must be received on or before July 12, 1992.


The service information referenced in this AD may be obtained from Short Brothers, PLC, 2011 Crystal Drive, Suite 713, Arlington, Virginia 22202–9719. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.


SUPPLEMENTARY INFORMATION: The Civil Aviation Authority (CAA), which is the airworthiness authority for the United Kingdom, recently notified the FAA that an unsafe condition may exist on certain Short Brothers, PLC, Model SD3–30, SD3–66, and SD3–SHERPA series airplanes. The CAA advises that, during non-routine maintenance, corrosion has been detected on the horizontal leg of the distance piece associated with the wing strut pick up on the stub wing. This condition, if not corrected, could result in failure of the distance piece, which could result in reduced strength of the wing strut attachment to the stub wing on the fuselage, and subsequently, reduced structural strength of the main wing.

This is considered to be interim action until final action is identified, at which time the FAA may consider further rulemaking.

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

Comments Invited

Although this action is in the form of a final rule that involves requirements affecting flight safety and, thus, was not preceded by notice and an opportunity for public comment, comments are invited on this rule. Interested persons are invited to comment on this rule by submitting such written data, views, or arguments as they may desire.

Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified under the caption "ADDRESSES." All communications received on or before the closing date for comments will be considered, and this rule may be amended in light of the comments received. Factual information that supports the commenter's ideas and suggestions is extremely helpful in evaluating the effectiveness of the AD action and determining whether additional rulemaking action would be needed.

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

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed. stamped postcard on which the following statement is made: "Comments to Docket Number 93–NM–50–AD." The postcard will be date stamped and returned to the commenter.

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12812, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

The FAA has determined that this regulation is an emergency regulation and that it is not considered to be major under Executive Order 12291. It is impracticable for the agency to follow the procedures of Order 12291 with respect to this rule since the rule must be issued immediately to correct an unsafe condition in aircraft. It has been determined further that this action involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979). If it is determined that this emergency regulation otherwise would be significant under DOT Regulatory Policies and Procedures, a final regulatory evaluation will be prepared and placed in the Rules Docket. A copy of it, if filed, may be obtained from the
27930

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Rules Docket at the location provided
under the caption "ADDRESSES."
List of Subjects in 14 CFR Part 39
Air transportation, Aircraft. Aviation

safety, Incorporation by reference,
Safety.
Adoption of the Amendment

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

follows:
PART 39-AIRWORTHINESS
DIRECTIVES

1. The authority citation for part 39
continues to read as follows:
Authority: 49 U.S.C. App. 1354(a), 1421
and 1423; 49 U.S.C. 106(8); and 14 CFR
11.89.

*39.13

[Amended]

2. Section 39.13 is amended by

adding the following new airworthiness
directive:
93-09-08 Short Brothers, PLC: Amendment
39-8574. Docket 93-NM-50-AD.
Applicability: Model SD3-SHERPA series
airplanes, serial numbers SH3201 through
SH3216, inclusive; all Model SD3-60 series
airplanes; and all Model SD3-30 series
airplanes; certificated in any category.
Compliance:Required as indicated, unless
accomplished previously. To prevent failure
of the distance piece, which could result in
reduced strength of the wing strut attachment
to the stub wing on the fuselage and,
subsequently, reduced structural strength of
the main wing, accomplish the following:
(a) Within 30 days after the effective date
of this AD, perform a one-time visual
inspection to detect corrosion in the pockets
on the horizontal leg of the distance piece
associated with the wing strut pick up on the
left- and right-stub wings, in accordance with
Shorts Service Bulletin SD3 SHERPA-53-1,
dated March 29, 1993 (for Model SD3SHERPA series airplanes); Shorts Service
Bulletin SD360-53-38, dated March 25, 1993
(for Model SD3-60 series airplanes); or
Shorts Service Bulletin SD330-53-65, dated
March 29, 1993 (for Model SD3-30 series
airplanes); as applicable.
(1) If any corrosion is detected that is
within the limits specified in the applicable
service bulletin, prior to further flight, repair
in accordance with the applicable service
bulletin.
(2) If any corrosion is detected that is
outside the limits specified in the applicable
service bulletin, prior to further flight, repair
in accordance with a method approved by
the Manager, Standardization Branch, ANM113, FAA. Transport Airplane Directorate.
(b) Within 10 days after accomplishing the
inspection required by paragraph (a) of this
AD. submit a report of all inspection
findings. including nil defects, to Short
Brothers, PLC Information collection

requirements contained in this regulation
have been approved by the Office of
Management and Budget (OMB) under the
provisions of the Paperwork Reduction Act of
1980 (44 U.S.C. 3501 at seq.) and have been
assigned OMB Control Number 2120-0056.
(c) An alternative method of compliance or
adjustment of the compliance time that
provides an acceptable level of safety may be
used if approved by the Manager.
Standardization Branch, ANM-113, FAA.
Transport Airplane Directorate. Operators
shall submit their requests through an
appropriate FAA Principal Maintenance
"Inspector, who may add comments and then
send it to the Manager, Standardization
Branch, ANM-113.
Note: Information concerning the existence
of approved alternative methods of
compliance with this AD, if any; may be
obtained from the Standardization Branch,
ANM-1 13.
(d) Special flight permits may be issued in
accordance with FAR 21.197 and 21.199 to
operate the airplane to a location where the
requirements of this AD can be
accomplished.
(a) The inspections and certain repairs
shall be done in accordance with Shorts
Service Bulletin SD3 SHERPA-53-1, dated
March 29, 1993 (for Model SD3-SHERPA
series airplanes); Shorts Service Bulletin
SD360-53-38, dated March 25, 1993 (for
Model SD3-60 series airplanes); or Shorts
Service Bulletin SD330-53-65, dated March
29, 1993 (for Model SD3-30 series airplanes);
as applicable. This incorporation by
reference was approved by the Director of the
Federal Register in accordance with 5 U.S.C.
552(a) and I CFR part 51. Copies may be
obtained from Short Brothers, PLC, 2011
Crystal Drive, Suite 713, Arlington, Virginia
22202-3719. Copies may be inspected at the
FAA, Transport Airplane Directorate, 1601
Lind Avenue, SW., Renton, Washington; or at
the Office of the Federal Register, 800 North
Capitol Street, NW., suite 700, Washington,
DC.
(f) This amendment becomes effective on
May 27, 1993.
Issued in Renton, Washington, on May 6,
1993.

David G. Hmilel,
Acting Manager,TransportAirplane
Directorate,Aircraft CertificationService.
[FR Doc. 93-11266 Filed 5-11-93; 8:45 am)
BILUNG CODE 4910-13-P

DEPARTMENT OF COMMERCE
Bureau of Export Administration
15 CFR Part 799
[Docket No. 921246-3111]
Foreign Availability Determination and
General Ucense GFW Eligibilityfor
Voice Band Modems Controlled by
ECCN 5A02.c.1 With a "Dats Signalling
Rate" not Exceeding 19,200 Bite Per
Second
AGENCY: Bureau of Export
Administration, Commerce.
ACTION: Interim rule and request for
comments.
SUMMARY: On April 7, 1993, the
Department of Commerce determined
that foreign availability exists, within
the meaning of section 5(f) of the Export
Administration Act (EAA) and part 791
of the Export Administration
Regulations (EAR), for voice band
modems controlled by ECCN 5A02.c.1
that are capable of operating at a "data
signalling rate" not exceeding 19,200
bits per second.
This interim rule removes national
security-based validated export license
requirements for exports of these
modems to most non-controlled
countries (i.e. Country Groups T and V,
except the People's Republic of China)
by making the modems eligible for
export under General License GFW.
Pursuant to section 5(f)(8) of the EAA,
this rule also removes national securitybased validated license requirements for
exports to non-controlled countries of
certain items that are not covered by the
foreign availability determination, but
possess performance thresholds or other
functional characteristics not exceeding
the technical parameters of the modems
determined to be available.
A validated export license continues
to be required for exports of these
modems to controlled destinations, i.e.,
Country Groups Q, W Y, and Z and the
People's Republic of China. A validated
license also continues to be required to
the following noncontrolled
destinations: Iran, Syria, Country Group
S, and the South African military and
police. Exporters should also be aware
that the Department of the Treasury
maintains embargoes against other
destinations, such as Iraq, Haiti, and the
Federal Republic of Yugoslavia (Serbia
and Montenegro).
The United States is submitting to
COCOM a proposal to remove validated
license requirements for exports of these
modems to controlled destinations.
This rule is expected to result In a
reduction in the number of export


Section 5(f)(3) of the EAR and part 791 of the EAR set forth the procedures and criteria for determining the foreign availability of items controlled for national security reasons. The Secretary of Commerce, or the Secretary's designee, is authorized to determine whether foreign availability exists.

With limited exceptions, the Department of Commerce may not maintain national security controls on exports of an item to countries when the Department determines that items of comparable quality are available in fact to such countries from foreign sources in quantities sufficient to render the controls ineffective in achieving their purpose.

On December 7, 1992, the Office of Foreign Availability (OFA) initiated a foreign availability assessment of voice band modems controlled by ECCN 5A022.1. The assessment was initiated in response to a claim filed with OFA pursuant to section 791 of the EAR. The Department published a notice of the initiation of the assessment in the Federal Register on January 11, 1993 (58 FR 3531).

On April 7, 1993, the Acting Assistant Secretary, having considered the assessment and other relevant information provided by OFA, determined that foreign availability of voice band modems operating at a "data signalling rate" not exceeding 19,200 bits per second exists within the meaning of section 5(f) of the EAR and part 791 of the EAR. The Department provided all interested agencies an opportunity to review and comment on the assessment and determination.

This interim rule reflects the foreign availability determination as it applies to most non-controlled countries, i.e., Country Groups T and V, except the People's Republic of China. In addition, pursuant to section 5(f)(8) of the EAA, this rule removes national security controls for exports to non-controlled countries not covered by the foreign availability determination. Under section 5(f)(8), whenever Commerce removes national security controls from an item for foreign availability reasons, Commerce may not maintain such controls on any similar item whose function, technological approach, performance thresholds, or other attributes that form the basis for such controls do not exceed the technical parameters of the item determined to be available.

As a result of this regulatory action, exports of modems controlled by 5A02.2.1 that use the "bandwidth of one voice channel" and operate at a "data signalling rate" not exceeding 19,200 bits per second no longer require a validated license for national security reasons to any destination in Country Group T or V (except the People's Republic of China). Subject to the restrictions in § 771.2(c), eligible commodities may now be exported to most Country Group T and V destinations under General License GFW. General License GFW is not available for exports to Iran, Syria, the People's Republic of China, or the South African military or police. Exporters should be aware that the Department of the Treasury's Office of Foreign Assets Control maintains an embargo on other destinations, such as Iraq, Haiti, and the Federal Republic of Yugoslavia (Serbia and Montenegro).

General License GFW was originally established for commodities described in the Advisory Notes in the Commerce Control List that indicate a likelihood of approval for Country Groups Q, W, and Y. However, GFW is also used for commodities not covered by such Advisory Notes when so indicated in the GFW paragraph under the Requirements heading of an entry. A validated license continues to be required for national security reasons for exports to all destinations in Country Groups T and V of voice band modems controlled by 5A02.2.1 that operate at a "data signalling rate" exceeding 19,200 bits per second.

A validated license requirement also continues to apply to exports of modems controlled by 5A02.2.1 to all destinations in Country Groups Q, S, W, Y and Z, and the People's Republic of China. Foreign policy-based validated license requirements remain in effect for exports to Iran or Syria of all modems controlled by 5A02.2.1. All other foreign policy-based validated license requirements also remain in effect.

The United States is submitting to COCOM a proposal for removing national security-based validated license requirements for modems controlled by 5A02.2.1 at a "data signalling rate" not exceeding 19,200 bits per second. Following a multilateral review of this proposal by COCOM, the Department will take appropriate action, consistent with the provisions of section 5(f)(3) of the EAA and § 791.7 of the EAR, to remove national security-based validated license requirements for exports of these modems to controlled destinations.

Rulemaking Requirements

1. This rule is consistent with Executive Orders 12291 and 12661.
2. This rule involves collections of information subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). These collections have been approved by the Office of Management and Budget under control numbers 0969-0005 and 0969-0010.
3. This rule does not contain policies with Federalism implications sufficient to warrant preparation of a Federalism assessment under Executive Order 12612.
4. Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule by section 553 of the Administrative Procedure Act (5 U.S.C. 553) or by any other law, under section 3(a) of the Regulatory Flexibility Act (5 U.S.C. 603(a) and 604(a)) no initial or final Regulatory Flexibility Analysis has to be or will be prepared.
5. The provisions of the Administrative Procedure Act, 5 U.S.C. 553, requiring notice of proposed rulemaking, the opportunity for public participation, and a delay in the effective date, are inapplicable because this rule is not a rule of agency organization, procedure or practice applicable to the entire United States. Section 13(b) of the EAA does not require that this rule be published in proposed form because this rule does not impose a new control. Further, no other law requires that a notice of proposed rulemaking and an opportunity for public comment be given for this rule.

However, because of the importance of the issues raised by these regulations, this rule is issued in interim form and comments will be considered in the development of final regulations. Accordingly, the Department
encourages interested persons who wish to comment so to do at the earliest possible time to permit the fullest consideration of their views.

The period for submission of comments will close June 11, 1993. The Department will consider all comments received before the close of the comment period in developing final regulations. Comments received after the end of the comment period will be considered if possible, but their consideration cannot be assured. The Department will not accept public comments accompanied by a request that a part or all of the material be treated confidentially because of its business proprietary nature or for any other reason. The Department will return such comments and materials to the person submitting the comments and will not consider them in the development of final regulations. All public comments on these regulations will be a matter of public record and will be available for public inspection and copying. In the interest of accuracy and completeness, the Department requires comments in written form. Oral comments must be followed by written memoranda, which will also be a matter of public record and will be available for public review and copying. Communications from agencies of the United States Government or foreign governments will not be made available for public inspection.

The public record concerning these regulations will be maintained in the Bureau of Export Administration Freedom of Information Records Inspection Facility, room 4525, Department of Commerce, 14th Street and Pennsylvania Avenue, NW., Washington, DC 20230. Records in this facility, including written public comments and memoranda summarizing the substance of oral communications, may be inspected and copied in accordance with regulations published in part 4 of title 15 of the Code of Federal Regulations. Information about the inspection and copying of records at the facility may be obtained from Margaret Cornejo, Bureau of Export Administration Freedom of Information Officer, at the above address or by calling (202) 482-5653.

List of Subjects in 15 CFR parts 730-799

Exports, Reporting and recordkeeping requirements.

Accordingly, part 799 of the Export Administration Regulations (15 CFR parts 730-799) is amended as follows: PART 799—[AMENDED]

1. The authority citation for 15 CFR part 799 is revised to read as follows:


2. In Supplement No. 1 to § 799.1 (the Commerce Control List), Category 5 (Telecommunications and “Information Security”), Section I (Telecommunications), ECCN 5A02A is amended by revising the Requirements section to read as follows:

5A022 "Telecommunications transmission equipment" or systems and specially designed components and accessories therefor, having any of the following characteristics, functions or features.

Requirements

Validated License Required: QSTVWYZ.

Unit: Equipment in number; parts and accessories in $ value.

Reason for Control: NS.

GLY: $5,000.

CCT: Yes.

GFW: Yes for items identified in Telecommunications Advisory Notes 11, 14, 19, 20, and 21 and for modems described in 5A02.c.1 with a “data signalling rate” not exceeding 19,200 bits per second.

Dated: May 7, 1993.

Iain S. Baird,

Acting Assistant Secretary for Export Administration.

[FR Doc. 93-11261 Filed 5-11-93; 8:45 am]

BILLING CODE 3810-0T-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 93N-0172]

Misleading Containers; Nonfunctional Slack-Fill

AGENCY: Food and Drug Administration, HHHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that, in accordance with section 6(b)(3)(D)(iii) of the Nutrition Labeling and Education Act of 1990 (the 1990 amendments) to the Federal Food, Drug, and Cosmetic Act (the act), the regulation that it proposed on January 6, 1993 (58 FR 2957), to implement section 403(d) of the act in accordance with section 6 of the 1990 amendments is now considered a final regulation. The proposed regulation defines the circumstances in which the slack-fill within a package is nonfunctional and, therefore, misleading.

DATES: The final regulation implementing section 403(d) of the act will become effective on May 10, 1993.


SUPPLEMENTARY INFORMATION:

I. Background

The 1990 amendments to the act became law on November 8, 1990. Section 6 of the 1990 amendments established a procedure under which FDA was given 30 months from the date of their enactment to promulgate final rules implementing that section. Pursuant to that procedure, FDA published a proposal on January 6, 1993 (58 FR 2957), to amend its regulations to define the circumstances in which a food is misbranded under section 403(d) of the act.

Section 6(b)(3)(D)(ii) of the 1990 amendments provides that, if the final rule to implement section 403(d) of the act is not promulgated within 30 months, then the regulation proposed to implement this section is to be considered a final regulation. Further, this section provides that States and political subdivisions shall be preempted with respect to section 403(d) of the act at that time.

The 30-month period established by the 1990 amendments expired on Saturday, May 8, 1993. Therefore, FDA
is issuing this document announcing that the regulation that it proposed in January 1993 is now considered a final regulation by operation of law. The agency proposed that 21 CFR part 100 be amended as follows:

PART 100—GENERAL

2. New subpart F, consisting of § 100.100, is added to read as follows:

Subpart F—Misbranding for Reasons Other Than Labeling

§ 100.100 Misleading containers.

In accordance with section 403(d) of the act, a food shall be deemed to be misbranded if its container is so made, formed, or filled as to be misleading.

(a) A container shall be considered to be filled as to be misleading if it contains nonfunctional slack-fill.

"Slack-fill" is the difference between the actual capacity of a container and the volume of product contained therein. "Nonfunctional slack-fill" is the empty space in a package that is filled to substantially less than its capacity for reasons other than:

(1) Protection of the contents of the package;
(2) The requirements of the machines used for enclosing the contents in such package;
(3) Normal product settling during shipping and handling;
(4) The need for the package to perform a specific function (e.g., where packaging plays a role in the preparation or consumption of a food), where such function is inherent to the nature of the food and is clearly labeled;

or

(5) The fact that the product is a gift product consisting of a food or foods combined with a reusable gift container, where the container is intended for further use after the food is consumed.

(b) [Reserved]

The 1990 amendments state that FDA is to promptly publish notice of the new status of the proposed regulation in the Federal Register. This notice is issued in response to that requirement.

The agency notes that this document is part of a separate rulemaking contemplated by Congress if the final regulation was not issued by May 8, 1993. It bears a separate docket number from the one assigned to the January 1993 rulemaking to distinguish it from that rulemaking, which is ongoing. The agency intends to issue a regulation in the near future that will supersede the regulation that is considered final by operation of law. FDA intends to issue a final regulation based on the comments it received in the January 1993 rulemaking.


Michael R. Taylor,
Deputy Commissioner for Policy.
[FR Doc. 93-11024 Filed 5-10-93; 3:32 pm]
BILLING CODE 4100-01-F

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 117

[CGD9-93-08]

Drawbridge Operation Regulations,
Chicago River, IL

AGENCY: Coast Guard, DOT.

ACTION: Notice of temporary deviation.

SUMMARY: The Coast Guard is hereby providing notice that the City of Chicago has been granted permission to temporarily deviate from regulations governing the opening of certain drawbridges over the Chicago River, from April 26 to May 31, 1993, for the purpose of evaluating the reasonableness of possible changes to the permanent regulations. This deviation reduces the periods during which the City must open the draws for recreational vessels, requires the vessels to give advance notice, and requires the vessels to pass through the draws in organized flotillas.

EFFECTIVE DATES: The period of deviation to from the beginning of Monday, April 26, 1993, to the beginning of Monday, May 31, 1993.

ADDRESSES: Comments may be sent to Robert W. Bloom, Jr., Bridge Program Manager, Ninth Coast Guard District, room 2083D, 1240 East Ninth Street, Cleveland, Ohio 44199-2060, telephone (216) 522-3993.

FOR FURTHER INFORMATION CONTACT: Contact Robert W. Bloom, Jr., Bridge Program Manager, Ninth Coast Guard District, room 2083D, 1240 East Ninth Street, Cleveland, Ohio 44199-2060, telephone (216) 522-3993.

SUPPLEMENTARY INFORMATION: Presently, the bridges owned and operated by the City of Chicago are governed in accordance with 33 CFR 117.39 which allows the City to not open the draws during peak vehicle traffic periods during the morning and afternoon rush hours. In addition, certain bridges need not open unless notice is given in advance of a vessel’s time of intended passage through the draws. The boat yards that are located on the North and South Branches of the Chicago River are faced with two critical periods when there are as many as five to twenty-five boats per day leaving the Chicago River system in the spring and returning in the fall. The City has requested that multiple boat transits be restricted to only Saturday and Sunday mornings, unless there is a special event on these days, at which time a bridge may not be required to open for vessel traffic to pass. In addition, the City submits that it is unduly burdensome to open the bridges for the passage of single recreational vessels within the Chicago River System. This temporary period of deviation is being granted to the City of Chicago in order to evaluate the reasonableness of possible changes to the permanent regulations. The deviation is intended to best accommodate both recreational vessels transiting the Chicago River System and the City of Chicago. During information discussions with representatives of the City and the marinas, it became apparent that it might be most practical to accommodate both interests by establishing a regulatory structure which requires the formation of organized flotillas for the passage of recreational vessels. Traditionally, the Coast Guard has sought to avoid regulations which specify the type and number of vessels entitled to demand an opening. However, it appears that this may be a case in which such a regulatory structure is appropriate, and this deviation is intended to provide an evaluation period which will provide the Coast Guard a valuable test of the reasonableness of such a regulatory structure.

Request for Comments

The Coast Guard encourages interested persons to participate in this evaluation of possible changes to the regulations governing bridges operated by the City of Chicago by submitting written data, views, or arguments to the address above. Persons submitting comments should include their name and address, identify this docket number (CGD9-93-08) and specific provisions to which each comment applies, and give reasons for each comment. Persons wanting acknowledgment of receipt of comments should enclose a stamped, self-addressed postcard or envelope. At such time as it appears appropriate to propose a permanent change to the regulations, the Coast Guard plans to publish a notice of proposed rulemaking which will again request comments, and which will state a different period for the consideration of comments for those proposed regulations.

Notice

- Notice is hereby given that:
(1) The Coast Guard has granted the City of Chicago, Department of Transportation, a temporary deviation from the operating requirements at 33 CFR 117.391 governing certain bridges owned by the City of Chicago over the Chicago River, as follows:

**Main Branch**
- Lake Shore Drive
- Columbus Drive
- Michigan Avenue
- Wabash Avenue
- State Street
- Dearborn Street
- Clark Street
- La Salle Street
- Wells Street
- Franklin-Orleans Street

**South Branch**
- Lake Street
- Randolph Street
- Washington Street
- Madison Avenue
- Monroe Street
- Adams Street
- Jackson Boulevard
- Van Buren Street
- Eisenhower Expressway
- Harrison Street
- Roosevelt Road
- 18th Street
- Canal Street
- South Halsted Street
- South Loomis Street
- South Ashland Avenue

**North Branch**
- Grand Avenue
- Ohio Street
- Chicago Avenue
- North Halsted Street

(2) This deviation from normal operating regulations is authorized in accordance with the provisions of title 33 of the Code of Federal Regulations, §117.43, for the purpose of evaluating possible changes to the permanent regulations. This temporary deviation applies only to passage of recreational vessels. Under the deviation the bridges listed above operated by the City of Chicago need not open for the passage of recreational vessels unless the City of Chicago receives a twenty-four hour advance notice for passage, and need not open for recreational vessels except during the following periods, subject to the conditions indicated:

(a) From 6 a.m. on Saturdays through 7 p.m. on Sundays, the draws shall open for the passage of organized flotillas consisting of no less than five and not more than twenty-five vessels.

(b) On Tuesdays and Thursdays the draws shall open for the passage of organized flotillas consisting of no less than five and not more than twenty-five vessels, from 6:30 p.m. until all organized flotillas have safely completed passage.

(3) Notwithstanding this deviation, the City of Chicago, after receiving notice twenty-four hours in advance of the intended passage of the flotilla through the draws of the bridges, shall ensure that:

(a) The necessary bridge tenders are provided for the safe and prompt opening of the draws;

(b) The operating machinery of each draw is maintained in a serviceable condition; and

(c) The draws are operated at sufficient intervals to assure their satisfactory operation.

(4) The Kinzie Street bridge, mile 1.81 across the North Branch, and Cermak Road bridge, mile 4.05 across the South Branch, shall continue to operate in accordance with requirements presently established in 33 CFR 117.391.

(5) All draws shall open for commercial vessels in accordance with current regulations in 33 CFR 117.391. In accordance with current regulations, including 33 CFR 117.391, government vessels of the United States, state and local vessels used for public safety, and vessels in distress shall be passed through the draws of all bridges as soon as possible at all times.

(6) This period of deviation is effective from the beginning of Monday, April 26, 1993, to the beginning of Monday, May 31, 1993.

Dated: 30 April 1993.

A.B. Shepard,

Captain, U.S. Coast Guard, Commander, Ninth Coast Guard District.

[FR Doc. 93-11236 Filed 5-11-93; 8:45 am]

**DEPARTMENT OF VETERANS AFFAIRS**

38 CFR Part 20

**RIN 2900-AP90**

**Rules of Practice; Hearings Before the Board on Appeal**

**AGENCY:** Department of Veterans Affairs.

**ACTION:** Final rule.

**SUMMARY:** This document contains amendments to the Department of Veterans Affairs (VA) final Rules of Practice of the Board of Veterans' Appeals concerning hearings before the Board. References to hearings held by VA regional offices acting as "agents" for the Board have been deleted. This amendment is intended to clarify the opportunities available for hearings before the Board.

**EFFECTIVE DATE:** May 12, 1993.

FOR FURTHER INFORMATION CONTACT: Mr. Steven L. Keller, Counsel to the Chairman (01C), Board of Veterans' Appeals, 810 Vermont Avenue NW., Washington, DC 20420 (202) 233-2978.

**SUPPLEMENTARY INFORMATION:** The final regulations that are the subject of these amendments are the Board of Veterans' Appeals Rules of Practice concerning hearings.

The current regulations refer to hearings conducted by VA personnel acting as "agents" for the Board of Veterans' Appeals. This procedure will no longer be used. Therefore, this final rule removes references to hearings conducted by VA personnel acting as "agents" for the Board.

The Board of Veterans' Appeals has reexamined its relationship with the Veterans Benefits Administration (VBA) as it relates to the conduct of adjudicatory proceedings by both organizations. As a result of this review, we have concluded that a clear demarcation should exist between the conduct of hearings by the Board and hearings conducted by VBA employees at regional offices. The establishment of this demarcation resulted in the cessation of Board of Veterans' Appeals hearings being conducted by VBA employees as "agents" of the Board. The VBA will still conduct hearings by its hearing officers as part of its adjudicatory process, and a record of those hearings will be made a part of the claims file for review by the Board in the event an appeal is certified to the Board. The Board will, at its level in the appellate process, continue to afford an opportunity to each claimant to have a hearing before a Member or Members of the Board either in Washington, DC., or at a VA regional office.

This change will have the effect of providing an appellant an opportunity for a hearing before VBA personnel and then an opportunity for another hearing at the Board level.

In addition to deleting references to hearings held by regional office personnel acting as "agents" for the Board, amendments clarifying the opportunities for hearings held before the Board have been made.

This regulation is effective immediately. Notice of proposed rulemaking does not apply to this regulation under the exception provided in 5 U.S.C. section 553(b)(A) for interpretative rules, general statements of policy, or rules of agency organizations, procedure or practice.

The Secretary has determined that these regulations do not contain a major rule as that term is defined by Executive Order 12291, Federal Regulation. The regulations will not have a $100 million annual effect on the economy and will
not cause a major increase in costs or prices for anyone. They will have no significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

The Secretary hereby certifies that these regulatory amendments will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601–612. The reason for this certification is that the regulations have only a limited effect on claimants/appellants and their representatives. Therefore, pursuant to 5 U.S.C. 605(b), these regulations are exempt from the initial and final regulatory flexibility analyses requirements of §§603 and 604.

There are no Catalog of Federal Domestic Assistance numbers associated with these regulatory amendments.

List of Subjects in 38 CFR Part 20
Administrative practice and procedure, Claims, Lawyers, Legal services, Veterans.

Approved: April 13, 1993.

Jose Brown,
Secretary of Veterans Affairs.

For the reasons set forth in the preamble, 38 CFR part 20 is amended as follows:

PART 20—BOARD OF VETERANS’ APPEALS: RULES OF PRACTICE

1. The authority citation for part 20 continues to read as follows:

Authority: 38 U.S.C. 501(a)

2. In part 20, the heading for Subpart H is revised as follows:

Subpart H—Hearings before the Board on Appeal

3. In 38 CFR part 20, § 20.700 is amended by revising the first sentence of paragraph (c) to read as follows:


(c) Nonadversarial proceedings. Hearings conducted by the Board are ex parte in nature and nonadversarial.

4. Section 20.701 is revised to read as follows:

§ 20.701 Rule 701. Who may present oral argument.

Only the appellant and/or his or her authorized representative may appear and present argument in support of an appeal. At the request of an appellant, a Veterans Benefits Counselor of the Department of Veterans Affairs may present the appeal at a hearing before the Board of Veterans’ Appeals.

Authority: 38 U.S.C. 7102, 7104(a), 7105

5. In section 20.702, the heading, and paragraphs (a), (c), (d), and (e) are revised to read as follows:

§ 20.702 Rule 702. Scheduling and notice of hearings conducted by the Board of Veterans’ Appeals in Washington, DC.

(a) General. To the extent that officials scheduling hearings for the Board of Veterans’ Appeals determine that necessary physical resources and qualified personnel are available, hearings will be scheduled at the convenience of appellants and their representatives, with consideration of the travel distance involved. While a Statement of the Case should be prepared prior to the hearing, it is not a prerequisite for a hearing and an appellant may request that the hearing be scheduled prior to issuance of the Statement of the Case.

Authority: 38 U.S.C. 7102, 7104(a), 7105(a)

(b) * * *

(c) Requests for changes in hearing dates. (1) The appellant or the representative may request a different date for the hearing within 60 days from the date of the letter of notification of the time and place of the hearing, or not later than two weeks prior to the scheduled hearing date, whichever is earlier. The request must be in writing, but the grounds for the request need not be stated. Only one such request for a change of the date of the hearing will be granted, subject to the interests of other parties if a simultaneously contested claim is involved. In the case of a hearing conducted by the Board of Veterans’ Appeals in Washington, DC, such requests for a new hearing date must be filed with: Chief, Hearing Section (0141F), Board of Veterans’ Appeals, 810 Vermont Avenue NW., Washington, DC 20420.

(2) After the period described in paragraph (c)(1) of this section has passed, or after one change in the hearing date is granted based on a request received during such period, the date of the hearing will become fixed. After a hearing date has become fixed, an extension of time for appearance at a hearing will be granted only for good cause, with due consideration of the interests of other parties if a simultaneously contested claim is involved. Examples of good cause include, but are not limited to, illness of the appellant and/or representative, difficulty in obtaining necessary records, and unavailability of a necessary witness. The motion for a new hearing date must be in writing and must explain why a new hearing date is necessary. If good cause is shown, the hearing will be rescheduled for the next available hearing date after the appellant or his or her representative gives notice that the contingency which gave rise to the request for postponement has been removed. Ordinarily, however, hearings will not be postponed more than 30 days. In the case of a hearing conducted by the Board of Veterans’ Appeals in Washington, DC, whether good cause for establishing a new hearing date has been shown will be determined by the presiding Member of the hearing panel assigned to conduct the hearing. In the case of hearings to be conducted by the Board of Veterans’ Appeals in Washington, DC, the motion for a new hearing date must be filed with: Chief, Hearing Section (0141F), Board of Veterans’ Appeals, 810 Vermont Avenue, NW., Washington, DC 20420.

Authority: 38 U.S.C. 7102, 7104(a), 7105(a), 7105A

(d) Failure to appear for a scheduled hearing. If an appellant (or when a hearing only for oral argument by a representative has been authorized, the representative) fails to appear for a scheduled hearing and a request for postponement has not been received and granted, the case will be processed as though the request for a hearing had been withdrawn. No further request for a hearing will be granted in the same appeal unless failure to appear was with good cause and the cause for the failure to appear arose under such circumstances that a timely request for postponement could not have been submitted prior to the scheduled hearing date. A motion for a new hearing date following a failure to appear must be in writing; must be submitted not more than 15 days following the original hearing date; and must set forth the reason, or reasons, for the failure to appear at the originally scheduled hearing and the reason, or reasons, why a timely request for postponement could not have been submitted. In the case of hearings to be conducted by the Board of Veterans’ Appeals in Washington, DC, the motion must be filed with: Chief, Hearing Section (0141F), Board of Veterans’ Appeals, 810 Vermont Avenue, NW., Washington, DC 20420. If good cause is
shown, the hearing will be rescheduled for the next available hearing date after the appellant or his or her representative gives notice that the contingency which gave rise to the failure to appear has been removed. Ordinarily, however, hearings will not be postponed more than 30 days. In the case of hearings before the Board of Veterans' Appeals in Washington, DC, whether good cause for such failure to appear has been established will be determined by the presiding Member of the hearing panel to which the case was assigned.

(Authority: 38 U.S.C. 7102, 7104(a), 7105(a), 7105(a))

(a) Withdrawal of hearing requests. A request for a hearing may be withdrawn by an appellant at any time before the date of the hearing. A request for a hearing may not be withdrawn by an appellant's representative without the consent of the appellant. In the case of hearings to be conducted by the Board of Veterans' Appeals in Washington, DC, the notice of withdrawal must be sent to: Chief, Hearing Section (0141F), Board of Veterans' Appeals, 810 Vermont Avenue, NW., Washington, DC 20420.

(Authority: 38 U.S.C. 7102, 7104(a), 7105(a) (Approved by the Office of Management and Budget under control number 2005–0065.)

(b) Copy of hearing tape recording or written transcript. One copy of the tape recording of hearing proceedings before the Board of Veterans' Appeals, or the written transcript of such proceedings when such a transcript has been prepared in accordance with the provisions of paragraph (a) of this section, shall be furnished without cost to the appellant or representative if a request is made in accordance with §1.577 of this chapter.

(Authority: 38 U.S.C. 7102, 7104(a), 7105(a))

8. In section 20.714, paragraph (b) is removed, and paragraph (c) is redesignated as the new paragraph (b) and is revised to read as follows:

§20.714 Rule 714. Record of Hearings.

(a) * * *

(b) Copy of hearing tape recording or written transcript. One copy of the tape recording of hearing proceedings before the Board of Veterans' Appeals, or the written transcript of such proceedings when such a transcript has been prepared in accordance with the provisions of paragraph (a) of this section, shall be furnished without cost to the appellant or representative if a request is made in accordance with §1.577 of this chapter.

(Authority: 38 U.S.C. 7102, 7104(a), 7105(a))

9. Section 20.715 is revised to read as follows:

§20.715 Rule 715. Recording of hearing by appellant or representative.

An appellant or representative may record the hearing with his or her own equipment. Filming, videotaping or televising the hearing may only be authorized when prior written consent is obtained from all appellants and contesting claimants, if any, and made a matter of record. In no event will such additional equipment be used if it interferes with the conduct of the hearing or the official recording apparatus. In all such situations, advance arrangements must be made. In the case of hearings held before the Board of Veterans' Appeals in Washington, DC, arrangements must be made with the Chief of the Hearing Section (0141F), Board of Veterans' Appeals, 810 Vermont Avenue, NW., Washington, DC 20420. In the case of hearings held before traveling Sections of the Board, arrangements must be made through the office of the Department of Veterans Affairs official who signed the letter giving notification of the time and place of the hearing.

(Authority: 38 U.S.C. 7102, 7104(a), 7105(a))

10. Section 20.716 is revised to read as follows:

§20.716 Rule 716. Correction of hearing transcript.

The tape recording on file at the Board of Veterans' Appeals or a transcript prepared by the Board of Veterans' Appeals is the only official record of a hearing before the Board. Alternate transcript versions prepared by the appellant and representative will not be accepted. If an appellant wishes to seek correction of perceived errors in a hearing transcript, the appellant or his or her representative should move for the correction of the hearing transcript within 30 days after the date that the transcript is mailed to the appellant.

The motion must be in writing and must specify the error, or errors, in the transcript and the correct wording to be substituted. In the case of hearings held before the Board of Veterans' Appeals, whether in Washington, DC, or in the field, the motion must be filed with the Chief, Hearing Section (0141F), Board of Veterans' Appeals, 810 Vermont Avenue, NW., Washington, DC 20420. The ruling on the motion will be made by the presiding Member of the hearing panel concerned.

(Authority: 38 U.S.C. 7102, 7104(a), 7105(a), 7110)

11. In section 20.717, paragraphs (c) and (d) are revised to read as follows:


(a) * * *

(b) Where motion for a new hearing is filed. In the case of hearings held before the Board of Veterans' Appeals, whether in Washington, DC, or in the field, the motion must be filed with: Chief Hearing Section (0141F), Board of Veterans' Appeals, 810 Vermont Avenue, NW., Washington, DC 20420.

(d) Ruling on motion for a new hearing. Except as noted hereinafter, the ruling on the motion for a new hearing will be made by the presiding Member of the hearing panel concerned. If the presiding Member of the hearing panel is no longer available, the ruling on the motion may be made by any other member of the hearing panel who is available. In cases in which a final Board of Veterans' Appeals decision has already been promulgated with respect to the appeal in question, the ruling on the motion will be by the Chairman of the Board. Factors to be considered in ruling on the motion include, but shall not be limited to, the extent of the loss of the record in those cases where only a portion of a hearing tape is unintelligible or only a portion of a
ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[NM-14-1-6585; FRL-4651-3]

Approval and Promulgation of Air Quality Implementation Plans; New Mexico; Revision to the State Implementation Plan; Addressing New Source Review in Nonattainment Areas

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rulemaking.

SUMMARY: This document approves a revision to the New Mexico State Implementation Plan (SIP) to include revisions to Air Quality Control Regulation (AQCR) 709, the existing SIP-approved New Source Review (NSR) regulation for nonattainment areas in the State of New Mexico outside the boundaries of Indian Lands and Bernalillo County. These revisions were made in response to the NSR requirements outlined in the Clean Air Act Amendments (CAAA) of 1990.

DATES: This action will become effective on July 12, 1993 unless notice is received within 30 days of publication that someone wishes to submit adverse or critical comments.

ADDRESSES: Written comments on this action should be addressed to Mr. Thomas H. Diggs, Chief, Planning Section, at the EPA Regional Office listed below. Copies of the documents relevant to this proposed action are available for public inspection during normal business hours at the following locations. The interested persons wanting to examine these documents should make an appointment with the appropriate office at least twenty-four hours before the visiting day.

U.S. Environmental Protection Agency, Region 6, Air Programs Branch (GT-AP), 1445 Ross Avenue, Suite 700, Dallas, Texas 75202-2733

Mr. Jerry Kurtzweg (ANR-443), Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460

FOR FURTHER INFORMATION CONTACT: Mr. Mark Sather, Planning Section (GT-AP), Air Programs Branch, U.S. EPA Region 6, 1445 Ross Avenue, Dallas, Texas 75202-2733, Telephone (214) 655-7258.

SUPPLEMENTARY INFORMATION: One area in the State of New Mexico, Anthony, was designated nonattainment for PM-10 and classified as moderate under sections 107(d)(4)(B) and 188(a) of the Clean Air Act (Act), upon enactment of the CAAA of 1990. PM-10 is defined as particulate matter with an aerodynamic diameter less than or equal to a nominal 10 micrometers. One of the required items to be included in the Anthony PM-10 SIP was a revision to the existing nonattainment permit program. These revisions were to be submitted by June 30, 1992, to meet the requirements of section 173 of the Act for the construction and operation of new and modified major stationary sources of PM-10. Please reference section 189(a)(1)(A) of the Act. By cover letter dated June 12, 1992, the Governor of New Mexico submitted to the EPA revisions to AQCR 709, entitled Permits Nonattainment Areas, addressing NSR in nonattainment areas in the State of New Mexico outside the boundaries of Indian Lands and Bernalillo County. The revisions to AQCR 709 were filed with the State Records and Archives Center on June 25, 1992. AQCR 709 was initially approved by the EPA on June 4, 1990 (55 FR 22784). Further revisions were approved on August 21, 1990 (55 FR 34013), and on November 12, 1991 (56 FR 57492). The reader should refer to the previously cited Federal Register notices for the background information, history, and issues associated with this regulation. The current revisions to AQCR 709 discussed in this notice are straightforward and minimal as outlined below.

Analysis of State Submission

1. Procedural Background

The Act requires States to observe certain procedural requirements in developing implementation plans for submission to the EPA. Section 110(a)(2) of the Act provides that each implementation plan submitted by a State must be adopted after reasonable notice and public hearing.\(^1\) Section 110(l) of the Act similarly provides that each revision to an implementation plan submitted by a State under the Act must be adopted by such State after reasonable notice and public hearing.

The EPA also must determine whether a submittal is complete and therefore warrants further EPA review and action (see Section 110(k)(1) and 57 FR 13565). The EPA's completeness criteria for SIP submittals are set out at 40 CFR part 51, appendix V (1991), as amended by 56 FR 42216 (August 28, 1991). The EPA attempts to make completeness determinations within 60 days of receiving a submission. However, a submittal is deemed complete by operation of law if a completeness determination is not made by the EPA six months after receipt of the submission.

The State of New Mexico held a public hearing on June 12, 1992, to entertain public comments on proposed revisions to AQCR 709 addressing NSR. No public comments were received. Following the public hearing the SIP revision was adopted by the State and signed by the Governor on June 12, 1992. The SIP revision was received by the EPA on July 2, 1992.

The SIP revision was reviewed by the EPA to determine completeness shortly after its submittal, in accordance with the completeness criteria set out at 40 CFR part 51, appendix V (1991). A letter dated July 29, 1992, was forwarded to the Governor indicating the completeness of the submittal and the next steps to be taken in the review process. As noted in today's action, the EPA is approving this New Mexico NSR SIP submittal.

2. Revisions to Nonattainment NSR Permit Program

The State of New Mexico has revised AQCR 709 in order to meet requirements found in section 173 of the Act for the construction and operation of new and modified major stationary sources of PM-10. As referenced above, the State of New Mexico already has in place a Federally enforceable regulation for nonattainment NSR (AQCR 709). Very few revisions to AQCR 709 were required to incorporate new nonattainment NSR requirements outlined in the CAAA of 1990. The specific revisions to AQCR 709 are discussed below.

The CAAA of 1990 now requires that emission reductions obtained pursuant to section 173(c)(1), pertaining to

\(^1\) Also section 172(c)(7) of the Act requires that plan provisions for nonattainment areas meet the applicable provisions of Section 110(a)(2).
“Offsets”, assure that the total tonnage of increased emissions of an air pollutant from a new or modified source shall be offset by an equal or greater reduction, as applicable, in the actual emissions of such air pollutant from the same or other sources in the area. The State of New Mexico has revised the language in section D(3)(a) of AQCR 709 to adequately address this new requirement.

The CAAA of 1990 in section 173(a)(5) now also provides that as a condition for issuing a permit to construct a major stationary source or major modification in a nonattainment area, an analysis specifies alternative sites, sizes, production processes, and environmental control techniques for such proposed source demonstrates that benefits of the proposed source significantly outweigh the environmental and social costs imposed as a result of its location, construction, or modification. The State of New Mexico has added this language to AQCR 709 in section D(5).

The CAAA of 1990 in section 189(b)(3) also specifies that for any serious PM-10 nonattainment area, the terms “major source” and “major stationary source” include any stationary source or group of stationary sources located within a contiguous area and under common control that emits, or has the potential to emit, at least 70 tons per year of PM-10. In addition, section 189(b)(3) specifies alternative offsetting requirements for the permitting of increased emissions from rocket engines or motors. The State of New Mexico does not have to incorporate these provisions into AQCR 709 at this time because the State currently contains only one moderate nonattainment area (Anthony, New Mexico) in which the threshold level for a major source or major stationary source is 100 tons per year. Also, rocket engine and motor firing facilities in the State of New Mexico (e.g., White Sands Missile Range) are currently located in unclassified areas for the PM-10 National Ambient Air Quality Standards (NAAQS). No such facilities are located in the Anthony, New Mexico, PM-10 nonattainment area.

The remainder of the revisions being approved today result from clarifying, renumbering, and updating certain sections of AQCR 709. These changes, discussed in detail in the Technical Support Document, represent small and noncontroversial revisions to AQCR 709.

The EPA is currently in the process of reviewing its regulations in accordance with the CAAA of 1990 and expects to propose an amended 40 CFR 51.165 within the near future. These revisions to 40 CFR 51.165 will reflect the new nonattainment NSR provisions added by the CAAA of 1990 in sections 172 and 173. Thus, once the EPA promulgates final nonattainment NSR rules pursuant to the CAAA of 1990, the State of New Mexico will have to review AQCR 709 against the requirements found in the final promulgated regulations and submit any additional required revisions to the EPA for SIP approval.

Final Action

The EPA is today approving a revision to the New Mexico SIP to include revisions to AQCR 709 addressing NSR in nonattainment areas in the State of New Mexico outside the boundaries of Indian Lands and Bernalillo County. These revisions to AQCR 709 were filed with the State Records and Archives Center on June 25, 1992, and received by the EPA on July 2, 1992. The revisions incorporate new requirements in section 173 of the Act mandated by the CAAA of 1990 for the construction and operation of new and modified major stationary sources of PM-10 in nonattainment areas. However, the EPA is currently in the process of revising its regulations in accordance with the CAAA of 1990 and expects to propose an amended 40 CFR 51.165 within the near future. These revisions to 40 CFR 51.165 will reflect the new nonattainment NSR provisions added by the CAAA of 1990 in sections 172 and 173. Thus, once the EPA promulgates final nonattainment NSR rules pursuant to the CAAA of 1990, the State of New Mexico will have to review AQCR 709 against the requirements found in the final promulgated regulations and submit any additional required revisions to the EPA for SIP approval.

The EPA has reviewed these revisions to the New Mexico SIP and is approving them as submitted. The EPA is publishing this action without prior proposal because the Agency views this as a noncontroversial amendment and anticipates no adverse comments. This action will be effective July 12, 1993, unless, within 30 days of its publication, notice is received that adverse or critical comments will be submitted.

If such notice is received, this action will be withdrawn before the effective date by publishing two subsequent notices. One notice will withdraw the final action and another will begin a new rulemaking by announcing a proposal of the action and establishing a comment period. If no such comments are received, the public is advised that this action will be effective July 12, 1993.
Executive Order 12291

This action has been classified as a Table 2 action by the Regional Administrator under the procedures published in the Federal Register on January 19, 1989 (54 FR 2214-2225). On January 6, 1988, the Office of Management and Budget (OMB) waived Tables 2 and 3 SIP revisions (54 FR 2222) from the requirements of Section 3 of Executive Order 12291 for a period of two years. The EPA has submitted a request for a permanent waiver for Table 2 and 3 SIP revisions. OMB has agreed to continue the temporary waiver until such time as it rules on the EPA’s request.

List of Subjects in 40 CFR Part 52

Air pollution control, Carbon monoxide, Hydrocarbons, Incorporation by reference, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur dioxide, Volatile organic compounds.

Authority: 42 U.S.C. 7401-7671q.

Note: Incorporation by reference of the SIP for the State of New Mexico was approved by the Director of the Federal Register on July 1, 1982.

Dated: April 23, 1993

K Russell F. Rhoades,
Acting Regional Administrator (6A).

40 CFR part 52 is amended as follows:

PART 52—[AMENDED]

1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401-7671q.

Subpart GG—New Mexico

2. Section 52.1620 is amended by adding paragraph (c)(48) to read as follows:

§ 52.1620 Identification of plan.

(c) * * * * *

(48) A revision to the New Mexico SIP to include revisions to Air Quality Control Regulation 709—Permits—Nonattainment Areas, as filed with the State Records and Archives Center on June 25, 1992.

(i) Incorporation by reference.


[FR Doc. 93–11225 Filed 5–11–93; 8:45 am]

BILLING CODE 6566–95–P

40 CFR Part 52

[IA–6–1–5750; FRL–4618–6]

Approval and Promulgation of Implementation Plans; State of Iowa

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The state of Iowa has submitted a State Implementation Plan (SIP) revision which revises and updates certain state air regulations. EPA is taking final action to approve these changes. This action is necessary to make the changes federally enforceable and to keep the SIP current with changes to the state regulations.

EFFECTIVE DATE: This action will be effective July 12, 1993 unless notice is received by June 11, 1993 that adverse or critical comments will be submitted. If the effective date is delayed, timely notice will be published in the Federal Register.

ADDRESSES: Copies of the documents relevant to this action are available for public inspection during normal business hours at the: Environmental Protection Agency, Air Branch, 726 Minnesota Avenue, Kansas City, Kansas 66101; Iowa Department of Natural Resources, Henry A. Wallace Building, 900 East Grand, Des Moines, Iowa 50319; and Jerry Kurtzweg (ANR–443), Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460.


SUPPLEMENTARY INFORMATION: On January 5, 1993, the Iowa Department of Natural Resources (IDNR) submitted a revision to its SIP. This submittal contained revisions to the following air quality rules: Chapter 20, Definitions; Chapter 22, Controlling Pollution; Chapter 23, Emission Standards for Contaminants; Chapter 24, Excess Emission; Chapter 25, Measurement of Emissions; and Chapter 29. Qualification in Visual Determination of the Opacity of Emissions. Additionally, revisions were made to the Compliance Sampling Manual (CSM), referenced in Chapter 25. The major purpose for the revision was to update references to the Code of Federal Regulations (CFR) which are adopted by reference, to make minor corrections and revisions, and to update the test procedures contained in the CSM. Relevant actions are discussed below.

In Chapter 20, Definitions, the state added a definition of "ambient air" which is consistent with the EPA definition at 40 CFR 50.1(e). The definition of "opacity" was revised to include a reference to Chapter 29, which provides for the federal method of determination of opacity and the requirements for a qualified observer. Also, the definition of "Ringelmann chart" was deleted since it is replaced with the definition of opacity elsewhere in the state rules.

In Chapter 22, Controlling Pollution, subrule 22.3(1), Stationary sources other than anaerobic lagoons, a restriction was added which requires the state to withhold issuance of a construction or conditional permit if a source is in violation of a permit condition or compliance schedule. This enhances the state’s Enforcement powers. In subrule 22.4, Special requirements for nonmajor stationary sources in areas designated attainment or unclassified (prevention of significant deterioration (PSD)), and subrule 22.5, Special requirements for nonattainment areas, the state reference to the federal PSD rule at 40 CFR 52.21 was updated, as well as the reference to the attainment status designations table for Iowa at 40 CFR 81.316.

In Chapter 23, Emission Standards for Contaminants, subrules 23.3(2) (relating to sources generally), and 23.4(12) (relating to incinerators), the limitation on opacity deleted the reference to the Ringelmann chart so that the limitation is expressed as 40 percent opacity. In subrule 23.3(3), Sulfur compounds, the averaging period for sulfur dioxide emission limitations was changed from two hours to three hours, which makes it consistent with the test method requirements of 40 CFR parts 60.8 and 60.46. The test method in the CSM for sulfur dioxide continues to adopt by reference the federal method at 40 CFR Part 60, Appendix A, Method 6.

Minor revisions were made to Chapter 24, Excess Emission.

Chapter 25, Measurement of Emissions, subrule 25.17(7), “Test by owner,” was revised to require the source to provide the state with 30 instead of 15 days’ notice of a scheduled test, require a protest meeting between the source and the state, requires that new equipment be tested within a certain time period, requires the source to submit test results to the state within a specified time period, and gives the state authority to require testing of existing equipment. Subrule 25.1(6), Methods and procedures, was revised to update the reference to 40 CFR part 60, Appendix B—Performance.
Specifications, and Appendix F—
Quality Assurance Procedures, was added. Also, a provision was added to give the state authority to require testing to determine compliance with a permit condition. Chapter 25 references the state CSM, which in turn references federal test methods and procedures for source emission testing. The state made numerous revisions to the CSM and updated the reference to it in this rule. These revisions updated references to EPA methods and state rules, clarified existing language, and made minor corrections. The net effect is to improve the accuracy and enforceability of the document and Chapter 25.

Chapter 28, Qualification in Visual Determination of the Opacity of Emissions, was revised to delete the state requirements for visual determination of opacity of emissions and requirements for qualified observers and replacing it with adoption by reference of the federal method at 40 CFR part 60, appendix A, Method 9.

The state provided opportunity for public notice and comment prior to the adoption of these revisions pursuant to the requirements of 40 CFR 51.102.

Additional information on this rulemaking is contained in the Technical Support Document which is available from the EPA information contact above. EPA ACTION: EPA is taking final action to approve revisions to the Iowa SIP which amend and update the state air rules.

The EPA is publishing this action without prior proposal because the Agency views this as a noncontroversial amendment and anticipates no adverse comments. This action will be effective July 12, 1993 unless, June 11, 1993 notice is received that adverse or critical comments will be submitted.

If such notice is received, this action will be withdrawn before the effective date by publishing two subsequent notices. One notice will withdraw the final action and another will begin a new rulemaking by announcing a proposal of the action and establishing a comment period. If no such comments are received, the public is advised that this action will be effective July 12, 1993.

Nothing in this action should be construed as permitting or allowing or establishing a precedent for any future request for revisions to any SIP. Each request for revision to the SIP shall be considered separately in light of specific technical, economic, and environmental factors and in relation to relevant statutory and regulatory requirements.

Under the Regulatory Flexibility Act, 5 U.S.C. 603 et seq., EPA must prepare a regulatory flexibility analysis assessing the impact of any proposed or final rule on small entities (5 U.S.C. 603 and 604). Alternatively, EPA may certify that the rule will not have a significant impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and government entities with jurisdiction over populations of less than 50,000.

SIP approvals under section 110 and subchapter I, Part D of the Clean Air Act (CAA) do not create any new requirements, but simply approve requirements that the state is already imposing. Therefore, because the federal SIP approval does not impose any new requirements, EPA certifies that it does not have a significant impact on any small entities affected. Moreover, due to the nature of the federal-state relationship under the CAA, preparation of a regulatory flexibility analysis would constitute federal inquiry into the economic reasonableness of state action. The CAA forbids EPA to base its actions concerning SIPs on such grounds (Union Electric Co. v. U.S. EPA., 427 U.S. 246, 256–66 (1976); 42 U.S.C. 7410(a)(2)).

This action has been classified as a Table 3 action by the Regional Administrator under the procedures published in the Federal Register on January 19, 1989 (54 FR 2214–2225). EPA has submitted a request for a permanent waiver for Table 2 and 3 SIP revisions from the requirements of Section 3 of Executive Order 12291. The Office of Management and Budget has agreed to continue the temporary waiver until such time as it rules on EPA’s request.

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by July 12, 1993. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review, nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2)).

List of Subjects in 40 CFR Part 52

Air pollution control, Incorporation by reference, Intergovernmental relations, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, and Volatile organic compounds.

Dated: April 7, 1993.

William W. Rice,
Acting Regional Administrator.

40 CFR part 52 is amended as follows:

PART 52—[AMENDED]

1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401–7671q.

SUBPART G—Iowa

2. Section 52.820 is amended by adding paragraph (c)(57) to read as follows:

§ 52.820 Identification of plan.

* * * * *

(c) * * * (57) On January 5, 1993, the Iowa Department of Natural Resources (IDNR) submitted air quality rule revisions to Iowa Administrative Code, Chapters 20, 22, 23, 24, 25, 29, and revisions to the Compliance Sampling Manual.

(i) Incorporation by reference.

(A) Revisions to Chapter 20 (20.2), Scope of Title-Definitions-Forms-Rules of Practice; Chapter 22 (22.3(1), 22.4, 22.5(2)), Controlling Pollution; Chapter 23 (23.2(3), 23.3(2), 23.3(3), 23.4(12)), Emission Standards for Contaminants; Chapter 24 (24.1(1), 24.1(5)), Excess Emission; Chapter 25 (25.1(7), 25.1(9)), Measurement of Emissions and rescind 25.1(10)(d); and Chapter 29 (29.1), Qualification in Visual Determination of the Opacity of Emissions. These revisions were adopted by the Iowa Environmental Protection Commission on December 21, 1992, and became effective on February 24, 1993.

(ii) Additional material.


[FR Doc. 93–11226 Filed 5–11–93; 8:45 am]
BILLING CODE 6550–50–P

40 CFR Part 721

[OPPTS–50578A; FRL–4077–7]

Alkalai Metal Nitrates; Significant New Use Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is promulgating a significant new use rule (SNUR) under section 5(a)(2) of the Toxic Substances Control Act (TSCA) which will require persons to notify EPA at least 90 days before commencing the manufacture, import, or processing of alkali (e.g.,
sodium or potassium) metal nitrites (AMNs) for use as an ingredient in metalworking fluids (as defined in 40 CFR 721.3) containing amines (MWFAs). EPA believes this action is necessary because AMNs, when used as an ingredient in amine-containing metalworking fluids, have a high potential to form nitrosamines, which may be hazardous to human health. Activities associated with the use of AMNs as an ingredient in MWFAs may result in significant human exposure to nitrosamines and pose a significant hazard to human health. The required notice will provide EPA with the opportunity to evaluate the intended use and associated activities, and an opportunity to protect against unreasonable risks, if any, from exposure to the nitrosamines formed by reaction of AMNs with amines in metalworking fluids before it can occur.

EFFECTIVE DATE: This rule becomes effective on June 26, 1993. In accordance with 40 CFR 23.5, this rule shall be promulgated for purposes of judicial review at 1 p.m. eastern time on May 26, 1993.


Supplementary Information: The SNUR for AMNs published today will require persons to notify EPA at least 90 days before commencing the manufacture, import, or processing of AMNs for use as an ingredient in MWFAs. The required notice will provide EPA with the information needed to evaluate an intended use and associated activities, and an opportunity to protect against potentially adverse exposure to the nitrosamines formed from AMNs in combination with amines before it can occur.

I. Authority

Section 5(a)(2) of TSCA (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a "significant new use." EPA must make this determination by rule after considering all relevant factors, including those listed in section 5(a)(2). Once EPA determines that a use of a chemical substance is a significant new use, section 5(a)(1)(B) of TSCA requires persons to submit a notice to EPA at least 90 days before they manufacture, import, or process the chemical substance for that use. Section 26(c) of TSCA authorizes EPA to take action under section 5(a)(2) with respect to a category of chemical substances.

Persons subject to this SNUR must comply with the same notice requirements and EPA regulatory procedures as submitters of premanufacture notices (PMNs) under section 5(a)(1)(A) of TSCA. In particular, these requirements include the information submission requirements of section 5(b) and (d)(1), the exemptions authorized by section 5(h)(1), (h)(2), (h)(3), and (h)(5), and the regulations at 40 CFR part 720. Once EPA receives a SNUR notice, EPA may take action under section 5(e), (f), 6, or 7 to control the activities for which it has received a SNUR notice. If EPA does not take action, section 5(g) of TSCA requires EPA to explain in the Federal Register its reasons for not taking action.

Persons who intend to export a substance identified in a proposed or final SNUR are subject to the export notification provisions of TSCA section 12(b). The regulations that interpret section 12(b) appear at 40 CFR part 707.

II. Applicability of General Provisions

General regulatory provisions applicable to SNURs are codified at 40 CFR part 721, subpart A. In the Federal Register of August 17, 1988 (53 FR 31252), EPA promulgated a "User Fee Rule" (40 CFR part 700) under the authority of TSCA section 26(b). Provisions requiring persons submitting significant new use notices to submit certain fees to EPA are discussed in detail in that Federal Register document. Interested persons should refer to these documents for further information.

III. Summary of This Rule

The chemical substances which are the subjects of this SNUR are the nitrates of the alkali metals (Group IA in the periodic classification of chemical elements) lithium, sodium, potassium, rubidium, cesium, and francium. EPA is designating the manufacture, import, or processing of these substances for use as an ingredient in MWFAs as a significant new use. Thus, the rule requires persons who intend to manufacture, import, or process AMNs for use as an ingredient in MWFAs to submit a significant new use notice to EPA at least 90 days before starting such manufacture, import, or processing.

IV. Background Information on Alkali Metal Nitrates in Metalworking Fluids

This unit summarizes the background information for this rule. More complete information on production, use, and health effects of AMNs in MWFAs appears in the preamble to the proposed rule (56 FR 2733, January 24, 1991). Interested persons should refer to that document for further information.

Until recently, AMNs were used as a corrosion inhibitor in metalworking fluids. Based on available sources of information, including information from the metalworking industry, EPA has concluded that AMNs are no longer used as an ingredient in MWFAs.

Scientific evidence demonstrates that the use of metalworking fluids containing nitrates and amines may result in nitrosamine formation. The primary nitrosamine produced is N-nitrosodiethanolamine (NDELA), which is classified by EPA as a probable human carcinogen. Other nitrosamines which may cause adverse health effects may also be formed.

V. Objectives and Rationale for This Rule

Because use of AMNs as an ingredient in MWFAs was abandoned fairly recently, EPA recognizes that some metalworking facilities may still have supplies of metalworking fluids containing amines and nitrates. Because there are limited amounts of such supplies, EPA does not feel a ban on them is necessary or warranted. To allow these existing supplies to be depleted without triggering the significant new use notice requirements of this rule, EPA is clarifying the significant new use in this rule to be manufacture, import, or processing of AMNs for use as an ingredient in MWFAs.

To determine what would constitute a significant new use of AMNs, EPA considered relevant information on the toxicity of the chemical substances and the nitrosamine byproducts associated with their uses, likely exposures and releases associated with possible uses, and the four factors listed in section 5(a)(2) of TSCA. Based on these considerations, EPA wishes to achieve the following objectives with regard to the significant new use designated in this rule:

1. EPA wants to ensure that it will receive notice of any company's intent to manufacture, import, or process AMNs for use as an ingredient in MWFAs before that activity begins.

2. EPA wants to ensure that it will have an opportunity to review and evaluate data submitted in a significant new use notice before the notice submitter begins a significant new use of the chemical substances.

3. EPA wants to ensure that it will be able to regulate prospective manufacturers, importers, processors or users of AMNs before a significant new use occurs, provided that the degree of
potential health risk is sufficient to warrant such regulation. 

Data indicate that NDELA may be a human carcinogen. As NDELA is a known byproduct of the use of amine-containing metalworking fluids that contain nitrites, EPA is concerned that exposure to the nitrosamines formed when AMNs are used as an ingredient in MWFAs may present an unreasonable risk to human health. EPA has determined that use of AMNs as an ingredient in MWFAs has been abandoned, and that resuming such use therefore has a high potential to increase the magnitude and duration of exposure to NDELA from that which currently exists. (Public comments regarding possible ongoing uses of AMNs in MWFAs are addressed in Unit VIII.) Considering the toxicity/potential toxicity of NDELA, and to give EPA an opportunity to evaluate intended uses of AMNs as an ingredient in MWFAs and potential unreasonable risk from exposure to nitrosamines associated with such uses before it can occur, EPA is designating the use of AMNs as an ingredient in MWFAs as a significant new use.

The use of AMNs as an ingredient in MWFAs is currently subject to no Federal regulation that would notify the Federal Government of activities that might result in adverse exposures to these substances or provide a regulatory mechanism that could protect human health or the environment from potentially adverse exposures before they occur.

Given the toxicity/potential toxicity of NDELA, the reasonably anticipated situations that could result in exposure to it from the use of AMNs as an ingredient in MWFAs, and the lack of sufficient regulatory controls, individuals could be exposed to NDELA at levels which may result in adverse effects. For the foregoing reasons, EPA designates the use of AMNs as an ingredient in MWFAs as a significant new use.

The use of AMNs as an ingredient in MWFAs is currently subject to no Federal regulation that would notify the Federal Government of activities that might result in adverse exposures to these substances or provide a regulatory mechanism that could protect human health or the environment from potentially adverse exposures before they occur.

VI. Alternatives

In the proposed SNUR, EPA discussed alternative regulatory actions that were considered for AMNs in MWFAs, including a section 8(a) reporting rule and a section 6 rule. Public comments were received regarding the appropriateness of the SNUR regulatory approach; these comments are addressed in Unit VIII. For the reasons discussed in Unit VIII, and in the preamble to the proposed rule (56 FR 2733, January 24, 1991), EPA continues to believe that a SNUR is the most appropriate regulatory approach. Therefore, EPA has decided to proceed with the promulgation of a SNUR for these chemical substances.

VII. Applicability of Rule to Uses Occurring Before Effective Date of the Final Rule

EPA believes that the intent of section 5(a)(1)(B) is best served by designating as such a 'significant new use' as of the proposal date of the SNUR rather than as of the effective date of the final rule. If uses begun during the proposal period of a SNUR were considered ongoing (and therefore not "new") as of the effective date, it would be difficult for EPA to establish SNUR notice requirements, because any person could defeat the purpose of the SNUR by initiating a proposed significant new use before the rule became effective; this interpretation of section 5 would make it extremely difficult for EPA to establish SNUR notice requirements.

As stated in the proposed rule, persons who begin commercial production or processing of AMNs for use as an ingredient in MWFAs between proposal and the effective date of the SNUR may comply with this SNUR before it is promulgated. If a person were to meet the conditions of advance compliance as codified at § 721.45(h) (53 FR 28354, July 17, 1988), the person will be considered to have met the requirements of the final SNUR for those activities. If persons who begin commercial production or processing of AMNs for use as an ingredient in MWFAs between proposal and the effective date of the SNUR do not meet the conditions of advance compliance, they must cease that activity before the effective date of the rule. To resume their activities, these persons would have to comply with all applicable SNUR notice requirements and wait until the notice review period, including all extensions, expires.

VIII. Comments on Proposed Rule

EPA received comments on the proposed rule (58 FR 2733, January 24, 1991) from two manufacturers and one importer and distributor of AMNs.

One commenter suggested that this issue would be more appropriately addressed by the Occupational Safety and Health Administration (OSHA). Throughout 1988 and 1989, EPA and OSHA worked together to investigate ways to address the problems presented by AMNs in MWFAs. OSHA indicated its willingness to issue an advisory concerning AMNs in MWFAs and vigorously enforce the Hazard Communication Standard by providing special guidelines concerning nitrites in metalworking fluids to its field compliance officers. (The Hazard Communication Standard requires manufacturers of metalworking fluids to provide a Material Safety Data Sheet (MSDS) with each sale of their product noting, among other hazards, the risks posed by using metalworking fluids containing amines and nitrites.)

EPA responded by acknowledging that such actions would reduce risks presented by AMNs in MWFAs, and proposed ending its investigation of this matter. OSHA later indicated they were committed to doing spot checks to determine the breadth of the problem rather than pursuing vigorous enforcement of the Hazard Communication Standard at that time.

EPA believed that such action would not directly address whether or not AMNs are used as an ingredient in MWFAs or limit future reintroduction of such formulations, and that a SNUR could adequately address these issues. OSHA was consulted and demonstrated no objections to development of a SNUR. EPA therefore initiated the regulatory planning which culminated in this final rule.

The commenter also stated that his company does not necessarily know the purposes for which its customers use AMNs, and that, consequently, 40 CFR 721.5 would require the company to document one or more of the following for each of its customers: That the customer has been notified, in writing, of the SNUR; that the customer has knowledge of the SNUR; or that the customer cannot engage in the significant new use. The commenter maintained that these requirements would necessitate an expenditure of time, effort, and money without a corresponding benefit.

The regulation at 40 CFR 721.5(a)(2) requires manufacturers, importers, and processors of a substance subject to a SNUR who intend to distribute the substance in commerce to submit a significant new use notice (SNUN) unless one or more of the following can be documented for each recipient of the substance:

1. That the recipient has been notified, in writing, of the SNUR.
2. That the recipient has knowledge of the SNUR.
3. That the recipient cannot engage in the significant new use.

EPA realizes that it would be inappropriate for a company to submit a SNUN based on its customers' use of a substance if the company does not know what the substance is used for. In that case, it would be appropriate for the company to comply with 40 CFR 721.5(a)(2) by notifying its customers, in writing, that the substance they are buying is subject to a SNUR and
referring to the specific section in the CFR which identifies the substance and its designated significant new uses. Such notification might take the form of a statement on the MSDS accompanying shipments of AMNs. EPA has estimated that it would take 15 minutes to a maximum of 1 hour of technical time, costing approximately $13.00 to $51.00, to revise an MSDS to include SNUR information. Therefore, the Agency has no reason to believe that this general requirement will create a significant financial burden on any company subject to this SNUR.

The objective of any SNUR is to give EPA an opportunity to evaluate an intended use and an opportunity to protect against potential unreasonable risk from exposure before it occurs. The requirements of 40 CFR 721.5 serve to assure that EPA is notified of significant new uses, thus ensuring that the benefits of the SNUR (preventing potential unreasonable risks from exposure) are maximized. The benefits, which do not accrue to the firm that incurs the cost but to society as a whole, may be substantial. Although EPA has not quantified the benefits of the customer notifications, it believes they are significant. EPA believes that the benefits that derive from customer notification outweigh the time and effort needed to comply (e.g., to revise an MSDS).

Large quantities of nitrates the same commenter’s company manufactures are food grade or United States Pharmacopoeia (USP) grade, designations which reflect a degree of purity and care in manufacture. There may be industrial users of this grade material. The commenter asks if these nitrates are subject to the notification requirements mentioned above. The commenter’s company also exports both technical grade and food grade AMNs and wants to know if TSCA section 12(b) export notification would be required for both.

Any food, food additive, drug, cosmetic, or device (as such terms are defined in section 201 of the Federal Food, Drug, and Cosmetic Act (FFDCA, 21 U.S.C. section 321)) is excluded from the requirements of TSCA when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device. Under the FFDCA, articles recognized in the official USP are considered drugs (21 U.S.C. section 321(g)(1)(A)). However, such items are only excluded from TSCA when manufactured, processed, or distributed in commerce solely for use as a food, food additive, drug, cosmetic, or device. If the company’s products fall into any of these excluded categories (as indicated in TSCA section 3 (15 U.S.C. section 2602)) and they are intended solely for those specified purposes, they are not subject to the requirements of this or any other regulation under the authority of TSCA, including the export notification requirements under TSCA section 12(b). However, if the commenter intends for his products to have multiple uses, some of which are uses regulated under TSCA (as indicated in TSCA section 3 (15 U.S.C. section 2602)), those products intended for TSCA uses may be subject to this rule. (See Inventory Reporting Requirements, 42 FR 64572 at 64585, December 23, 1977.)

The commenter also suggested regulation of amines rather than nitrates. EPA decided to make AMNs the subject of this SNUR rather than amines because, when the Agency issued the proposed SNUR, it believed that the practice of adding AMNs to MWFAs had been abandoned by industry. Therefore, AMNs seemed an appropriate candidate for a SNUR. Amines were not an appropriate subject for the SNUR because they were and continue to be used widely in metalworking fluids.

The commenter also asks: Why regulate if no one has been involved in this action and no one proposes to do it in the future? To the best of EPA’s knowledge, no one is importing, manufacturing, or processing AMNs for use as an ingredient in MWFAs. However, someone may consider doing so in the future. The purpose of this SNUR is to ensure that EPA is aware of such uses so that the Agency can evaluate the use and associated activities, and prevent future unreasonable risks from exposure to amine-nitrite combinations. EPA cannot prevent such exposure if it is not aware of the significant new use.

Two other commenters had concerns that there were ongoing uses of AMNs in MWFAs and, therefore, a SNUR would not be appropriate. One commenter stated that his company marketed a metalworking fluid containing nitrates and amines and named other companies that he believed marketed similar products. Another commenter stated that, although she had no information about the specific use of AMNs in MWFAs, she believed it likely that these products were still being used because her company sells nitrites to companies which are involved in metalworking. This commenter identified customers to whom her company sold nitrites who are involved in metalworking or in selling products to that industry.

To investigate this matter, EPA wrote letters to these two commenters and to the companies mentioned in their comments asking for specific information on their use of AMNs in MWFAs. The responses indicated only one company continued to market a metalworking fluid containing amines and AMNs. This company has since discontinued its product. To the best of EPA’s knowledge, all manufacture, import, and processing of AMNs for use as an ingredient in MWFAs has been abandoned, and it is appropriate that this SNUR be issued in final form.

IX. Economic Analysis

EPA has evaluated the potential costs of establishing SNUR reporting requirements for AMNs. EPA’s complete economic analysis is available in the public record for this rule.

X. Rulemaking Record

EPA has established a record for this rulemaking (docket control number OPPTS–50878A). The record includes basic information considered by EPA in developing this rule.

A public version of the record, without any confidential business information, is available in the TSCA Nonconfidential Information Center (NCIC), also known as, TSCA Public Docket Office, from 8 a.m. to 12 noon and 1 p.m. to 4 p.m., Monday through Friday, except legal holidays. NCIC is located in Rm. E-G99, 401 M St., SW., Washington, DC. 20460. This record includes the following:

1. This final rule.
2. The proposed rule.
3. Economic analysis of the final rule.
4. Economic analysis in support of the TSCA section 12(b) reporting requirements for AMNs.
5. Reports on uses of nitrates in the metalworking industry.
6. Risk assessment for NDELA.
7. Public comments on the proposed rule.
8. Written communications to EPA regarding AMNs in MWFAs.

XI. Regulatory Assessment Requirements

A. Executive Order 12291

Under Executive Order 12291, EPA must judge whether a rule is “major” and therefore requires a Regulatory Impact Analysis. EPA has determined that this final rule would not be a “major” rule because it would not have an effect on the economy of $100 million or more, and it would not have a significant effect on competition,
costs, or prices. While there is no precise way to calculate the total annual cost of compliance with this final rule, EPA estimates that the reporting cost for submitting a significant new use notice would be approximately $2,200 to $10,000 per notice, plus a $2,500 user fee. EPA believes that, because of the nature of the final rule and the substances involved, there would be few significant new use notices submitted. Furthermore, while the expense of a notice and the uncertainty of possible EPA regulation may discourage certain innovation, that impact would be unlikely because such factors are unlikely to discourage an innovation that has high potential value. This final rule was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order 12291.

B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act (5 U.S.C. 605(b)), EPA has determined that this final rule would not have a significant impact on a substantial number of small businesses. EPA has not determined whether parties affected by the rule would likely be small businesses. However, EPA expects to receive few SNUR notices for these chemical substances. Therefore, EPA believes that the number of small businesses affected by the final rule would not be substantial, even if all of the SNUR notice submitters were small firms.

C. Paperwork Reduction Act

OMB has approved the information collection requirements contained in this final rule under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 et seq.) and has assigned OMB control number 2070-0038. Public reporting burden for this collection of information is estimated to vary from 30 to 170 hours per response, with an average of 100 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; and to Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503, marked “Attention: Desk Officer for EPA.”

List of Subjects in 40 CFR Part 721

Chemicals, Environmental protection, Hazardous materials, Recordskeeping and reporting requirements, Significant new uses.


Susan B. Wayland,
Acting Assistant Administrator for Prevention, Pesticides and Toxic Substances.

Therefore, 40 CFR part 721 is amended as follows:

PART 721—[AMENDED]

1. The authority citation for part 721 continues to read as follows:


2. By adding new § 721.4740 to subpart E to read as follows:

§ 721.4740 Alkali metal nitrites.

(a) Chemical substances and significant new use subject to reporting.

(1) The category of chemical substances which are nitrites of the alkali metals (Group IA in the periodic classification of chemical elements) lithium, sodium, potassium, rubidium, cesium, and francium, is subject to reporting under this section for the significant new use described in paragraph (a)(2) of this section.

(2) The significant new use is: Use as an ingredient in metalworking fluids (as defined in 40 CFR 721.3) containing amines.

(b) [Reserved]

(Approved by the Office of Management and Budget under OMB control number 2070-0038)

[FR Doc. 93-11253 Filed 5-11-93; 8:45 am]

BILLING CODE 6560-20-F

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 2 and 73

[MM Docket No. 87-267, FCC 93-198]

Broadcast Services; AM Radio

AGENCY: Federal Communications Commission.

ACTION: Final rule; petitions for reconsideration.

SUMMARY: This Memorandum Opinion and Order (MO&O), in response to 22 petitions for reconsideration of our Report and Order in this proceeding, enacts minor modifications to our AM technical standards, reorders the priorities governing migration to the AM expanded band, and otherwise affirms the decisions reached in the Report and Order. This proceeding was initiated to achieve a more competitive, improved AM service, and the actions taken in this decision are taken in furtherance of that goal.

EFFECTIVE DATE: June 11, 1993.

FOR FURTHER INFORMATION CONTACT: Larry Olson, (202) 254-3394, Policy and Rules Division, Mass Media Bureau.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission’s Memorandum Opinion and Order in MM Docket No. 87-26, FCC 93-198, adopted April 13, 1993, released April 29, 1993. The complete text of this MO&O is available for inspection and copying during normal business hours in the FCC Reference Center (room 239), 1919 M Street, NW., Washington, DC, and also may be purchased from the Commission’s copy contractor, International Transcription Service at (202) 857-3800, 2100 M Street, NW., suite 140, Washington, DC 20037.

Synopsis of the Memorandum Opinion and Order

1. This MO&O responds to petitions for reconsideration of the Report and Order in this proceeding (56 FR 24842, December 12, 1991), intended to improve technical standards, reduce the level of interference in the existing AM band, encourage certain existing licensees to move into the expanded portion of the AM band, and to consolidate existing broadcasting facilities in order to further reduce congestion and interference in the existing band.

2. The Report and Order relied on three essential and mutually supportive elements designed to assist in reducing congestion and interference in the AM band: (1) Technical Standards; (2) Migration, which opened ten new frequencies in the expanded band (1605-1705 kHz) to those existing stations that most significantly contribute to congestion and interference in the existing band; and (3) Consolidation. In addition, the Report and Order addressed the issues of AM stereo and receiver standards as means of making the AM service more competitive, and relaxed the rules pertaining to Travelers Information Stations to allow for the authorization (on a secondary basis) of such stations on any assignable frequency in the AM band. The Report and Order also dealt with several other miscellaneous and administrative matters necessary to the implementation of the various initiatives adopted.

3. Twenty-two petitions for reconsideration of the Report and Order were filed. (The parties filing petitions...
Commission finds that these proposals significantly lessen the benefit of the special case situations. Yet all of these would significantly diminish the major compromises in our approach. The Commission believes that any further FR of the proposals set forth in the Notice themselves a carefully crafted relaxation of the proposal. The standards and procedures adopted in the Report and Order strike an appropriate balance between the need to improve those situations where significant interference impairs a station's signal quality, and the need for flexibility in our treatment of applications for modification of station facilities where the interference involved is less significant.

Technical Standards

Nighttime Interference Calculations

4. The Commission considered, as suggested by several petitioners, whether to further relax the modified nighttime interference standards as suggested by several petitioners. We conclude, however, that with one exception, the rules and procedures adopted in the Report and Order strike an appropriate balance between the need to improve those situations where significant interference impairs a station's signal quality, and the need for flexibility in our treatment of applications for modification of station facilities where the interference involved is less significant.

5. Petitioners also commented on the requirement for a 10% signal reduction toward affected stations by stations seeking modifications of facilities. The requirement for a 10% signal reduction is the only provision adopted in the Report and Order that will directly reduce interference in the AM band. The standards and procedures adopted in the Report and Order were themselves a carefully crafted relaxation of the proposals set forth in the Notice of Proposed Rule Making (NPRM), 55 FR 31807, August 3, 1990, made in response to commenters concerns. The Commission believes that any further major compromises in our approach would significantly diminish the possibility of meaningful nighttime interference reduction in the AM band.

6. The Commission notes that virtually all of the suggestions presented by the petitioners involve exceptions to the 10% reduction provision for certain special case situations. Yet all of these proposals would, if put into effect, significantly lessen the benefit of the 10% reduction provision. The Commission finds that these proposals would defeat the intended goal of the 10% reduction provision, and therefore declines to make any substantial changes to the interference criteria adopted in the Report and Order.

7. However, concerning nighttime interference calculations, the Commission, in response to petitioners' concerns, revises its rules governing situations where a station proposing a change in facilities presently is included within the 50% RSS of another station, but with a reduction of less than 10% would drop into the mid-level 25% category. The rules are also revised in certain situations, where a 10% reduction could result in a station's interference contribution falling below that of other stations already in the 25% category. The rules, in these instances, will require either an interference reduction of 10% or a lesser amount that would be sufficient to remove the station's interference contribution from the 50% exclusion calculation, whichever is the smaller change.

8. The Commission disagrees with those petitioners who suggested that we establish a clear waiver policy for stations that must make involuntary changes. We believe that adoption of such a policy would likely limit our future flexibility to determine when waivers are warranted, and we continue to favor the case-by-case waiver policy articulated in the Report and Order. The Commission also disagrees with R. Morgan Burrow's (Burrow) opposition to the 3 tier approach and inclusion of adjacent channel signals. The Commission notes that Burrow offered no new information or argument and therefore, we deny his requested changes.

9. In response to the Association of Federal Communications Consulting Engineers (AFCCE) and Burrow's concerns about the potential consequences of applying domestic interference standards that are more strict than those contained in international agreements, the Commission indicates that it will carefully monitor any international activity that could possibly result in loss of domestic radiation rights. If it appears that U.S. stations could actually suffer any significant loss of radiation rights internationally, we will take whatever steps are necessary to preserve U.S. interests.

10. The Commission clarifies, in reply to AFCCE's concern, that we did not intend to make the 10% reduction applicable in routine directional antenna pattern augmentation cases necessitated by an out-of-tolerance proof-of-performance filed with a license application to cover an outstanding construction permit. On the other hand, we are convinced that augmentations necessitated by antenna readjustments caused by environmental changes or other circumstances beyond the licensee's control should be considered for waiver of the 10% reduction requirement, if otherwise applicable, on a case-by-case basis. Likewise, waivers related to reductions beyond the minimum pattern "Q factor," will also be handled on a case-by-case basis in accordance with Footnote 39 of the Report and Order.

Normally Protected Contour

11. Some petitioners disagreed with the decision in the Report and Order to retain the 0.5 mV/m protected contour for Class B stations operating during daytime. These petitioners proposed to make the 1 mV/m contour the Class B protected contour, which would allow many stations to increase power. However, these petitioners provided no new information in this matter beyond that considered in the Report and Order. Thus, the Commission finds no change in our earlier decision is warranted.

"Simple" Directional Antennas in the Expanded Band

12. AFCCE offered an alternative to the Report and Order's definition of simple directional antenna as one which uses two towers. Since interference prevention in the expanded band will be primarily accomplished by means of inter-station spacings, we decided that for simple directional antennas in the expanded band, a measured radial would be required only in the directions for which the facility is short-spaced to other co-channel or adjacent channel stations. AFCCE suggested that a simple directional antenna should be defined as one using series-fed radiators without top-loading or sectionalization and requests that a maximum-to-minimum radiation limit of 15 dB or less be established. The Commission's experience with AM directional arrays leads us to continue in our belief that the definition of a "simple" directional antenna as one with two towers is sufficient for the limited purpose of distinguishing those antennas for which full Proof-of-Performance can be waived without being unnecessarily complex. Thus the Commission chooses not to alter the conclusions of the Report and Order.

80% Coverage Criteria

13. The Report and Order codified a Commission policy that 80% coverage of the principle community is sufficient for AM nighttime coverage requirements. AFCCE noted that the Commission has applied this 80%
coverage criterion to the fulltime service of FM stations in recent years, and requests clarification as to whether the 80% coverage criterion will be applied to the daytime operations of AM stations as well. The Commission did not intend to extend the existing "substantial compliance" policy for nighttime daytime operation of AM stations, but merely intended to codify the existing policy. The Commission believes for a number of reasons that it is not unreasonable to draw a distinction between coverage standards for day and night service. For this reason and because AFCCE has shown no compelling need for a relaxation of AM daytime coverage requirements, the Commission finds that a relaxation of coverage requirements is inconsistent with the focus of this proceeding, the improvement of the AM service as a whole, and so makes no changes in this rule.

Section 73.37(b)

14. Several petitioners requested that the Commission reverse its decision to delete § 73.37(b) of the Rules. The removal of § 73.37(b) means that a first local AM service will not be permitted to receive added interference within its 0.5 mV/m contour and up to its 1 mV/m contour. Petitioners argue that this decision is unfair to daytime facilities and to those stations authorized as first service under § 73.37(b) who wish to change their community of license, and that retention of the provisions of § 73.37(b) would not have a deleterious effect on the availability of wideband radios since this rule applies to co-channel received interference only. The Commission finds that the petitioners have not presented compelling new evidence, and so we continue to believe that § 73.37(b) encourages substandard operations and permits increased AM congestion and distorted service areas. Finally, regarding the National Association of Broadcasters' (NAB) suggestion that we delete § 73.37 (c) and (d), we conclude that these sections should be maintained to accommodate modifications for the existing Class C stations.

Applications for New Daytime-Only Stations in the Existing Band

15. The Commission discontinued the authorization of new daytime-only stations in 1987. In the Report and Order the Commission decided not to authorize new daytime-only stations in the expanded band. Jeffrey Eustis supported acceptance of certain daytime-only applications in the existing band under limited circumstances. NAB supported the freeze and new AM daytime-only stations as well as its logical extension to the expanded band. The Commission determines that the petitioner presents no new information or arguments to persuade us that a continuation of the prohibition on the authorization of new daytime-only AM applications is not in the public interest. Thus, we decline to encourage the filing of more AM daytime-only stations.

Migration

16. The Report and Order decided to limit initial eligibility for the expanded band to existing stations and it declined to reserve channels in the expanded band for minorities or non-commercial operations. It also concluded that little, if any, overall improvement in AM reception in the existing band would be gained by allowing Class C (formerly Class IV) stations to migrate to the expanded band. Additionally, the Report and Order established an order of priority for migration by existing licensees to the expanded band. Petitioners requested that we reconsider: (a) Our decision to restrict eligibility to migrate initially to existing licensees excluding Class C stations; (b) the order of migration priority among the eligible classes of existing licensees; and (c) the improvement factor we would use to rank applicants within each of these categories.

Migration Eligibility

17. Reserve Channels for Minorities. Petitioners contend that awarding some of the expanded band to minorities would substantially alleviate the current underrepresentation of minorities in the ownership of broadcast stations and they propose a scheme whereby incumbent broadcasters migrating to the expanded band would be issued tax certificates for selling their existing band stations to minorities. Again, the petitioners have offered no persuasive reason for altering the Report and Order with respect to the issue of reserved channels in the expanded band. Although the petitioners refer to a study by the NTIA that shows a decrease in the percentage and number of minority owned stations between 1990–91, they fail to make a case that this one year statistical change is cause for the Commission to reverse its fundamental decision to initially restrict migration eligibility. Petitioners' new proposal regarding the use of tax certificates is not a viable option in light of our decision to limit initial migration to the expanded band to existing licensees, and to require the eventual deletion of one existing station for every expanded band station authorized and is untimely as it is an entirely new proposal that should have been submitted earlier as a comment in response to the NPRM.

18. Class C Licensees. NAB asked that the Commission consider giving Class C licensees a chance to migrate to the expanded band during the "second round" of licensing. However, the NAB has failed to refute our conclusion that little, if any, overall improvement in reception in the existing AM band would be gained by allowing Class C stations to migrate, and we decline to grant its request.

Existing Stations Causing Interference and Preferred Migrants

19. After the close of the comment period in this proceeding, Congress amended section 331 of the Communications Act to add section 331(b), which requires that, if technically feasible, the Commission must find a means to enable current daytime-only stations located in communities of more than 100,000 and within a Class I station primary service area to provide service to those communities 24 hours a day, if these licensees notify the Commission that they seek to provide fulltime service. In its petition for reconsideration, Radio Elizabeth, Inc., licensee of daytime-only AM station WDVM, Elizabeth, New Jersey, notified the Commission that it seeks to provide fulltime service to Elizabeth, New Jersey which has a population of more than 100,000 and is located within the primary service area of a Class I (now Class A) station. It contends that revising § 73.30 of the Rules on reconsideration to give an overriding preference for migration to the expanded band to this special class of daytime-only AM stations is the obvious means of complying with the goals of section 331(b) of the Act.

20. The NPRM in this proceeding gave notice of our intention to establish a set of priorities for the migration of existing AM licensees to the expanded band. While the Report and Order placed stations such as WDVM, in Elizabeth, New Jersey in the number 2 priority category, we now revise our criteria. Accordingly, § 73.30 of the Commission's Rules is amended to provide that stations defined in section 331(b) of the Communications Act be given the first priority for migration to the expanded band. See Policy Statement In the Matter of Amendment of Section 331 of the Communications Act of 1934, 7 FCC Rcd 2905 (1992).
**Improvement Factors**

21. AFCCE and Lahm, Suffa & Cavell, Inc. (LSC) asserted that the ratio used to rank licensees seeking to migrate to the expanded band does not take service gains and losses directly into account and therefore does not satisfy section 307(b) considerations. AFCCE suggested that the ratio be redefined "by using the sum of the migrating station's and other stations' service differences as the numerator and the migrator's existing service as the denominator." Schober maintained that if a former Class II-S and III-S (now Class D) station enters the 25% exclusion RSS of some stations, it should be given nighttime improvement factor credit in priority ranking for the expanded band. Schober also suggested that "immediate" migrators be given some priority enhancement because they will improve the interference situation immediately as opposed to 5 years from now. Finally, Polnet maintained that the Commission's prioritization scheme is contradictory.

22. The Commission has carefully reviewed the factors chosen in the Report & Order to define the ratio that will rank applicants within each preference category. We remain convinced that this carefully crafted formula will permit an equitable selection of migrants to the expanded band and improve service quality in the existing band. We also do not believe that it is appropriate to revise the improvement factor calculations to consider the nighttime improvement that would result from the migration of former Class II-S and III-S facilities that enter the 25% exclusion RSS. We further decline to revise the ranking factor calculation to remove the distinction between unlimited time and daytime only categories because we believe that, wherever possible, a licensee's migrating to the expanded band should produce a net reduction in interference experienced during nighttime hours. Nor do we find compelling reason to favor applications of "immediate" migrants in effect, such a move would tend to forego greater long term benefits for lesser short term gains. Finally, while operations on 1590 and 1600 kHz do impose some constraints on the use of the expanded band, all assignments, in both the existing and expanded bands, impose constraints upon future assignment flexibility to some degree. Such an imposition of constraints is not, in and of itself, sufficient justification, in our view, to warrant a favored status among applicants for the expanded band channels.

**AM Receiver Standards**

23. The Report and Order declined to set mandatory standards for either AM stereo capability or technical quality of AM receivers. Instead, the Commission encouraged receiver manufacturers to market receivers with AM stereo capability as well as NRSC-3 characteristics, on a voluntary basis. Burrow argued that the Commission should direct receiver manufacturers to incorporate expanded band and variable bandwidth I.F. and audio stages in new units. Burrow also maintained that the Commission should require stereo reception capability for automotive and high-end receivers. No new information has been submitted that persuades us that our initial conclusion, that industry is in a better position than government to ascertain and respond to consumer demand, is wrong. Thus, the Commission decides to continue to rely on marketplace factors to determine the characteristics appropriate for AM receivers.

**Travelers Information Stations**

Travelers Information Service Operating Frequency and Technical Standards

24. In the Report and Order, the Commission decided to permit Travelers Information Stations (TIS) to operate on any channel in the AM band, on a secondary basis, and adopted co-channel separation criteria in part 90 of the Rules. A number of petitioners opposed this decision and proposed alternatives. Petitioners renew arguments concerning TIS stations that the Report and Order already considered and rejected. The Report and Order addressed, for example, NTIA's argument concerning the dedication of 1700 kHz to TIS, explaining that such an action would not achieve the principal goal of this proceeding, a reduction of interference in the existing AM band. Moreover, our decision to provide multiple channel assignment flexibility for TIS offers new prospects for the growth of the TIS service, as well as imposing minimal impact on existing use of 1610 kHz by the TIS service.

"The Intermodal Surface Transportation Efficiency Act of 1991" cited by NTIA was not previously considered in this proceeding. Since this law (adopted December 18, 1991) does not address TIS operations as part of the IVHS, its relevance to this proceeding is unclear. Regarding NAB's suggestion to use 530 kHz and 1710 kHz for TIS, we note that 530 kHz is already available for use and that since it is already outside of the broadcast band under consideration in this proceeding, it is too late to consider making it available for TIS in this proceeding. We are sensitive to concerns that public reliance on TIS requires that such service not be subject to undue disruption. Therefore, in a future proceeding, we will reexamine the status of travelers' information stations and explore the feasibility of a primary allocation for TIS at 1710 kHz. Federal government TIS operations will continue on 1610 kHz on a co-primary basis until they can be reaccommodated in an orderly fashion on an alternative frequency.

25. Cohen, Dippell and Everist, P.C. (CDE) and duTrell, Lundin and Rackley, Inc. (DLR) proposed that the frequency tolerance for TIS comply with that specified for the AM band (20 Hz compared to current 100 Hz for TIS) in order to minimize interference and that TIS be made generally subject to the same technical standards as AM stations. CDE laid out a comprehensive procedure for accomplishing that end in seven detailed recommendations based upon a worst-case application of the technical standards now proposed for TIS in part 90. CDE's approach to the administration of the TIS would place what the Commission sees as an unnecessary, substantial paper work burden on the applicants, who currently certify compliance with Part 90, and do not submit detailed engineering exhibits. Numerous other petitioners also raised the issue of whether the Commission should change the existing 100 Hz frequency tolerance for TIS stations. Once again, however, we note that TIS stations will be operating on a secondary basis to broadcasting. Additionally, we understand that typical TIS equipment now in use meets a much higher standard (around 20 Hz). For these reasons, we find that changing the existing frequency tolerance is not necessary.

**Other Matters**

26. Cuban Interference Relief STA's. Comments were filed by Cox Enterprises, Inc. (Cox), parent company of the licensees of two stations that face similar, though somewhat exceptional, difficulties, WIOD, Miami, Florida and WSUN, St. Petersburg, Florida. Both stations currently operate under separate Special Temporary Authorizations (STA's) to permit increased power levels to compensate for interference received from Cuban stations that were not coordinated under the terms of relevant international notification agreements. Cox cited the persistent nature of the Cuban interference and the substantial expense involved in upgrading each of the affected facilities, and therefore requested that WIOD and WSUN be
antenna pattern augmentation requests, adopted in the Report and Order, LSC and the AFCCE asked whether additional tolerance should be permitted at non-monitored azimuths after the analysis of measurement data indicates a radiated field in excess of the permitted value. Commenters claimed that the "no-tolerance" approach is inconsistent with the procedures established in the Report and Order in Docket No. 21473 (46 FR 11983, February 12, 1981) and propose that a 5% tolerance be added in those directions.

31. The Commission notes that Standard Pattern Conversion made in Docket No. 21473 presented general guidelines to be used for the conversion of many hundreds of theoretical patterns into standard and modified standard antenna patterns. Most of these individual conversions required unique administrative manipulation because they defied the application of a simple computerized methodology for processing of these theoretical patterns. The focus of our efforts now is concentrated on the concept of AM improvement and reducing the potential for interference within the band rather than accommodating a large number of difficult-to-adjust antenna systems. Thus, there is little justification for applying procedures that were never intended for use beyond the initial pattern conversion project and will not achieve an improved AM service. The petitioners' request is accordingly denied, and the text of Section 73.152 will remain as stated in the Report and Order.

32. Class B Power Restrictions

Imposed by NARBA, LSC and dLR raised concerns about limitations placed on Class B (formerly Class III) stations wishing to increase power above 5 kW but restricted by North American Regional Broadcasting Agreement (NARBA) requirements pertaining to this country, the Bahama Islands and the Dominican Republic. These limitations prohibit power levels beyond 5 kW on the former Class III frequencies. The Commission has been working with the Dominican Republic and the Bahamas for a substantial time in an effort to replace the NARBA requirements. Further discussions are to be held in the months ahead. Until an agreement can be reached terminating the NARBA, we will use the Note to § 73.23(b).

33. Night Power for Class D Stations.

In response to the AFCCE petition, we clarify that the calculation of permissible night power for Class D stations specified in § 73.99(f)(7) will employ a 25% exclusion, since such stations can be classified as "low" interferers. The rule will be corrected to read as follows:

"(7) For protection purposes, the nighttime 25% RSL limit will be used in the determination of maximum permissible power:"

Administrative Matters

34. Processing Procedures.

The Report and Order stated that, upon lifting of the freeze on AM applications: (1) New applications must comply with the new technical standards; (2) applications currently on file that have been "cut-off" were not required to amend; and (3) all others were given sixty days from the effective date of the Report and Order to file amendments to satisfy the requirements of the revised rules. In a petition for reconsideration, Romar Communications, Inc. noted that it filed an application for a new AM station in Lansing, NY before the AM freeze went into effect. That application was returned as defective and Romar after the freeze took effect refiled an amended application and a request for acceptance since it was "cut off." Romar asked that the Report and Order be revised so that the new technical standards will not apply to applications with a status similar to its Lansing application. The Commission denies Romar's request because the necessity for definitive processing line procedures requires that the new technical rules be applied in the manner specified in the Report and Order.

Regulatory Flexibility Act

35. Pursuant to the Regulatory Flexibility Act of 1980, the Commission included a final analysis in the Report and Order detailing (i) the need for and purpose of the rules, (ii) the summary of issues raised by public comment in response to the initial regulatory flexibility analysis, Commission assessment, and changes made as a result, and (iii) significant alternatives considered and rejected. The petitions for reconsideration have triggered no substantive changes to the earlier decision and consequently to that final analysis.

Ordering Clauses

36. Accordingly, it is ordered that the petitions for reconsideration filed in this proceeding are granted to the extent...
indicated herein and are otherwise denied.

37. It is further ordered that pursuant to authority contained in Sections 4(i), 301, 303 (b), (f), (g), (l), and (j), 307(d), 308(a), 310, 312, 313, 314 and 331(b) of the Communications Act of 1934, as amended, 47 U.S.C. Sections 4(i) 301, 303 (b), (f), (g), (l), and (j), 307(d), 308(a), 310, 312, 313, 314 and 331(b), part 73 of the Commission’s rules and regulations, 47 CFR part 73, is amended as set forth below. The rules will go into effect 30 days after publication of this Memorandum Opinion and Order in the Federal Register.

§ 2.106 Table of Frequency Allocations

<table>
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<tr>
<th>Region-1 Allocation kHz</th>
<th>Region-2 Allocation kHz</th>
<th>Region-3 Allocation kHz</th>
<th>United States table</th>
<th>FCC use designators</th>
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<td>(2)</td>
<td>(3)</td>
<td>(4)</td>
<td>(5)</td>
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<td>1635–1900, Maritime Mobile/Fixed/Land Mobile/480A, 483, 484, 488.</td>
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</tr>
</tbody>
</table>

§ 73.30 Petition for authorization of an allotment in the 1605-1705 kHz band.

(a) Any party interested in operating an AM broadcast station on one of the ten channels in the 1605–1705 kHz band must file a petition for the establishment of an allotment to its community of license. Each petition must include the following information:

(1) Name of community for which allotment is sought;
(2) Frequency and call letters of the petitioner’s existing AM operation; and
(3) Statement as to whether or not AM stereo operation is proposed for the operation in the 1605–1705 kHz band.

(b) Petitions are to be filed during a filing period to be determined by the Commission. For each filing period,
eligible stations will be allotted channels based on the following steps:

1. Stations are ranked in descending order according to the calculated improvement factor.
2. The station with the highest improvement factor is initially allotted the lowest available channel.
3. Successively, each station with the next lowest improvement factor is allotted an available channel taking into account the possible frequency and location combinations and relationship to previously selected allotments. If a channel is not available for the subject station, previous allotments are examined with respect to an alternate channel, the use of which would make a channel available for the subject station.
4. When it has been determined that, in accordance with the above steps, no channel is available for the subject station, that station is no longer considered and the process continues to the station with the next lowest improvement factor.

(c) If awarded an allotment, a petitioner will have sixty (60) days from the date of public notice of selection to file an application for construction permit on FCC Form 301. (See §§ 73.24 and 73.37(e) for filing requirements). Unless instructed by the Commission to do otherwise, the application shall specify Model I facilities. (See § 73.14).

Upon grant of the application and subsequent construction of the authorized facility, the applicant must file a license application on FCC Form 302.

Note 1: Until further notice by the Commission, the filing of these petitions is limited to licensees of existing AM stations (excluding Class C stations) operating in the 535–1605 kHz band. First priority will be assigned to Class D stations located within the primary service contours of U.S. Class A stations that are licensed to serve communities of 100,000 or more for which there exists no local fulltime aural service.

Note 2: Selection among competing petitions will be based on interference reduction. Notwithstanding the exception contained in Note 5 of this section, within each operational category, the station demonstrating the highest value of improvement factor will be afforded the highest priority for an allotment, with the next priority assigned to the station with next lowest value, and so on, until available allotments are filled.

Note 3: The Commission will periodically evaluate the progress of the movement of stations from the 535–1605 kHz band to the 1605–1705 kHz band to determine whether the 1605–1705 kHz band should continue to be administered on an allotment basis or modified to an assignment method. If appropriate, the Commission will later develop further procedures for use of the 1605–1705 kHz band by existing station licensees and others.

Note 4: Other than the exception specified in note 1 of this section, existing fulltime stations are considered first for selection as described in note 2 of this section. In the event that an allotment availability exists for which no fulltime station has filed a relevant petition, such allotment may be awarded to a licensed Class D station. If more than one Class D station applies for this migration opportunity, the following priorities will be used in the selection process: First priority—Class D station located within the 0.5 mV/m–50% contour of a U.S. Class A station and licensed to serve a community of 100,000 or more, for which there exists no local fulltime aural service; Second priority—Class D stations ranked in order of improvement factor, from highest to lowest, considering only those stations with improvement factors greater than zero.

Note 5: The preference for AM stereo in the expanded band will be administered as follows: when an allotment under consideration (candidate allotment) conflicts with one or more previously selected allotments (established allotments) and cannot be accommodated in the expanded band, the candidate allotment will be substituted for the previously established allotment provided that: the petitioner for the candidate allotment has made a written commitment to the use of AM stereo and the petitioner for the established allotment has not; the difference between the ranking factors associated with the candidate and established allotments does not exceed 10% of the ranking factor of the candidate allotment; the substitution will not require the displacement of more than one established allotment; and both the candidate allotment and the established allotment are within the same priority group.

3. Paragraph (f)(7) § 73.99 is revised as follows:

§ 73.99 Prosunrise service authorization (PSRA) and postsunset service authorization (PSSA).

(a) * * * * *

(f) * * *

(7) For protection purposes, the nighttime 25% RSS limit will be used in the determination of maximum permissible power.

* * * * *

4. Paragraph (k)(4) and the table in paragraph (q) of §73.182 are revised to read as follows:

§ 73.182 Engineering standards of allocation.

(a) * * * * *

(k) * * *

(4) The RSS value will not be considered to be increased when a new interfering signal is added which is less than the appropriate exclusion percentage as applied to the RSS value of the interference from existing stations, and which at the same time is not greater than the smallest signal included in the RSS value of interference from existing stations.

* * * * *

(q) * * *

<table>
<thead>
<tr>
<th>Class of station</th>
<th>Class of channel used</th>
<th>Signal strength contour of area protected from objectionable interference (μV/m)</th>
<th>Permissible interfering signal (μV/m)</th>
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</thead>
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<tr>
<td></td>
<td></td>
<td>Day ²</td>
<td>Night²</td>
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<tr>
<td>A</td>
<td>Clear</td>
<td>SC 100</td>
<td>SC 500 50% SW</td>
</tr>
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<td>A (Alaskan)</td>
<td>do</td>
<td>AC 500</td>
<td>AC 500 GW</td>
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<tr>
<td>B</td>
<td>Clear</td>
<td>AC 100</td>
<td>AC 100 50% SW</td>
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<tr>
<td>C</td>
<td>Regional</td>
<td>AC 500</td>
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<td>500</td>
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proceeding was initiated

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<th>Class of station</th>
<th>Class of channel used</th>
<th>Signal strength contour of area protected from objectionable interference (μV/m)</th>
<th>Permissible Interfering signal (μV/m)</th>
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<tbody>
<tr>
<td>Regional</td>
<td></td>
<td>Day²</td>
<td>Night</td>
</tr>
</tbody>
</table>

1 When a station is already limited by interference from other stations to a contour of higher value than that normally protected for its class, this higher value contour shall be the protection standard for such station. Changes proposed by Class A and B stations shall be required to comply with the following restrictions. Those interferers to another station’s RSS using the 50% exclusion method are required to either reduce their contributions to that RSS by 10%, or to a level at which their contributions no longer enter into the 50% RSS value, whichever is the lesser amount of reduction. Those interferers that contribute to a station’s RSS using the 25% exclusion method but do not contribute to that station’s RSS using the 50% exclusion method may make changes not to exceed their present contribution. Interferers not included in a station’s RSS using the 25% exclusion method as long as the 25% exclusion threshold is not equaled or exceeded. In no case will a reduction be required that would result in a contributing value that is below the pertinent value specified in the table. This note does not apply to Class C stations; or to the protection of Class A stations which are normally protected on a single signal, non-RSS basis.

2 Skywave field strength for 10 percent or more of the time.

3 During nighttime hours, Class C stations in the contiguous 48 States may treat all Class B stations assigned to 1230, 1240, 1340, 1400, 1450 and 1490 kHz in Alaska, Hawaii, Puerto Rico and the U.S. Virgin Islands as if they were Class C stations.

Note: SC=Same channel; AC=Adjacent channel; SW=Skywave; GW=Groundwave.

**INTERSTATE COMMERCE COMMISSION**

**49 CFR PARTS 1039 AND 1145**

[Ex Parts No. 394 (Sub-No. 10)]

**Railroad Rates on Recyclables—Exemptions**

**AGENCY:** Interstate Commerce Commission.

**ACTION:** Final rule.

**SUMMARY:** The Commission has amended its rules by exempting from some aspects of regulation rail transportation of nonferrous recyclable commodities that have been found to recover revenues that are lower than the variable costs of the transportation. Under the amended rules, railroads will no longer have to file tariffs showing the rates on commodities subject to the partial exemption, and as to those commodities they will not be subject to the evidentiary requirements that govern other recyclable commodities in connection with the annual recyclables compliance proceedings. Traffic subject to the partial exemption will continue to be subject to the provisions of 49 U.S.C. 10731(e) prohibiting railroads from increasing individual rates that are already above the maximum recyclables rate ceiling.

**EFFECTIVE DATE:** The final rule is effective June 10, 1993.

**FOR FURTHER INFORMATION CONTACT:**

David Groves, (202) 927-6395, Craig Keats, (202) 927-6046 [TDD for hearing impaired: (202) 275-1721].

**SUPPLEMENTARY INFORMATION:** This proceeding was initiated by a notice of proposed rulemaking published in the Federal Register, 57 FR 41122 (September 9, 1992). Five comments were submitted in response to the notice. Additional information is contained in the Commission’s decision. To purchase a copy of the full decision, write to, call, or pick up in person from: Dynamic Concepts, Inc., Room 2229, Interstate Commerce Commission Building, Washington, DC 20423. Telephone: (202) 289-4357/4359. [Assistance for the hearing impaired is available through TDD services (202) 927-5721.]

**Regulatory Flexibility Analysis**

The Commission certifies that this action will not have a significant impact on a substantial number of small entities. No new regulatory burdens are imposed, directly or indirectly, on such entities. The purpose of the partial exemption is to reduce regulation where regulation is not necessary to protect shippers. The economic impact on small entities will be minimal, because the partial exemption will not substantially change the rates paid by most shippers of recyclables, and the parties most affected by the slightly lessened regulatory burdens are primarily larger railroads. Accordingly, the impact of the partial exemption is not significant within the meaning of the Regulatory Flexibility Act.

This action will not significantly affect either the quality of the human environment or conservation of energy resources.

**List of Subjects**

49 CFR Part 1039

- Intermodal transportation
- Manufactured commodities, Railroads

49 CFR Part 1145

- Administrative practice and procedure, Freight, Railroads


By the Commission, Chairman McDonald, Vice Chairman Simmons, Commissioners Phillips, Philbin, and Walden.

Sidney L. Strickland, Jr.,

Secretary.

For the reasons set forth in the preamble, title 49, chapter X, parts 1039 and 1145 of the Code of Federal Regulations are amended as follows:

**PART 1039—EXEMPTIONS**

1. The authority citation for part 1039 is revised to read as follows:


§ 1039.11 [Amended]

2. Section 1039.11(a) is amended by adding the words "(Note: Certain recyclable commodities may be partially exempted pursuant to the provisions of 49 CFR 1145.9)" after the words "by the Commission at 356 I.C.C. 445-447").

**PART 1145—RAILROAD RATES ON RECYCLABLE COMMODITIES**

3. The authority citation for Part 1145 is revised to read as follows:


4. Part 1145 is amended by adding a new § 1145.9, to read as follows:

§ 1145.9 Exemptions.

Unless otherwise ordered in a revocation proceeding, commodity groups whose revenues, both in the aggregate and for any carriers reporting individually, have been found in an annual compliance proceeding under the rules in this part to be below the variable costs of providing the service
for all territories will not be subject to the tariff filing provisions of the Act or to the requirement that they be made the subjects of future annual compliance proceedings. Recyclable commodity groups to which this partial exemption applies will continue to be subject to the statutory provision prohibiting railroads from increasing individual rates that are already above the cap. Recyclable commodity groups will not be exempted if any individual movements of a commodity in the group have been shown by a shipper to exceed the statutory rate cap. Commodity groups currently qualifying for the partial exemption are Standard Transportation Commodity Code (STCC) 20511, Bakery Products; STCC 22994, Packing or Wiping Cloths or Rags (Processed Textile Matter); STCC 30311, Reclaimed Rubber; STCC 40261, Rubber or Plastic Scrap or Waste; and STCC 41115, Articles, Used, Returned for Repair or Reconditioning.
Proposed Rules

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

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 20, 21, 31, 34, 35, and 61

Potential Amendments to NRC Regulations; Meeting

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of meeting.

SUMMARY: The Nuclear Regulatory Commission (NRC) staff plans to convene a public meeting with representatives of Agreement States to discuss the provisions of proposed revisions of its regulations in several different areas. The revisions are needed to clarify and enhance certain requirements designed to protect the safety of the public and radiation workers. The revisions are also needed to clarify some existing definitions and to incorporate additional definitions in order to bring NRC regulations more in line with regulations used by other organizations that regulate similar byproduct and source material.

DATES: The public meeting will be held on May 20, 1993, from 2 p.m. to 7 p.m.

ADDRESSES: The meeting is to be held at the Westin St. Francis Hotel, 335 Powell Street, San Francisco, California, Telephone (415) 397-7000.

FOR FURTHER INFORMATION CONTACT: James H. Myers, Office of State Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Telephone (301) 504-2326.

SUPPLEMENTARY INFORMATION: The regulations in 10 CFR part 20 address the basic standards for protection against radiation. Potential rulemaking will be discussed which will enhance the ability to implement part 20. A revision to the criteria for releases to the sanitary sewer will be examined and a clarification of the patient release limits (in conjunction with 10 CFR part 35) will be undertaken. The regulations in 10 CFR part 21 regarding the requirements to report defects and non-compliance of materials at facilities other than part 50 and also in Agreement States will be introduced.

The regulations in 10 CFR parts 31 and 32 regarding revised requirements for the possession industrial devices and the accessible air-gap for generally licensed devices will be reviewed. The regulations in 10 CFR part 34 regarding the potential revisions to the radiography and the radiation safety requirements for radiographic operations will be reviewed. The regulations in 10 CFR part 35 regarding requirements for minimizing radiation exposure to the embryo, fetus, or breast-feeding children will be reviewed. The radiopharmacy rule and clarification of the patient release criteria will be discussed in conjunction with part 20. The regulations in 10 CFR part 61 regarding a proposed rulemaking to require financial assurance for long-term care of low-level waste (LLW) facilities will be presented. Also to be covered under part 61 are performance objectives for above-ground disposal of LLW.

A draft paper entitled, "Issues for the Proposed Policy on Compatibility of Agreement States, May 5, 1993" will also be discussed.

The workshop will be Chaired by Mr. Carlton Kammerer, Director, Office of State Programs, U.S. Nuclear Regulatory Commission. The public meeting will be conducted in a manner that will expedite the orderly conduct of business. A transcript of the public meeting will be available for inspection and copying for a fee, at the NRC Public Document Room, 2120 L Street, NW. (Lower Level), Washington, DC 20555 on or about June 10, 1993.

The following procedures apply to public attendance at the workshop:

1. Questions or statements from attendees other than participants, i.e., participating representatives of each Agreement State and participating NRC staff will be entertained as time permits.

2. Seating for the public meeting will be on a first-come, first-served basis.

Dated at Rockville, Maryland, this 6th day of May 1993.

For the Nuclear Regulatory Commission.

Carlton Kammerer,
Director, Office of State Programs.

[FR Doc. 93-11201 Filed 5-11-93; 8:45 am]

BILLING CODE 7550-01-M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Chapter I

[Summary Notice No. PR-93-10]

Petition for Rulemaking; Summary of Petitions Received; Dispositions of Petitions Issued

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of petitions for rulemaking received and of dispositions of prior petitions.

SUMMARY: Pursuant to FAA's rulemaking provisions governing the application, processing, and disposition of petitions for rulemaking (14 CFR part 11), this notice contains a summary of certain petitions requesting the initiation of rulemaking procedures for the amendment of specified provisions of the Federal Aviation Regulations and of denials or withdrawals of certain petitions previously received. The purpose of this notice is to improve the public's awareness of, and participation in, this aspect of FAA's regulatory activities. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of any petition or its final disposition.

DATES: Comments on petitions received must identify the petition docket number involved and must be received by July 12, 1993.


The petition, any comments received, and a copy of any final disposition are filed in the assigned regulatory docket and are available for examination in the Rule Docket (AGC-10), room 915G, FAA Headquarters Building (FOB 10A), 800 Independence Ave., SW., Washington, DC 20591; telephone (202) 267-3132.

FOR FURTHER INFORMATION CONTACT: Mr. Frederick M. Haynes, Office of Rulemaking (ARM-1), Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone (202) 267-3939.

This notice is published pursuant to paragraphs (b) and (f) of §11.27 of part
14 CFR Part 39  
[Docket No. 93–NM–47–AD]  
Airworthiness Directives; Aerospatiale Model ATR42–300 and ATR42–320 Series Airplanes  
AGENCY: Federal Aviation Administration, DOT.  
ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the adoption of a new airworthiness directive (AD) that is applicable to certain Aerospatiale Model ATR42–300 and ATR42–320 series airplanes. This proposal would require an inspection to determine the proper installation of rivets in the key holes of certain fuselage frames; an inspection to detect cracks in the area of the key holes where rivets are missing; and correction of discrepancies. This proposal is prompted by the discovery of cracks around key holes on fuselage frames 25 and 27 where rivets were missing. The actions specified by the proposed AD are intended to prevent the loss of strength of the fuselage frames.

DATES: Comments must be received by July 7, 1993.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–103, Attention: Rules Docket No. 93–NM–47–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056. Comments may be inspected at this location between 9 a.m. and 3 p.m., Monday through Friday, except Federal holidays.

The service information referenced in the proposed rule may be obtained from Aerospatiale, 316 Route de Bayonne, 31060 Toulouse, Cedex 03, France. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington.


SUPPLEMENTARY INFORMATION:  
Comments Invited  
Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this notice may be changed in light of the comments received.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA–public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self–addressed, stamped postcard on which the following statement is made: “Comments to Docket Number 93–NM–47–AD.” The postcard will be date stamped and returned to the commenter.

Availability of NPRMs  

Discussion  
The Direction Générale de l’Aviation Civile (DGAC), which is the airworthiness authority for France, recently notified the FAA that an unsafe condition may exist on certain Aerospatiale Model ATR42–300 and ATR42–320 series airplanes. The DGAC advises that, during a full–scale fatigue test conducted by the manufacturer, cracks were discovered around key holes (positioning holes used during manufacturing) on fuselage frames 25 and 27. The cracking apparently was due to the absence of a rivet in the hole located between stringers 13 and 14. Such cracking, if not detected and corrected in a timely manner, could result in loss of strength and structural integrity of the fuselage frames.

Aerospatiale has issued Service Bulletin ATR42–53–0070, Revision 1, dated June 12, 1992, that describes procedures for a visual inspection to determine the proper installation of rivets in the key holes on main fuselage frames 25 and 27; an eddy current inspection to detect cracks at the key holes where rivets are missing; and the replacement of missing rivets. The DGAC classified this service bulletin as mandatory and issued French
This document proposes the adoption of a new airworthiness directive (AD) that is applicable to certain British Aerospace Model Bae 146-100A, -200A, and -300A series airplanes. This proposal would require modification of the warning horns for the forward and rear lavatory smoke detectors. This proposal is prompted by a report that, during a recent flight of a Model Bae 146 series airplane, the smoke warning horn for the forward lavatory smoke detector did not emit a sound loud enough for the cabin crew members to hear from the passenger cabin. The actions specified by the
Comment Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this notice may be changed in light of the comments received.

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

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: “Comments to Docket Number 93–NM–33–AD.” The postcard will be date stamped and returned to the commenter.

Availability of NPRMs


Discussion

The Civil Aviation Authority (CAA), which is the airworthiness authority for the United Kingdom, recently notified the FAA that an unsafe condition may exist on certain British Aerospace Model BAe 146–100A, –200A, and –300A series airplanes equipped with Hosiden Besson Limited “Cybertone” smoke warning horns. The CAA advises that, during a recent flight of a Model BAe 146 series airplane, the forward lavatory smoke detector triggered the smoke warning horn. The smoke warning horn did not emit a sound loud enough for the cabin crew members to hear from the passenger cabin. This condition, if not corrected, could result in a fire in the lavatory not being discovered and extinguished promptly.

British Aerospace has issued Modification Service Bulletin SB.26–32–36128A, dated April 30, 1992, that describes procedures for modification of the warning horns for the forward and rear lavatory smoke detectors. This modification involves installing a resonator on the smoke warning horn, which will increase the audibility of the horn so that it can be heard by cabin crew members in the passenger cabin. The CAA classified this service bulletin as mandatory.

This airplane model is manufactured in the United Kingdom and is type certificated for operation in the United States under the provisions of § 21.29 of the Federal Aviation Regulations and the applicable bilateral airworthiness agreement. Pursuant to this bilateral airworthiness agreement, the CAA has kept the FAA informed of the situation described above. The FAA has examined the findings of the CAA, reviewed all available information, and determined that AD action is necessary for products of this type design that are certificated for operation in the United States.

Since an unsafe condition has been identified that is likely to exist or develop on other airplanes of the same type design registered in the United States, the proposed AD would require modification of the warning horns for the forward and rear lavatory smoke detectors. The actions would be required to be accomplished in accordance with the service bulletin described previously.

The FAA estimates that 49 airplanes of U.S. registry would be affected by this proposed AD, that it would take approximately 2.5 work hours per airplane to accomplish the proposed actions, and that the average labor rate is $35 per work hour. Required parts would cost approximately $105 per airplane. Based on these figures, the total cost impact of the proposed AD on U.S. operators is estimated to be $11,882.50, or $242.50 per airplane. This total cost figure assumes that no operator has yet accomplished the proposed requirements of this AD action.

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

For the reasons discussed above, I certify that this proposed regulation (1) is not a “major rule” under Executive Order 12291; (2) is not a “significant rule” under the DOT Regulatory Policies and Procedures (44 FR 11034, February 23, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

2. Section 39.13 is amended by adding the following new airworthiness directive:

British Aerospace: Docket 93–NM–33–AD.


Compliance: Required as indicated, unless accomplished previously.

To prevent a fire in the lavatory from not being discovered and extinguished promptly.

(a) Within 5 months after the effective date of this AD, modify the smoke warning horns for the forward and aft lavatory smoke detectors in accordance with British Aerospace Modification Service Bulletin SB.26–32–36128A, dated April 30, 1992.

(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Standardization Branch, ANM–113.

(c) Special flight permits may be issued in accordance with FAR 21.197 and 21.198 to operate the airplane to a location where the requirements of this AD can be accomplished.

Issued in Renton, Washington, on May 6, 1993.

Bill R. Boxwell,
Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

Federal Register / Vol. 58, No. 90 / Wednesday, May 12, 1993 / Proposed Rules 27957

SUMMARY: This document proposes to supersede Airworthiness Directive (AD) 89–06–02, which currently requires repetitively inspecting acrylic cabin and cockpit windows for cracks on certain Fairchild Aircraft (Fairchild) SA26, SA226, and SA227 series airplanes, and replacing any cracked window. The proposed action requires the same inspections as the current AD, but shortens the repetitive inspection interval. Several acrylic window failures have occurred on the affected airplanes prior to the currently required inspection intervals. The actions specified by the proposed AD are intended to prevent acrylic cockpit or cabin window failures, which could result in airframe damage and decompression injuries.

DATES: Comments must be received on or before July 8, 1993.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Central Region, Office of the Assistant Chief Counsel, Attention: Rules Docket No. 93–CE–03–AD, room 1558, 601 E. 12th Street, Kansas City, Missouri 64106. Comments may be inspected at this location between 8 a.m. and 4 p.m., Monday through Friday, holidays excepted.

Service information that applies to the proposed AD may be obtained from Fairchild Aircraft, P.O. Box 790490, San Antonio, Texas 78279–0490; Telephone (512) 824–9421. This information also may be examined at the Rules Docket at the address above.

FOR FURTHER INFORMATION CONTACT: Mr. Hung Viet Nguyen, Aerospace Engineer, FAA, Airplane Certification Office, 4400 Blue Mound Road, Fort Worth, Texas 76193–0150; Telephone (817) 624–5155; Facsimile (817) 624–5029.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications should identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this notice may be changed in light of the comments received.

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

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: “Comments to Docket No. 93–CE–03–AD.” The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Central Region, Office of the Assistant Chief Counsel, Attention: Rules Docket No. 93–CE–03–AD, room 1558, 601 E. 12th Street, Kansas City, Missouri 64106.

Discussion

AD 89–06–02, Amendment 39–6153 (54 FR 10139, March 10, 1989), currently requires repetitively inspecting acrylic cabin and cockpit windows for cracks on certain Fairchild SA26, SA226, and SA227 series airplanes, and replacing any cracked window. These actions are accomplished in accordance with the instructions in the following Fairchild service bulletins (SB), as applicable:


The FAA has received several reports of these acrylic windows failing on several of the affected airplanes that are in compliance with AD 89–06–02. The failures are occurring at the latter end of the repetitive inspection interval. The FAA has determined that the repetitive inspection interval established by AD 89–06–02 should be shortened to prevent the referenced acrylic window failures, and that the Model SA227–TT airplanes should be added to the applicability list since they are of similar design.

Fairchild has updated and replaced the service information that was required to comply with AD 89–06–02, consisting of the following:

The FAA has determined that AD action should be taken in order to prevent acrylic cockpit or cabin window failures, which could result in airframe damage and decompression injuries. Since an unsafe condition has been identified that is likely to exist or develop in other Fairchild SA26, SA226, and SA227 series airplanes of the same type design, the proposed action would supersede AD 89–06–02, Amendment 39–6153, with a new AD that would retain the requirements of repetitively inspecting the acrylic cabin and cockpit windows, and replacing any cracked windows but would shorten the repetitive inspection interval. It would also add the Model SA227–TT airplanes to the applicability list of the proposed AD. The proposed AD would be accomplished in accordance with the revised service bulletins referenced above, as applicable.

The compliance time for the proposed AD is presented in both hours time-in-service (TIS) and calendar time. The referenced acrylic cabin and cockpit windows are affected by those conditions present while the airplane is in flight and while the airplane is on the ground. In addition, the utilization rates of the affected airplanes vary among operators. For example, operators in unscheduled service utilize their airplanes an average of approximately 300 to 400 hours TIS annually, while those in commuter service (scheduled) utilize their airplanes an average of approximately 2,000 hours TIS annually. Based on this wide utilization rate variance and the fact that these windows are affected when the airplane is in flight and on the ground, the FAA has determined that the affected acrylic cabin and cockpit windows should be repetitively inspected every 1,000 hours TIS, or every 12 calendar months, whichever occurs first.

The FAA estimates that 633 airplanes in the U.S. registry would be affected by the proposed AD, that it would take approximately 3 workhours per airplane to accomplish the proposed action, and that the average labor rate is approximately $55 an hour. Based on these figures, the total cost impact of the proposed AD on U.S. operators is estimated to be $104,445. AD 89–06–02 currently requires the same inspections as the proposed AD for all affected models except the Model SA227–TT airplanes, which have been added to the applicability of the proposed AD; however, the proposed AD would reduce the interval time between the repetitive inspections. Therefore, the cost impact of the proposed AD on U.S. operators of all affected models other than the Model SA227–TT airplanes is the same as AD 89–06–02, except for an increase in the number of inspection repetitions.

The regulations proposed herein would not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this proposal would not have sufficient federalism implications to warrant the preparation of a Federalism Assessment. For the reasons discussed above, I certify that this action (1) is not a “major rule” under Executive Order 12291; (2) is not a “significant rule” under DOT Regulatory Policies and Procedures (44 FR 11034, February 22, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action has been placed in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption ADDRESSES.

List of Subjects in 14 CFR Part 39
Air transportation, Aircraft, Aviation safety, Safety

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

2. Section 39.13 is amended by removing AD 89–06–02, Amendment 39–6153 (54 FR 10139, March 10, 1989), and by adding the following new airworthiness directive:


Note 1: The applicability of this AD takes precedence over that specified in the service information.

Compliance: Required within the next 50 hours time-in-service (TIS) after the effective date of this AD, unless already accomplished within the last 1,000 hours TIS (compliance with AD 89–06–02), and thereafter at intervals not to exceed 1,000 hours TIS or every 12 calendar months, whichever occurs first.

To prevent acrylic cockpit or cabin window failures, which could result in airframe damage and decompression injuries, accomplish the following:

(a) Visually inspect all acrylic cabin side windows for cracks in accordance with the following service bulletins (SB), as applicable:

<table>
<thead>
<tr>
<th>Model</th>
<th>Service bulletin</th>
</tr>
</thead>
<tbody>
<tr>
<td>SA26–T</td>
<td>25–56–20–042,</td>
</tr>
<tr>
<td></td>
<td>Issued: No.</td>
</tr>
<tr>
<td></td>
<td>November 28,</td>
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<tr>
<td></td>
<td>1988, Revised:</td>
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<td></td>
<td>November 26,</td>
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<tr>
<td>SA26–AT</td>
<td>25–56–20–042,</td>
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<td>Issued: No.</td>
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<td>November 28,</td>
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<td>1988, Revised:</td>
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<td>November 26,</td>
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<tr>
<td>SA226–T</td>
<td>226–56–001,</td>
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<td>Issued: February</td>
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<td></td>
<td>2, 1983, Revised:</td>
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<td></td>
<td>February 7,</td>
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<tr>
<td>SA226–T(B)</td>
<td>226–56–001,</td>
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<td>Issued: February</td>
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<td>2, 1983, Revised:</td>
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<td>February 7,</td>
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<tr>
<td>SA226–AT</td>
<td>226–56–002,</td>
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<td>Issued: March 3,</td>
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<td>1983, Revised:</td>
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<td>SA226–TC</td>
<td>226–56–002,</td>
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<td></td>
<td>Issued: March 3,</td>
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<td>1983, Revised:</td>
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<td>SA227–AT</td>
<td>227–56–002,</td>
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<td>Issued: January</td>
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<td></td>
<td>5, 1984, Revised:</td>
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<td>April 1, 1993.</td>
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<td>SA227–AC</td>
<td>227–56–002,</td>
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<td>Issued: January</td>
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<td>5, 1984, Revised:</td>
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<td></td>
<td>April 1, 1993.</td>
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<tr>
<td>SA227–TT</td>
<td>227–56–001,</td>
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<td></td>
<td>Issued: February</td>
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<td></td>
<td>2, 1983, Revised:</td>
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<td>November 26,</td>
</tr>
</tbody>
</table>

(b) Visually inspect all acrylic cockpit windows for cracks in accordance with the following service bulletins, as applicable:

<table>
<thead>
<tr>
<th>Model</th>
<th>Service bulletin</th>
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</thead>
<tbody>
<tr>
<td>SA26–T</td>
<td>25–56–10–038,</td>
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<tr>
<td></td>
<td>Issued: October</td>
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<td>8, 1984, Revised:</td>
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<td>February 7, 1991</td>
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<td>25–56–10–038,</td>
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<td>Issued: October</td>
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<td>8, 1984, Revised:</td>
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<td>February 7, 1991</td>
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</table>
Federal Energy Regulatory Commission

18 CFR Part 284

[Docket No. RM93-4-000]

Standards for Electronic Bulletin Boards Required Under Part 284 of the Commission's Regulations

Issued May 7, 1993.

AGENCY: Federal Energy Regulatory Commission, DOE.

ACTION: Notice of informal conference.

SUMMARY: The Federal Energy Regulatory Commission (Commission) will be holding an informal conference as agreed at the last conference in this matter. This conference is part of a series of conferences on developing standards for electronic bulletin boards as announced by the notice issued March 10, 1993 (58 FR 14530, March 18, 1993).

DATES: Tuesday, May 18, 1993, beginning at 1 p.m. and Wednesday, May 19, 1993, beginning at 8 a.m.

ADDRESSES: Federal Energy Regulatory Commission, Hearing Room 1, 810 First Street NE., Washington, DC 20426.

FOR FURTHER INFORMATION CONTACT:


DEPARTMENT OF ENERGY

Food and Drug Administration

21 CFR Parts 182 and 184

[Docket No. 77N-0223]

Gelatin; Tentative Affirmation of GRAS Status as a Direct Human Food Ingredient

AGENCY: Food and Drug Administration, HHS.

ACTION: Tentative final rule.

SUMMARY: The Food and Drug Administration (FDA) is tentatively affirming that gelatin is generally recognized as safe (GRAS) for use as a direct human food ingredient. The safety of the ingredient has been obtained from the Fort Worth Airplane Certification Office.

(g) All persons affected by this directive may obtain copies of the document referred to herein upon request to Fairchild Aircraft, P.O. Box 790490, San Antonio, Texas 78279-0490; or may examine this document at the FAA, Central Region, Office of the Assistant Chief Counsel, room 1556, 601 E. 12th Street, Kansas City, Missouri 64106.

(b) This amendment supersedes AD 89-06-02, Amendment 23-6351.

Issued in: Kansas City, Missouri, on May 4, 1993.

Barry D. Clements
Manager, Small Airplane Directorate, Aircraft Certification Office.

[FR Doc. 93-11193 Filed 5-11-93; 8:45 am] BILLING CODE 4810-15-P
evaluated under the comprehensive safety review conducted by the agency.

DATES: Written comments by July 12, 1993.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.


SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of November 11, 1977 (42 FR 58763), FDA published a proposal to affirm that gelatin is GRAS for use as a direct and indirect human food ingredient. The proposal was based on FDA's review of safety information developed by the Select Committee on GRAS Substances (the Select Committee) of the Federation of American Societies for Experimental Biology. That proposal was published in accord with the announced FDA review of the safety of GRAS and prior-sanctioned food ingredients.

In accordance with §170.35 (21 CFR 170.35), copies of the scientific literature review on gelatin and the report of the Select Committee on gelatin have been made available for public review in the Dockets Management Branch (address above). Copies of these documents have also been made available for public purchase from the National Technical Information Service, as announced in the proposal.

In addition to proposing to affirm the GRAS status of gelatin, FDA gave public notice that it was unaware of any prior-sanctioned food ingredient uses for this substance, other than the proposed conditions of use. Persons asserting additional or extended uses, in accordance with approvals granted by the U.S. Department of Agriculture (USDA) or FDA before September 6, 1958, were given notice to submit proof of those sanctions, so that the safety of any prior-sanctioned use could be determined. That notice was also an opportunity to have prior-sanctioned uses of gelatin recognized by issuance of an appropriate regulation under Part 181—Prior-Sanctioned Food Ingredients (21 CFR part 181) or affirmed as GRAS under 21 CFR part 184 or 186, as appropriate. FDA also gave notice that failure to submit proof of an applicable prior sanction in response to the proposal would constitute a waiver of the right to assert such a sanction at any future time.

No reports of a prior-sanctioned use for gelatin were submitted in response to the proposal. Therefore, in accordance with the proposal, any right to assert a prior sanction for the use of gelatin under conditions different from those set forth in this final rule has been waived.

II. Comments

FDA received 16 comments in response to the agency's proposal on gelatin. Nine comments came from food manufacturers (four foreign and five domestic manufacturers); five comments came from trade associations (four domestic and one foreign association); one comment came from a foreign research and development firm; and one comment came from a food scientist. A summary of the comments and the agency's responses follow.

A. Hides Used to Make Gelatin

Seven comments addressed FDA's proposed action to find that gelatin manufactured from hides preserved with pentachlorophenol (PCP) is not GRAS. Some comments rationalized that PCP-exposed hides could be used to manufacture food-grade gelatin because the procedures used to obtain gelatin from PCP-exposed hides would result in the elimination of PCP and other contaminants. One comment stated that the analytical method for determining PCP levels was sensitive to 1 part per million (ppm). Four of the comments requested that a specification for PCP in gelatin be set, so that PCP-treated hides could be used as a source material for gelatin manufacture.

The agency disagrees with these comments. In the 1977 proposal, the agency clearly stated its concern that PCP is known to contain, and to condense to form, hexa-, hepta-, and octachlorodibenzo-p-dioxins which are extremely toxic. It was because of this concern that the agency proposed to find that gelatin from PCP-treated hides is not GRAS.

Although some comments claimed that PCP can be reduced to low levels, that an analytical method for PCP is available, and that specifications should be set, no data were presented by these comments as to how manufacturing procedures reduce PCP levels, the levels of PCP that can be attained for gelatin, and whether these levels are safe.

Data from the FDA Total Diet Study have shown the presence of PCP in a number of gelatin samples collected as part of the program. The Total Diet Study is a continuing FDA program that determines the levels of various pesticide residues and contaminants in foods. From 1965 to 1976, PCP analyses as part of the FDA Total Diet Study found that gelatin was a significant source of PCP in the American diet. Some samples analyzed during those years showed PCP levels in gelatin as high as 17 ppm. More recently (1982 to 1987), the FDA Total Diet Study has found PCP levels of generally less than 20 parts per billion (ppb) in gelatin.

Additional data concerning PCP in domestic and imported food-grade gelatin were provided in a small gelatin PCP contamination study conducted by FDA in 1985. FDA collected and analyzed 12 domestic and 2 import samples. There was no PCP detected in the domestic samples; however, the two import samples contained 90 and 74 ppb of PCP.

After the agency published its proposal on gelatin, the Environmental Protection Agency (EPA) issued a series of notices on PCP and pentachlorophenol.

In the Federal Register of October 18, 1978 (43 FR 48443), EPA issued a notice of rebuttable presumption against registration (RPAR) for pesticide products containing PCP. This notice stated that PCP and its derivatives had been found to exceed certain risk criteria, as set forth in EPA regulations (40 CFR 162.11). The presumption set for the document was that PCP meets or exceeds the risk criteria relating to its teratogenic and fetotoxic effects in mammalian species.

In the Federal Register of February 19, 1981 (46 FR 13020), EPA issued a preliminary notice of determination concluding the RPAR of various wood preservatives. The document concluded that, on the basis of information received after the issuance of the October 18, 1978 notice, PCP and its sodium salt posed a risk of oncogenicity because of the presence of the contaminants hexachlorodibenzo-p-dioxin and hexachlorobenzene. EPA stated that these contaminants also had the potential to produce teratogenic and fetotoxic effects.

In the Federal Register of July 13, 1984 (49 FR 28666), EPA issued a notice of intent to cancel registration for wood preservative uses of creosote, PCP (including its salts), and inorganic arsenicals. This action concluded the RPAR of wood preservative uses of PCP and its salts. EPA also announced certain changes in the terms and conditions of registration requirements for manufacturers and users of PCP products used as wood preservatives.

In the Federal Register of January 10, 1986 (51 FR 1334), EPA published an amendment of its July 13, 1984, notice of intent to cancel the wood preservative uses of PCP and its salts.
The amendment was issued in response to hearings in which several trade associations and certain registrants suggested alternative or mutually agreeable mechanisms for accomplishing the regulatory goals of the July 13, 1984, notice. The changes accepted were minor.

Lastly, in the Federal Register of January 21, 1987 (52 FR 2282), EPA published a “Final Determination and Intent to Cancel and Deny Applications for Registrations of Pesticide Products Containing Pentachlorophenol for Non-Wood Uses.” This action was based on EPA’s concern that PCP poses risks of fetotoxicity and teratogenicity, as well as carcinogenicity, because of the presence of the contaminants hexachlorodibenz-p-dioxin and hexachlorobenzene. In this notice, EPA announced its final decision to cancel registrations of all products containing PCP, including its salts and esters for nonwood use, except for pulp/paper mill, oil well operation, and cooling tower uses. EPA announced its determination that the risks of the nonwood preservative uses of PCP were greater than the social, economic, and environmental benefits of these uses. Accordingly, EPA denied applications and cancelled regulations for products containing PCP, including its salts and esters. Among the applications cancelled was the use of PCP in leather tanning. The use of existing stocks of PCP products in tanning uses in the United States was officially stopped on January 21, 1988.

In evaluating the safety of PCP, FDA reviewed the 1989 National Toxological Program (NTP) technical report entitled “Toxicology and Carcinogenesis Studies of Two Pentachlorophenol Technical Grade Mixtures.” The NTP toxicology studies of PCP were conducted by adding PCP to the diet of B6C3F1 mice for 2 years in two forms: (1) Technical-grade PCP and (2) a commercial product known as Dowicide EC-7, both of which contained approximately 90 percent PCP. The impurities found in the technical-grade PCP included various chlorinated compounds such as tetrachlorophenol (3.8 percent), octachlorodibenzofuran (1.9 percent), nonachlorohydroxydibenzofuran (0.5 percent), and other chlorinated dibenzodioxins and dibenzofurans which were present at concentrations ranging from 1.4 to 1.386 ppm. Dowicide EC-7, on the other hand, contained tetrachlorophenol (9.4 percent) and concentrations of chlorinated dibenzodioxins and dibenzofurans at less than 0.68 ppm.

The results of the studies revealed significant, dose-related increases in hepatocellular neoplasms and adrenal gland medullary pheochromocytomas in male mice with both forms of PCP. The female mice showed a significant increase in these tumors only at the 600-ppm level for Dowicide EC-7. By contrast, increases in the incidence of female mice with hemangiomata or hemangiosarcoma of the circulatory system were observed with both forms of PCP.

The agency also investigated the impurities found in these preparations to determine if the carcinogenic effect is related to their presence. The most abundant impurity in both products was tetrachlorodibenzofuran, found at 3.8 percent and 9.4 percent in the technical-grade PCP and in Dowicide EC-7, respectively. The presence of the numerous chlorinated compounds in the technical-grade PCP did not cause a significant difference in the mice’s response to this compound as compared to Dowicide EC-7. These results show that the neoplasms found in the mice were likely induced by PCP rather than by the impurities found in the test materials.

Based on its comprehensive review of available data, FDA tentatively concludes that bioassays have shown that PCP itself induces carcinogenic neoplasms in mice. In addition, PCP may contain impurities, such as hexachlorodibenz-p-dioxin and hexachlorobenzene, that have been shown to have carcinogenic, oncogenicity, teratogenicity, and fetotoxicity (see the Federal Register of January 21, 1987 (52 FR 2284)).

Therefore, based upon EPA’s actions and because PCP has been shown to be a carcinogen, the agency finds no basis to change its position, as stated in the proposal, concerning PCP. Since EPA has cancelled the registration concerning the use of PCP in leather tanning, the agency no longer has a concern about gelatin prepared from domestic hides. However, there is a potential for gelatin prepared from imported hides to be contaminated with PCP.

Therefore FDA has modified the proposed regulation to state in §184.1319(b) that there shall be no detectable levels of PCP in gelatin when tested by the method referenced in this regulation. The method has been demonstrated to reliably detect PCP at 20 ppb (14th ed., Association of Official Analytical Chemists (AOAC), 1st supp., March 1985, sections 29.A14 to 29.A18).

2. Seven comments addressed the agency’s proposal to limit the use of tannery waste material in the manufacture of food-grade gelatin and stated that the proposed gelatin regulation does not clearly define tannery waste material. The comments further asserted that all portions of hides that have not been tanned should be considered suitable raw materials for the production of food-grade gelatin. One comment made the point that hide trimmings may be considered waste material to the tanner in his operations, but that this part of the hide would be useful to the gelatin manufacturer because these trimmings did not undergo tanning treatment.

FDA agrees with these comments. The intent of the proposal was to provide only that those hides or parts of hides that were exposed to tanning processes would not be acceptable as source materials in the manufacture of GRAS gelatin. The agency finds it unfortunate that it used the term “tannery waste materials” in proposed §184.1318(a) (now §184.1319(a)) because this term includes raw materials, such as salted or brined hide trimmings, tanned and dehaired hides, hide trimmings and splits, and pickled hide trimmings, that have not been exposed to tanning substances that would bind hide protein.

Furthermore, based upon information provided in the comments, it appears that the multistage process by which hides are converted to leather includes removal of irregular portions of the hide. The remaining hide part is then brine- or salt-cured, and the hide may be further trimmed, limed to remove hair, and processed to split the grain side of the hide from the flesh side. The hide is then pickled and enters the tanning process. The tanning process consists of treating the hides with chemical tanning agents that insolubilize its protein. The hide is then further treated to produce leather.

The agency understands the confusion that resulted because the term “tannery waste materials” was not well-defined. In response to these comments, and in keeping with the intent of the proposal, the agency tentatively concludes that hides exposed to chromium chemical tanning agents are not suitable raw materials used to manufacture food-grade gelatin because of the potential for certain chromium components to produce adverse health effects. However, those portions of animal hides that have not been subjected to chemical treatment with tanning agents are suitable source materials in the manufacture of gelatin. Therefore, the agency has modified its proposal in this tentative final rule by removing the term “tannery waste materials” from the last sentence of §184.1319(a) and inserting in its place the term “tanning agents used to insolubilize protein.” FDA believes that...
this change will eliminate this misunderstanding.

3. One comment stated that FDA had issued a prior sanction for hides treated with chromium salts or chromium tanning agents that concluded that these hides were suitable for the preparation of food-grade gelatin. In support of this claim, the comment submitted a letter issued by FDA on January 25, 1961. Additionally, the comment stated the belief that hides containing chromium tanning agents were suitable for use in the manufacture of gelatin.

FDA disagrees with this comment. A prior decision, as defined under section 201(a)(4) of the Federal Food, Drug, and Cosmetic Act, is a sanction or approval granted by FDA or USDA with respect to use of a substance in food prior to September 6, 1958. Because the letter submitted by the comment was issued in 1961, it does not qualify as a prior sanction.

In a Federal Register notice published on April 9, 1970 (35 FR 5810) (as amended at 35 FR 9855 (June 16, 1970)), the agency revoked earlier informal opinions concerning articles intended for use as components of or in contact with food. This action was based on the need to reexamine such opinions in light of more current scientific information. The agency received no requests for reexamination of the chromium issue following the June 16, 1970 publication.

Additionally, the comment failed to identify the chromium compounds currently used to treat hides. Therefore, the agency has no basis upon which to give further consideration to this comment.

4. One comment reported the development of a process for the preparation of gelatin from chromium-treated hides that resulted in a level of chromium in the gelatin of no more than 100 ppm. The comment noted that toxicity testing of the product in rats had begun. However, the final report on this testing was not available to ensure that there was no safety concern. The comment requested that FDA defer action on the use of chromium-treated tanning substances until present animal studies on gelatin prepared from chromium-treated hides have been completed and evaluated.

Fourteen years have passed since the comment was received. During that interval, no data were submitted to support this comment. Therefore, the agency is not making any changes in the proposal on the basis of this comment. Therefore, the agency is not making any changes in the proposal on the basis of this comment.

B. Food-grade Specifications for Gelatin

5. Eleven comments addressed the proposed food-grade specifications for gelatin. Some objected to the establishment of any specifications for gelatin, while others stated that the proposed specifications are arbitrary and capricious and not in conformity with the known properties of gelatin or with industry practice, particularly the proposed specifications for acid, moisture, and protein content. The comments stated that the percentage limitations for these components were either incorrect, too rigid, or not relevant to the safety of gelatin. The comments specifically stated that the percentage variability of moisture in gelatin was caused by humidity variation in storage areas and might be as high as 16 percent rather than the 10 percent upper limit set forth in the proposal.

In the time since issuance of this proposal, the agency has been working with the Food Chemicals Codex Committee of the National Academy of Sciences to establish specifications for gelatin. FDA tentatively concludes that the specifications developed in the proposal are not necessarily appropriate for food-grade gelatin. Therefore, the agency has removed the specifications from the tentative final rule. In the Federal Register of November 22, 1991 (56 FR 58910), FDA announced an opportunity for public comment on certain Food Chemicals Codex monographs, including one for gelatin. When the specifications for gelatin are finalized, the agency will propose to incorporate them into this regulation. Until the specifications are finalized, FDA believes that the public health will be adequately protected if gelatin complies with the description in the regulation and is of food-grade purity (21 CFR 170.30(h)(1) and 182.1(b)(3)).

6. Several comments were concerned about the proposed limit of 40 ppm of sulfur dioxide in gelatin. The comments contended that the proposed limit is very low in relation to permitted sulfur dioxide content in other foods. The comments further stated that the proposed limitation on sulfur dioxide is insignificant and unwarranted because it does not relate to any potential safety concern.

As pointed out in response to the previous comment, FDA is working with the Food Chemicals Code Committee to develop specifications for gelatin. Therefore, FDA does not intend at this time to adopt the 40 ppm limit for sulfur dioxide in gelatin. The Food Chemicals Code Committee will develop an appropriate specification for sulfur dioxide based upon available scientific evidence.

The agency points out, however, that residues of sulfites in gelatin can cause allergic-type reactions in sensitive individuals. In the Federal Register of July 9, 1986 (51 FR 25012), the agency adopted 21 CFR 101.100(a)(4), which requires that detectable amounts of sulfites in a finished food be declared on the label regardless of whether the sulfites have been directly or indirectly added to the food. Thus, contrary to the assertion in the comments, the level of sulfites in a food can present a safety concern.

C. Methods of Preparation of Gelatin

7. Eleven comments addressed the methods of preparation of gelatin. Some of the comments stated that the definitions for type A (acid) and type B (alkaline) gelatins in the proposed regulation did not reflect industry practice that these definitions appear to restrict pig skins to acid processing and cattle hides and bones to alkaline or lime processing. The comments stated that these sources of gelatin are routinely subjected to either type of processing. In addition, the comments suggested that the sources for both types of gelatin be described as “collagenous raw materials” rather than specify the particular animal.

FDA has redefined type A and B gelatins in accordance to current industry practice and has modified §184.1310(a) so as not to restrict gelatin type A processing only to pig skins and gelatin type B processing only to cattle hides and bones. The revised regulation makes clear that both A and B types can be obtained from either pig or cattle sources by selecting the appropriate acid or alkaline processing method. However, the agency finds it necessary to identify the animal source (pigs and cattle) of the skin, hide, or bone to clearly indicate the sources that it evaluated in making its tentative GRAS determination. The proposal did not imply that other sources were permitted in the manufacture of gelatin.

D. Food Categories and Levels of Use

8. Ten comments took issue with the proposed list of food categories in which the agency proposed to affirm that the use of gelatin is GRAS and the levels of use of gelatin in those food categories. Although some suggested additional uses, such as meat aspics, poultry aspics, ice cream, and other milk products, and levels of use, the majority of these comments expressed the opinion that there should be no restrictions on its use except for current good manufacturing practice (CGMP).
The comments further stated that the use of gelatin in food is self-limiting because excessive use of gelatin would form rubbery, unpalatable products.

In procedural regulations that it published in the Federal Register of October 19, 1983 (48 FR 48567), FDA stated that it no longer intends to list routinely food categories, technical effects, and general use for ingredients that are affirmed as GRAS with no limitation other than CGMP. In response to the comments that it received on gelatin, the agency has tentatively concluded that it is not necessary to list specific food categories, levels of use, and technical effects in the GRAS regulation for this ingredient. As explained in the proposal, a large margin of safety exists for the use of this substance as described in § 184.1318, and a reasonably foreseeable increase in the levels of use of this substance will not adversely affect human health. Therefore, the agency is proposing to affirm the GRAS status of gelatin based upon CGMP in accordance with § 184.1(b)(1).

Two comments addressed the use of hard and soft gelatin capsules for use as carriers of dietary supplements. One of the comments pointed out that encapsulation was mentioned in the preamble as a use for gelatin, but that there was no mention of it in the regulation. The comment suggested that this use should be specifically mentioned in §§ 184.1318 and 186.1318.

While, as explained in the previous comment, such a specific mention is not necessary, in response to these comments FDA has included the statement in § 184.1319(c) that gelatin may be used as a formulation aid under § 170.3(o)(14) and as a surface-finishing agent under § 170.3(o)(30) to make gelatin capsules.

III. Conclusions

This action is being issued as a tentative final rule because the proposal to affirm gelatin was published 15 years ago in the Federal Register of November 11, 1977 (42 FR 58763). The agency needs a feel for how to update comments on the proposed action.

Consistent with its traditional practice, FDA proposed to establish separate regulations for gelatin in parts 186 and 188 to govern its direct and indirect GRAS uses, respectively. However, as announced in the Federal Register of October 19, 1983 (48 FR 49456), FDA has reconsidered its traditional practice and has concluded that a duplicative listing in part 186 is unnecessary as a general rule and may cause confusion. Thus, unless safety considerations make it necessary to impose specific purity specifications or other restrictions on the indirect use of a GRAS substance, FDA does not list in part 186 substances that are affirmed as GRAS for direct use in part 184. In keeping with this change in policy, FDA is withdrawing proposed § 186.1318.

FDA believes that the general requirement that indirect GRAS ingredients be of a purity suitable for their intended use in accordance with CGMP is sufficient to ensure the safe use of this ingredient. Therefore, the agency is not proposing any specific purity specifications for its indirect use. The indirect uses of gelatin proposed for inclusion in § 186.1318 will be affirmed as GRAS under §§ 184.1318 and 184.1(a) when, and if, FDA adopts the former section.

The format of this final regulation is different from that in the proposal. FDA has revised § 184.1318(c) to make clear the agency’s determination that GRAS affirmation is based upon CGMP conditions of use. In addition, FDA has redesignated § 184.1318 as § 184.1319 to accommodate the sections in part 184. These changes have no substantive effect but are made merely for clarity. The agency has determined under 21 CFR 25.24(b)(7) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Economic Impact

FDA has examined the economic implications of the tentative final rule affirming that gelatin is GRAS for use as a direct human food ingredient, as required by Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96-354). Executive Order 12291 compels agencies to use cost-benefit analysis when making decisions. The Regulatory Flexibility Act requires regulatory relief for small businesses where feasible. The agency finds that this tentative final rule is not a major rule as defined by Executive Order 12291. In accordance with the Regulatory Flexibility Act, FDA has also determined that this tentative final rule will not have a significant adverse impact on a substantial number of small businesses.

The compliance cost to firms using imported hides to manufacture gelatin is estimated to be zero because FDA believes no current activity is prohibited by this tentative final rule. Firms using imported hides to manufacture gelatin and the foreign manufacturer of those hides may undergo compliance cost due to the specification of no detectable levels of PCP in gelatin. Potential benefits include health benefits due to a reduction of the amount of PCP in gelatin and resources saved by eliminating the need to prepare further petitions to affirm the GRAS status of this substance.

Interested persons may, on or before July 12, 1993, submit to the Dockets Management Branch written comments regarding this tentative final rule. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects

21 CFR Part 182

Food ingredients, Food packaging, Spices and flavorings.

21 CFR Part 184

Food ingredients, Incorporation by reference.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, it is proposed that 21 CFR parts 182 and 184 be amended as follows:

PART 182—SUBSTANCES GENERALLY RECOGNIZED AS SAFE

1. The authority citation for 21 CFR part 182 continues to read as follows:


§ 182.70 [Amended]

2. Section 182.70 Substances migrating from cotton and cotton fabrics used in dry food packaging is amended by removing the entry for “Gelatin.”

PART 184—DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

3. The authority citation for 21 CFR part 184 continues to read as follows:


4. New § 184.1319 is added to subpart B to read as follows:

§ 184.1319 Gelatin.

(a) Gelatin (CAS Reg. No. 9000-70-8) is the product obtained by the hydrolysis of collagen (the chief protein component of connective tissue of the
animal body). The resulting gelatin is one of two types, commonly referred to as type A and type B. Type A is produced by acid processing. Type B is produced by alkaline or lime processing. Either process may be used to process pig skins, cattle hides, or pig or cattle bones. The pig skins, cattle hides, or pig or cattle bones shall not have been exposed to pentachlorophenol (PCP) nor to tanning agents used to insolubilize protein.

(b) The development of food-grade specifications for gelatin is being undertaken by the agency in cooperation with the National Academy of Sciences. In the interim, this ingredient must be of a purity suitable for its intended use. Additionally, there shall be no detectable level of PCP as determined by the "Gas Chromatographic Method" as described in sections 29.A14 through 29.A18 of the Official Methods of Analysis of the Association of Official Analytical Chemists, 14th ed. (1985), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or an equivalent method. Copies of the "Gas Chromatographic Method" may be obtained from the Association of Official Analytical Chemists, 2200 Wilson Blvd., suite 400, Arlington, VA 22201-9907, or available for inspection at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice and may be used as a formulation aid under § 170.3(o)(14) of this chapter and as a surface-finishing agent under § 170.3(o)(30) to make gelatin capsules.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT
Office of the Assistant Secretary for Public and Indian Housing
24 CFR Part 909
[Docket No. R-83-1850; FR-3464-P-01]
RIN 2577-AB22
Choice In Public Housing Management
AGENCY: Office of the Assistant Secretary for Public and Indian Housing, HUD.
ACTION: Proposed rule.
SUMMARY: This proposed rule would add new regulations to implement the provisions of the Choice in Public Housing Management program that are required by new regulation. The Choice in Public Housing Management program, which is authorized by section 121 of the Housing and Community Development Act of 1992 ("the Act"), authorizes funding to enable residents of severely distressed public housing owned or operated by troubled public housing agencies to hire alternative managers to operate and rehabilitate their projects. This rule would provide the foundation for development of program guidelines and a Notice of Fund Availability, which would eventually be incorporated into a more far-reaching rule.
DATES: Comment Due Date: June 11, 1993.
ADDRESSES: Interested persons are invited to submit comments regarding this rule to the Rules Docket Clerk, Office of General Counsel, room 10276, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410.
Communications should refer to the above Docket Number and title. A copy of each communication submitted will be available for public inspection and copying between 7:30 a.m. and 5:30 p.m. weekdays at the above address.
FURTHER INFORMATION CONTACT: Roger Brainer, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410; (202) 708-1380 (voice); (202) 708-0850 (TDD for the hearing- or speech-impaired). (Telephone numbers are not toll-free.)
SUPPLEMENTARY INFORMATION:
I. Information Collections
The information collections contained in §§ 909.110 and 909.120 have been submitted to the Office of Management and Budget (OMB) for review under the Paperwork Reduction Act of 1980 (42 U.S.C. 3501-3520). The public reporting burden for these information collection requirements are described under the topic of Other Matters in this Preamble. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the HUD Rules Docket Clerk, at the address stated above, and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for HUD, Washington, DC 20503.
II. Introduction
Section 121 of the Housing and Community Development Act of 1992 (Pub. L. No. 102-550) added a new section 25 to the United States Housing Act of 1937, to authorize the Choice in Public Housing Management program. Under this program, the Secretary may approve up to 25 applications from resident councils in eligible public housing projects for the transfer of the management from the public housing agency to an alternative manager. To be eligible for the program, a project must be a severely distressed project owned or operated by a troubled public housing agency. An entire project or one or more buildings in the project may be transferred to an alternative manager. A troubled public housing agency is one with 250 or more units that (1) has been designated as a troubled public housing agency for the current fiscal year and for the two preceding fiscal years under the Public Housing Management Assessment Program (PHMAP) or HUD's previous program to designate troubled PHAs, and (2) has not met its targets for improved performance under PHMAP (24 CFR part 901).
There are two independent bases on which a project can be determined to be severely distressed for purposes of this program, in accordance with section 24 of the United States Housing Act of 1937.
The project could satisfy the distress criteria that the project: "(1) Requires major redesign, reconstruction or redevelopment, or partial or total demolition, to correct serious deficiencies in the original design (including appropriately [sic] high population density), deferred maintenance, physical deterioration or obsolescence of major systems and other deficiencies in the physical plant of the project; [(2)] is occupied predominantly by families with children who are in a severe state of distress, characterized by such factors as high rates of unemployment, teenage pregnancy,
Environmental Policy Act of 1969 (42 U.S.C. 4321), HUD’s implementing regulations at 24 CFR part 50, and the environmental laws and authorities listed in 24 CFR 50.4. Final selection and approval of a grant will be contingent upon the results of these environmental reviews.

After a project has been selected to participate in the program, HUD will enter into a contract with the manager for the transfer of management and will enable the manager to receive the operating subsidies and capital improvements funding attributable to the project directly and, where funding has been requested and approved, rehabilitation grants available under this program.

Fifty million dollars was appropriated for this program, which amount is subject to budgetary adjustments. Of that amount, up to five percent can be allocated for technical assistance to residents of public housing and resident councils.

III. Provisions Requiring Regulations

For the first of the two provisions for which the Act requires regulations, the Department has chosen to model the fidelity bonding and insurance requirements for this program after those established for Resident Management Corporations (24 CFR part 964), because of the similarity between the responsibilities of alternative managers and RMCs. The RMC requirements have been edited slightly to reflect the direct contractual relationship between HUD and the alternative manager.

For the most part, the selection criteria in this rule are simply those that are statutorily mandated. However, the Department has made a few additions to the selection criteria. First, the extent to which the PHA has cooperated and will continue to cooperate in the transfer of management has been added. It is the Department’s belief that without the cooperation of the PHA at each step of the transfer, the alternative manager and the resident council will have difficulty in successfully managing the project. Second, the criterion on the capacity of the alternative manager to operate and manage rehabilitation of the project has been divided into two selection criteria, to reflect the possibility that some alternative managers might have very good capacity for management of the project but not the same level of capacity for supervising the rehabilitation, or vice versa. Third, different selection criteria have been used for projects requesting transfer of management and rehabilitation grant funding and those requesting only transfer of management. The Department will rate these two types of applications separately but select applications based on ranking them together.

IV. Other Matters

Justification for Short Comment Period

In accordance with 24 CFR 10.1, the Department usually provides a comment period of 60 days for proposed rules. However, upon a determination that there is good cause for a shorter comment period, a shorter period can be used. In this case, the Department is under a statutory deadline to publish a proposed rule, solicit public comments, and publish a final rule by April 26, 1993. In addition, the Secretary has decided that this rule must be published in time to permit funding to proceed under the program before September 30, 1993. With these constraints, the Department has determined that it would be contrary to the public interest to delay the rulemaking process by providing for a 60-day comment period and that a 30-day comment period is justified.

Impact on the Economy

This rule does not constitute a "major rule" as that term is defined in section 1(b) of the Executive order on Federal Regulations issued by the President on February 17, 1981. An analysis of the rule indicates that it does not (1) have an annual effect on the economy of $100 million or more; (2) cause a major increase in costs or prices for consumers, individual industries, federal, state, or local government agencies, or geographic regions; or (3) have a significant adverse effect on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

Environmental Review

A Finding of No Significant Impact with respect to the environment has been made in accordance with HUD regulations at 24 CFR part 50 that implement section 102(2)(C) of the National Environmental Policy Act of 1969. 42 U.S.C. 4332. The Finding of No Significant Impact is available for public inspection and copying during regular business hours (7:30 a.m. to 5:30 p.m.) in the Office of the Rules Docket Clerk, room 10276, 451 Seventh Street, SW., Washington, DC 20410-0500.
Impact on Small Entities

The Secretary, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this rule before publication and by approving it certifies that this rule does not have a significant economic impact on a substantial number of small entities.

Federalism Impact

The General Counsel, as the Designated Official under section 6(a) of Executive Order 12612, Federalism, has determined that the policies contained in this rule will not have substantial direct effects on states or their political subdivisions, or the relationship between the federal government and the states, or the distribution of power and responsibilities among the various levels of government. As a result, the rule is not subject to review under the order.

Impact on the Family

The General Counsel, as the Designated Official under Executive Order 12866, The Family, has determined that some of the policies in these guidelines will have a potential significant impact on the formation, maintenance and general well-being of the family. The rule would help empower low-income residents of public housing by enabling them to select the manager of their project. The rule would also promote the economic independence and self-sufficiency of these low-income families by awarding points in the selection criteria to those projects that have adequately addressed the needs of residents to become self-sufficient. Thus, alternative management of public housing can be expected to support family values, by empowering low-income families to become involved in the state and condition of their housing and their neighborhood and by giving them the skills and the means to live independently in mainstream American society. Since the impact on the family is beneficial, no further review is necessary.

Public Reporting Burden

The Department has determined that there are information collection requirements contained in this rule and has estimated the public reporting burden involved. The estimates of burden include the time for reviewing the instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

### Choice in Public Housing Management (FR 3464)—Burden Hours

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<th>Total annual responses</th>
<th>Hours per response</th>
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Regulatory Agenda

This rule was listed as item 1562 in the Department's Semiannual Agenda of Regulations published on April 26, 1993 (58 FR 24382, 24434) in accordance with Executive Order 12291 and the Regulatory Flexibility Act.

List of Subjects in 24 CFR Part 909

Grant programs—housing and community development, Public housing.

Accordingly, part 909 is proposed to be added to 24 CFR as follows:

PART 909—CHOICE IN PUBLIC HOUSING AGENCY (PHA) MANAGEMENT

§ 909.100 Eligible projects.

(a) General. An application for transfer of management may request either:

1. Approval to transfer management to an eligible alternative manager and rehabilitation grant for the eligible housing; or

2. If rehabilitation funding is not necessary, approval to transfer management to an eligible alternative manager.

(b) Selection criteria for applications requesting rehabilitation funding.

The following selection criteria will be used by HUD for selecting applications to be funded from among those requesting rehabilitation funding:

1. The quality of the plan for rehabilitating the eligible housing;

2. The extent to which the capacity or potential capacity of the proposed manager to manage the housing;

3. The extent to which the planned rehabilitation will result in the long-term viability of the housing at a reasonable cost; and

4. The extent to which the PHA has cooperated and will continue to cooperate with the proposed rehabilitation and alternative management.

(c) Selection criteria for applications not requesting rehabilitation funding.

The following selection criteria will be used by HUD for selecting applications to be funded from among those not requesting rehabilitation funding:

1. Approval to transfer management to an eligible alternative manager and rehabilitation grant for the eligible housing; or

2. If rehabilitation funding is not necessary, approval to transfer management to an eligible alternative manager.
(1) The extent of the capacity or potential capacity of the proposed manager to manage the housing;
(2) The extent to which a program is proposed to enable the residents to achieve economic independence and self-sufficiency; and
(3) The extent to which the PHA has cooperated and will continue to cooperate with the proposed alternative management.

(d) HUD review and ranking. HUD will review all applications submitted in response to a Notice of Fund Availability for the Choice in Public Housing Management program and assign points in accordance with the selection criteria, depending on whether or not rehabilitation grant funding is requested. HUD will then rank order the two types of applications together and make selections based on this ranking.

Dated: March 12, 1993.

Michael B. Janis,
General Deputy Assistant Secretary for Public and Indian Housing.

[FR Doc. 93-11178 Filed 5-11-93; 8:45 am]
BILLING CODE 4210-05-M

DEPARTMENT OF THE INTERIOR
Office of Surface Mining Reclamation and Enforcement

30 CFR Part 906
Colorado Permanent Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Proposed rule; extension of comment period.

SUMMARY: OSM is announcing receipt of a request for an extension of a comment period pertaining to a previously proposed amendment to the Colorado permanent regulatory program (hereinafter, the “Colorado program”) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The proposed amendment would revise provisions of Colorado’s rules concerning backfilling and grading for elimination of highwalls and limited variances from approximate original contour requirements. The proposed amendment is intended to revise the State program to be consistent with the corresponding Federal regulations and improve operational efficiency.

This notice sets forth the times and locations that the Colorado program and proposed amendment to that program are available for public inspection and the comment period during which interested persons may submit written comments on the proposed amendment.

DATES: Written comments must be received by 4 p.m., m.d.t., May 29, 1993.

ADDRESSES: Written comments should be mailed or hand delivered to Robert H. Hagen at the address listed below.

Copies of the Colorado program, the proposed amendment, the additional explanatory information, and all written comments received in response to this notice will be available for public review at the addresses listed below during normal business hours, Monday through Friday, excluding holidays. Each requester may receive one free copy of the proposed amendment by contacting OSM’s Albuquerque Field Office.

Robert H. Hagen, Director, Albuquerque Field Office, Office of Surface Mining Reclamation and Enforcement, 505 Marquette Avenue, NW., suite 1200, Albuquerque, NM 87102. Telephone: (505) 766-1486.

Colorado Division of Minerals and Geology, Department of Natural Resources, 215 Centennial Building, 1313 Sherman Street, Denver, Colorado 80203. Telephone: (303) 866-3567.

FOR FURTHER INFORMATION CONTACT: Robert H. Hagen, Telephone: (505) 766-1486.

SUPPLEMENTARY INFORMATION:
I. Background on the Colorado Program
On December 15, 1980, the Secretary of the Interior conditionally approved the Colorado program. General background information on the Colorado program, including the Secretary’s findings, the disposition of comments, and the conditions of approval of the Colorado program can be found in the December 15, 1980, Federal Register (55 FR 82173).

Subsequent actions concerning Colorado’s program and program amendments can be found at 30 CFR 906.15, 906.16, and 906.30.

II. Discussion of Request for Extension of Comment Period for Proposed Amendment
By letter dated March 19, 1993 (Administrative Record No. CO-536), Colorado submitted a proposed amendment to its program pursuant to SMCRA. Colorado submitted the proposed amendment at its own initiative.

Colorado proposed to revise Rule 4.14.1(2) (a) to (1) reference proposed and existing rules containing exemptions from the requirement that all disturbed areas be backfilled and graded to their approximate original contour, and (2) exempt underground and remaining operations from the requirement for complete highwall elimination if they meet the criteria proposed at Rules 4.14.1(2)(f) and (g).

Colorado proposed new Rules 4.14.1(2) (f) and (g) setting forth performance standards by which underground mining operations or remaining operations would be permitted if exempted from the
requirement for complete elimination of face-up areas and highwalls. Both (1) underground mining operations, with an existing highwall that was in place prior to August 3, 1977, and (2) remaining operations initiated after August 3, 1977, on sites that were mined and abandoned prior to August 3, 1977 with a preexisting highwall, would be exempted if the volume of all reasonably available spoil is insufficient to completely backfill the highwall and face-up area so as to achieve a safety factor of 1.3. The proposed performance standards are:

(1) All reasonably available spoil in the immediate vicinity of the highwall shall be used to backfill the area and shall be included in the permit area.

(2) The backfill shall be graded to a slope that is compatible with the approved postmining land use and which provides adequate drainage and meets a minimum static safety factor of 1.3.

(3) The highwall remnant shall be sufficiently stable so as not to pose a hazard to the public health and safety or to the environment.

(4) Exposed coal seams, toxic and acid forming materials, and combustible materials shall be adequately covered or treated in accordance with Rule 4.14.3, and (5) spoil placed on the outslope during mining operations that occurred prior to August 3, 1977 shall not be disturbed if such disturbance will cause instability of the remaining spoil or otherwise increase the hazard to the public health and safety or to the environment.

Colorado proposed to revise Rule 4.14.1(2) to specify that the requirements of Rule 4.14.2, which addresses general grading requirements, may be modified by the Division of Minerals and Geology (Division) for (1) steep slope mining pursuant to Rule 4.27, (2) underground operations pursuant to Rules 4.14.1(2) (e) and (f), and (3) remining operations pursuant to Rule 4.14.1(2)(g). Colorado proposed to revise Rule 4.14.2(1)(b) to exempt an operation from complete elimination of a highwall if retention of a highwall remnant is approved by the Division pursuant to proposed Rules 4.14.1(2)(f) of 4.14.1(2)(g).

OSM published a notice in the April 14, 1993, Federal Register (58 FR 19387) announcing receipt of the amendment and inviting public comment on the adequacy of the proposed amendment (Administrative Record No. CO-541). The public comment period would have closed May 14, 1993. OSM has not yet completed its review of the proposed amendment and Colorado has not submitted any new information. However, by letter dated April 29, 1993, the Citizens' Coal Council requested an extension of time, until May 26, 1993, in which to review and possibly provide comments on the proposed amendment (Administrative Record No. CO-543). Accordingly, OSM is extending the comment period for 15 days.

III. Public Comment Procedures

OSM is extending the comment period on the proposed Colorado amendment to provide the public additional opportunity to consider the adequacy of the amendment. In accordance with the provisions of 30 CFR 732.17(h), OSM is seeking comments on whether the proposed amendment satisfies the applicable program approval criteria of 30 CFR 732.15. If the amendment is deemed adequate, it will become part of the Colorado program.

Written Comments

Written comments should be specific, pertain only to the issues proposed in this rulemaking, and include explanations in support of the commentor's recommendations. Comments received after the time indicated under DATES or at locations other than the Albuquerque Field Office will not necessarily be considered in the final rulemaking or included in the administrative record.

IV. Procedural Determinations

Executive Order 12291

On July 12, 1984, the Office of Management and Budget (OMB) granted OSM an exemption from sections 3, 4, 7 and 8 of the Executive Order 12291 for actions related to approval or conditional approval of State regulatory programs, actions, and program amendments. Therefore, preparation of a regulatory impact analysis is not necessary and OMB regulatory review is not required.

Executive Order 12778

The Department of the Interior has conducted the reviews required by section 2 of Executive Order 12778 and has determined that this rule meets the applicable standards of subsections (a) and (b) of this section. However, these standards are not applicable to the actual language of State regulatory programs and program amendments since each such program is drafted and implemented by a specific State, not by OSM. Under sections 503 and 305 SMCRA (30 U.S.C. 1253 and 12550) and the Federal regulations at 30 CFR 730.11, 732.15, and 732.17(h)(10), decisions on proposed State regulatory programs and program amendments submitted by the States must be based solely on a determination of whether the submittal is consistent with SMCRA and its implementing Federal regulations and whether the other requirements of 30 CFR parts 730, 731, and 732 have been met.

National Environmental Policy Act

No environmental impact statement is required for this rule since section 702(d) of SMCRA (30 U.S.C. 1292(d)) provides that agency decisions on proposed State regulatory program provisions do not constitute major Federal actions within the meaning of section 102(2)(C) of the National Environmental Policy Act (42 U.S.C. 4332(2)(C)).

Paperwork Reduction Act

This rule does not contain information collection requirements that require approval by OMB under the Paperwork Reduction Act (44 U.S.C. 3507 et seq.).

Regulatory Flexibility Act

The Department of the Interior has determined that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 et seq.). The State submittal that is the subject of this rule is based upon counterpart Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. Accordingly, this rule will ensure that existing requirements previously promulgated by OSM will be implemented by the State. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions for the counterpart Federal regulations.

List of Subjects in 30 CFR Part 306

Intergovernmental relations, Surface mining, Underground mining.
DEPARTMENT OF TRANSPORTATION
Coast Guard
33 CFR Part 165
[CGD1 93-021]
Safety Zone; Heritage of Pride, Fireworks Display, New York, New Jersey
AGENCY: Coast Guard, DOT.
ACTION: Notice of proposed rulemaking.
SUMMARY: The Coast Guard proposes to establish a safety zone in the Lower Hudson River 200 yards southwest of pier 45, Manhattan, for a fireworks program. The event, sponsored by Heritage of Pride Inc., will take place on Sunday, June 27, 1993 from 10 p.m. until 11 p.m. This safety zone in the Lower Hudson River is needed to protect spectators and participants from the hazards associated with exploding pyrotechnics in the area.

DATES: Comments must be received on or before June 28, 1993.

ADDRESSES: Comments should be mailed to Commander, Coast Guard Group New York, Bldg. 106, Governors Island, New York 10004-5096, or may be delivered to the Waterways Management Office, Bldg. 109, between 8 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

Any person wishing to visit the office must contact the Waterways Management Office at (212) 688-7933 to obtain advance clearance due to the fact that Governors Island is a military installation with limited access.

FOR FURTHER INFORMATION CONTACT: Lieutenant (junior grade) J.J. Gleason, Waterways Management Officer, Coast Guard Group New York (212) 688-7933.

SUPPLEMENTARY INFORMATION:
Request for Comments
The Coast Guard encourages interested persons to participate in this rulemaking by submitting written data, views, or arguments. Persons submitting comments should include their names and addresses, identify this notice (CGD1-93-021) and the specific section of the proposal to which their comments apply, and give reasons for each comment. Persons wanting acknowledgment of receipt of comments should enclose a stamped, self-addressed postcard or envelope.

The Coast Guard will consider all comments received during the comment period. It may change this proposal in view of the comments. The Coast Guard plans no public hearing. Persons may request a public hearing by writing to the Project Manager at the address under ADDRESSES. If it is determined that the opportunity for oral presentations will aid this rulemaking, the Coast Guard will hold a public hearing at a time and place announced by a later notice in the Federal Register.

Drafting Information
The drafters of this notice are LTJG J.J. Gleason, Project Manager, Captain of the Port, New York and LCDR J. Stieb, Project Attorney, First Coast Guard District, Legal Office.

Background and Purpose
On March 18, 1993, Heritage of Pride Inc. submitted a request to hold a fireworks program in the Lower Hudson River, New York and New Jersey. This safety zone is needed to protect boaters from the hazards associated with the exploding of pyrotechnics in the area.

Discussion of Proposed Amendments
The Coast Guard proposes to establish a safety zone in the Lower Hudson River, 200 yards southwest of pier 45, Manhattan, within a 300 yard radius of two fireworks barges located at or near 40°43'55"N and 74°01'03"W. The safety zone will be in effect from 10 p.m. until 11 p.m. on June 27, 1993. This closure is needed to protect spectators and participants from the hazards that accompany a fireworks program. No vessel will be permitted to enter or move within this area unless permitted to do so by the Coast Guard Captain of the Port, New York or the sponsor.

Regulatory Evaluation
These regulations are not major under Executive Order 12291 and not significant under Department of Transportation Regulatory Policies and Procedures (44 FR 11040; February 26, 1979). Due to the limited duration of the event and the extensive advisories that will be made to the affected maritime community the Coast Guard expects the economic impact of this proposal to be so minimal that a Regulatory Evaluation is unnecessary.

Small Entities
Under the Regulatory Flexibility Act (5 U.S.C. 601 et seq.), the Coast Guard must consider whether this proposal will have a significant economic impact on a substantial number of small entities. "Small entities" include independently owned and operated small businesses that are not dominant in their field and that otherwise qualify as "small business concerns" under Section 3 of the Small Business Act (15 U.S.C. 632).

For reasons set forth in the above Regulatory Evaluation, the Coast Guard certifies under 5 U.S.C. 605(b) that this proposal, if adopted, will not have a significant economic impact on a substantial number of small entities.

Collection of Information
This proposal contains no collection of information requirements under the Paperwork Reduction Act (44 U.S.C. 3501).

Federalism
The Coast Guard has analyzed this action in accordance with the principles and criteria contained in Executive Order 12291 and has determined that this proposal does not raise sufficient federalism implications to warrant the preparation of a Federalism Assessment.

List of Subjects in 22 CFR Part 165
Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

Proposed Regulations
For reasons set out in the preamble, the Coast Guard proposes to amend 33 CFR part 165 as follows:
1. The authority citation for Part 165 continues to read as follows:
Authority: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05-1(g), 8.94-1, 8.94-6, and 160.5, 49 CFR 1.46.
2. A temporary section, 165.T01-021
is added to read as follows:
§ 165.T01-021 Heritage of Pride Fireworks Display, New York and New Jersey
(a) Location. The safety zone will include all waters within a 300 yard radius of two fireworks barges located at or near 40°43'55"N and 74°01'03"W approximately 200 yards southwest of pier 45, Manhattan, in the Lower Hudson River.
SUPPLEMENTARY INFORMATION:
Request for Comments

The Coast Guard encourages interested persons to participate in this rulemaking by submitting written data, views, or arguments. Persons submitting comments should include their name and address, identify this notice (CGD1-93-010), the specific section of the proposal to which their comments apply, and give reasons for each comment. Persons wanting acknowledgment of receipt of comments should enclose a stamped, self-addressed postcard or envelope.

The Coast Guard will consider all comments received during the comment period. It may change this proposal in view of the comments. The Coast Guard plans no public hearing. Persons may request a public hearing by writing to the Project Manager at the address under "ADDRESSES." If it is determined that the opportunity for oral presentations will aid this rulemaking, the Coast Guard will hold a public hearing at a time and place announced by a later notice in the Federal Register.

Drafting Information

The drafters of this notice are LTJG L.D. Johnson, Project Manager, Captain of the Port, New York and LCDR J. Stieb, Project Attorney, First Coast Guard District, Legal Office.

Background and Purpose

On February 26, 1993, Macy’s submitted a request to hold a fireworks program in the Lower Hudson River on July 4, 1993. The proposed regulations would establish a safety zone in the Lower Hudson River in order to protect boaters from the hazards associated with the exploding of pyrotechnics in the area.

DATES: Comments must be received on or before June 28, 1993.

ADDRESSES: Comments should be mailed to Commander, Coast Guard Group New York, Bldg. 108, Governors Island, New York 10004-5096 or may be delivered to the Waterways Management Office, Bldg. 109, between 8 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

Any person wishing to visit the office must contact the Waterways Management Office at (212) 668-7933 to obtain advance clearance due to the fact that Governors Island is a military installation with limited access.

FOR FURTHER INFORMATION CONTACT:
Lieutenant (junior grade) L.D. Johnson, Waterways Management Officer, Coast Guard Group New York (212) 668-7933.
Proposed Regulations

For reasons set out in the preamble, the Coast Guard proposes to amend 33 CFR part 165 as follows:

1. The authority citation for part 165 continues to read as follows:


2. A temporary § 165.T01-010 is added to read as follows:

§ 165.T01-010 Macy's Fourth of July Fireworks New York and New Jersey.

(a) Location. The safety zone includes all waters of the Lower Hudson River from the North Cove Yacht Club, north to Pier 42 along the Manhattan shoreline, across the river to the Lackawanna Canal, south to Morris Street along the New Jersey shoreline thence back to the North Cove Yacht Club.

(b) Effective period. This regulation will be effective from 8 p.m. until 10 p.m. on July 4, 1993.

(c) Regulations. (1) No person or vessel may enter, transit, or remain in this safety zone during the effective period of regulation unless participating in the event as authorized by the sponsor or the Coast Guard Captain of the Port, New York.

(2) All persons and vessels shall comply with the instructions of the COTP or the designated on scene personnel. U.S. Coast Guard patrol personnel include commissioned, warrant, and petty officers of the Coast Guard. Upon hearing five or more blasts from a U.S. Coast Guard vessel, the operator of a vessel shall proceed as directed.

Dated: April 12, 1993.

R.M. Larabee,
Captain, U.S. Coast Guard, Captain of the Port, New York.

[FR Doc. 93-11237 Filed 5-11-93; 8:45 am]
BILLING CODE 4410-14-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52
[CA 37-7-5713; FRL-4654-7]

Approval and Promulgation of Implementation Plans California State Implementation Plan Revision; San Bernardino County Air Pollution Control District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed rulemaking (NPR).

SUMMARY: EPA is proposing a limited approval and limited disapproval of revisions to the California State Implementation Plan (SIP) adopted by the San Bernardino County Air Pollution Control District (SBCAPCD) on March 3, 1992. The California Air Resources Board (CARB) submitted this revision to EPA on June 19, 1992. The revision concerns SBCAPCD Rule 1116, Automotive Refinishing Operations, which controls the emission of volatile organic compounds (VOCs) during the refinishing of automobiles. EPA has evaluated Rule 1116 and is proposing a limited approval under section 110(k)(3) and 301(a) of the Clean Air Act, as amended in 1990 (CAA or the Act) because this rule strengthens the SIP. At the same time, EPA is proposing a limited disapproval under section 110(k)(3) and 301(a) of the CAA because Rule 1116 does not meet the Part D, section 182(e)(2)(A) requirement of the CAA.

DATES: Comments must be received on or before June 11, 1993.

ADDRESSES: Comments may be mailed to: Daniel Moor, Rulemaking Section II (A-9-3), Air and Toxics Division, Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105.

Copies of Rule 1116 and EPA’s evaluation report of Rule 1116 are available for public inspection at EPA’s Region 9 office during normal business hours. Copies of the submitted Rule 1116 are also available for inspection at the following locations:

California Air Resources Board, Stationary Source Division, Rule Evaluation Section, 2030 L Street, Sacramento, CA 95814.

San Bernardino County Air Pollution Control District, 15428 Civic Drive, Victorville, California 92392.

For Further Information Contact:

Chris Stamou, Rulemaking Section II (A-9-3), Air and Toxics Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105. Telephone: (415) 744-1187.

SUPPLEMENTARY INFORMATION:

Background

On September 12, 1979, EPA promulgated a list of ozone nonattainment areas under the provisions of the 1977 Clean Air Act (1977 CAA or pre-amended Act), that included SBCAPCD. (44 FR 53081; 40 CFR 81.305) Because SBCAPCD was unable to reach attainment by the statutory attainment date of December 31, 1982, California requested under pre-amended section 172(a)(2), and EPA approved, an extension of the attainment date to December 31, 1987. (40 CFR 52.222) SBCAPCD did not attain the ozone standard by the approved attainment date. On May 26, 1988, EPA notified the Governor of California, pursuant to section 110(a)(2)(H) of the pre-amended Act, that SBCAPCD’s portion of the SIP was inadequate to attain and maintain the ozone standard and requested that deficiencies in the existing SIP be corrected (EPA’s SIP-Call). On November 15, 1990, amendments to the 1977 CAA were enacted. (Pub. L. 101–548, 104 Stat. 2399, codified at 42 U.S.C. section 7492.) In amended section 182(a)(2)(A) of the CAA, Congress statutorily adopted the requirement that nonattainment areas fix their deficient reasonably available control technology (RACT) rules for ozone and established a deadline of May 15, 1991 for states to submit corrections of those deficiencies.

Section 182(a)(2)(A) applies to areas designated as nonattainment prior to enactment of the amendments and classified as marginal or above as of the date of enactment. It requires such areas to adopt and correct RACT rules pursuant to pre-amended section 172(b) as interpreted in pre-amendment guidance. EPA’s SIP-Call used that guidance to indicate the necessary corrections for specific nonattainment areas. San Bernardino Air Basin is classified as severe; therefore, this area is subject to the RACT fix up requirement and the May 15, 1991 deadline.

The State of California submitted many revised and new RACT rules to EPA for incorporation into its SIP on June 19, 1992, including the rule being acted on in this notice. This notice addresses EPA’s proposed action for Rule 1116, Automotive Refinishing Operations. Submitted Rule 1116 was found to be complete on March 2, 1992 pursuant to EPA’s completeness criteria that are set forth in 40 CFR part 51, appendix V and is being proposed for

Among other things, the pre-amendment guidance consists of those portions of the proposed post-1987 ozone and carbon monoxide policy that concern RACT, 52 FR 45044 (November 24, 1987);

“Issues Relating to VOC Regulation Cutpoints, Deficiencies, and Deviations, Clarification to Appendix D of November 24, 1987 Federal Register Notice” (Blue Book) (notice of availability was published in the Federal Register on May 25, 1988); and the existing control technique guidelines (CTGs).

SBCAPCD retained its designation and was classified by operation of law pursuant to sections 107(d) and 181(a) upon the date of enactment of the CAA. See 56 FR 56694 (November 8, 1991).

EPA adopted the completeness criteria on February 16, 1990 (55 FR 5830) and, pursuant to Continued
limited approval and limited disapproval.

Rule 1116 controls the emission of volatile organic compounds (VOCs) from automobile refinishing operations. VOCs contribute to the production of ground-level ozone and smog. Rule 1116 is a new rule which has been adopted to meet EPA's SIP Call and the section 182(a)(2)(A) CAA requirement. The following is EPA's evaluation and proposed action for SBCAPCD Rule 1116.

In determining the approvability of a VOC rule, EPA must evaluate the rule for consistency with the requirements of the CAA and EPA regulations, as found in section 110 and Part D of the CAA and 40 CFR Part 51 (Requirements for Preparation, Adoption, and Submittal of Implementation Plans). The EPA interpretation of these requirements, which forms the basis for today's action, appears in various EPA policy documents listed in footnote 1. Among these provisions is the requirement that a VOC rule must, at a minimum, provide for the implementation of RACT for stationary sources of VOC emissions. This requirement was carried forth from the pre-amended Act.

For the purpose of assisting states and local agencies in developing RACT rules, EPA prepared a series of Control Technique Guideline (CTG) documents. The CTGs are on the underlying requirements of the Act and specify the presumptive norm for what is RACT for specific source categories. Under the CAA, Congress ratified EPA's use of these documents, as well as other Agency policy, for requiring States to "fix-up" their RACT rules. See section 182(a)(2)(A). SBCAPCD's Rule 1116, Automotive Refinishing Operations, is a new rule which was adopted to control VOC emissions during the refinishing of automobiles. Presently there is no CTG applicable to automobile refinishing. Further interpretations of EPA policy are found in the Blue Book. In general, these guidance documents have been set forth to ensure that VOC rules are fully enforceable and strengthen or maintain the SIP.

EPA has evaluated SBCAPCD's submitted Rule 1116 for consistency with the CAA, EPA regulations, and EPA policy and has found that the rule is, for the most part, consistent with federal law and EPA policy.

Although SBCAPCD Rule 1116 will strengthen the SIP, this rule contains deficiencies which were required to be corrected pursuant to the section

182(a)(2)(A) requirement of Part D of the CAA. Rule 1116 allows the Air Pollution Control Officer discretion in choosing equivalent test methods for determination of compliance; Rule 1116 fails to require recordkeeping requirements for exempt facilities; and Rule 1116 contains inadequate rule applicability section. A detailed discussion of these deficiencies can be found in the Technical Support Document for Rule 1116 (1/25/93), which is available from the U.S. EPA, Region 9 office. Because of these deficiencies, the rule is not approvable pursuant to the section 182(a)(2)(A) of the CAA because it is not consistent with the interpretation of section 172 of the 1977 CAA as found in the Blue Book and may lead to rule enforceability problems.

Because of the above deficiencies, EPA cannot grant full approval of Rule 1116 under section 110(k)(3) and Part D. Also, because the submitted rule is not composed of separable parts which meet all the applicable requirements of the CAA, EPA cannot grant partial approval of Rule 1116 under section 110(k)(3). However, EPA may grant a limited approval of the submitted rule under section 110(k)(3) in light of EPA's authority pursuant to section 301(a) to adopt regulations necessary to further air quality by strengthening the SIP. The approval is limited because EPA's action also contains a simultaneous limited disapproval. In order to strengthen the SIP, EPA is proposing a limited approval of SBCAPCD's submitted Rule 1116 under sections 110(k)(3) and 301(a) of the CAA.

At the same time, EPA is also proposing a limited disapproval of this rule because it contains deficiencies that have not been corrected as required by section 182(a)(2)(A) of the CAA, and, as such, Rule 1116 does not fully meet the requirements of Part D of the Act. Under section 179(e)(2), if the Administrator disapproves a submission under section 110(k) for an area designated nonattainment, based on the submission's failure to meet one or more of the elements required by the Act, the Administrator must apply one of the sanctions set forth in section 179(b) unless the deficiency has been corrected within 18 months of such disapproval. Section 179(b) provides two sanctions available to the Administrator: sanctions related to highway funding and sanctions related to off-fence. The 18 month period referred to in section 179(a) will begin at the time EPA published final notice of this disapproval. Moreover, the final disapproval triggers the federal implementation plan (FIP) requirement under section 110(c). It should be noted that the rule covered by this NPR has been adopted by SBCAPCD and is currently in effect in San Bernardino County. EPA's limited disapproval action in this NPR does not prevent EPA or SBCAPCD from enforcing this rule.

Nothing in this action should be construed as permitting or allowing or establishing any precedent for any future request for revision to any state implementation plan. Each request for revision to the state implementation plan shall be considered separately in light of specific technical, economic, and environmental factors and in relation to relevant statutory and regulatory requirements.

**Regulatory Process**

Under the Regulatory Flexibility Act, 5 U.S.C. Section 600 et seq., EPA must prepare a regulatory flexibility analysis assessing the impact of any proposed or final rule on small entities. 5 U.S.C. sections 603 and 604. Alternatively, EPA may certify that the rule will not have a significant impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises and government entities with jurisdiction over populations of less than 50,000.

Limited approvals under section 110 and 301 and subchapter I, Part D of the CAA do not create any new requirements, but simply approve requirements that the State is already imposing. Therefore, because the federal SIP-approval does not impose any new requirements, I certify that it does not have a significant impact on any small entities affected. Moreover, due to the nature of the federal-state relationship under the CAA, preparation of a regulatory flexibility analysis would constitute federal inquiry into the economic reasonableness of state action.


EPA's limited disapproval of the State request under section 110 and 301 and subchapter I, Part D of the CAA does not affect any existing requirements applicable to small entities. Federal disapproval of the state submittal does not affect its federal or state enforceability. Moreover, EPA's limited disapproval of the submittal does not impose any new federal requirements.

Therefore, EPA certifies that this limited disapproval action does not have a significant impact on a substantial number of small entities because it does not remove existing
requirements nor does it impose any new federal requirements.

This action has been classified as a table 2 action by the Regional Administrator under the procedures published in the Federal Register on January 19, 1989 (54 FR 2214-2225). On January 6, 1989, the Office of Management and Budget (OMB) waived table 2 and table 3 SIP revisions (54 FR 2222) from the requirements of section 3 of Executive Order 12291 for a period of two years. EPA has submitted a request for a permanent waiver for table 2 and table 3 SIP revisions. OMB has agreed to continue the temporary waiver until such time as it rules on EPA’s request.

List of Subjects in 40 CFR Part 180

Air pollution control, Ozone, Hydrocarbons, Intergovernmental relations, Reporting and recordkeeping requirements.

Authority: 42 U.S.C. 7401-7671q.


John C. Wise, Acting Regional Administrator.

[FR Doc. 93-11249 Filed 5-11-93; 8:45 am]
BILLING CODE 6560-50-P

40 CFR Part 180

[OPP-300283; FRL-45828-9]
RIN No. 2070-AC18

Vinyl Acetate-Allyl Acetate-Monomethly Maleate Copolymer and Vinyl Acetate-Vinyl Alcohol-Dsodium Itaconate Copolymer; Tolerance Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: This document proposes that exemptions from the requirement of a tolerance be established for residues of vinyl acetate-allyl acetate-monomethly maleate copolymer and vinyl acetate-vinyl alcohol-disodium itaconate copolymer when used as inert ingredients (components of water-soluble film) in pesticide formulations applied to growing crops only. This proposed regulation was requested by Mitsui Plastics, Inc.

DATES: Comments, identified by the document control number [OPP-300283], must be received on or before June 11, 1993.

ADDRESSES: By mail, submit written comments to: Public Response and Program Resources Branch, Field Operations Division (H7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, deliver comments to: Rm. 1132, Crystal Mall Bldg. #2, 3801 Edmunds Hwy., Arlington, VA 22202. Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI).

Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential will be included in the public docket by EPA without prior notice. The public docket is available for public inspection in Rm. 1132 at the address given above, from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: Connie Welch, Registration Support Branch, Registration Division (H7505W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: 2800 Crystal Drive, North Tower, Arlington, VA 22202, (703)-308-8320.

SUPPLEMENTARY INFORMATION: Mitsui Plastics, Inc., 11 Martin Ave., White Plains, NY 10606, has submitted pesticide petitions, PP 2E4153 and PP 3E4178, to EPA requesting that the Administrator, pursuant to section 408(e) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 346a(e), propose to amend 40 CFR 180.1001(d) by establishing exemptions from the requirement of a tolerance for residues of vinyl acetate-allyl acetate-monomethly maleate copolymer (PP 2E4153) and vinyl acetate-vinyl alcohol-disodium itaconate copolymer (PP 3E4178) and when used as inert ingredients (components of water-soluble film) in pesticide formulations applied to growing crops only.

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125, and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term “inert” is not intended to imply nontoxicity; the ingredient may or may not be chemically active.

The data submitted in the petitions and other relevant material have been evaluated. As part of the EPA policy statement on inert ingredients published in the Federal Register of April 22, 1987 (52 FR 13305), the Agency established data requirements which will be used to evaluate the risks posed by the presence of an inert ingredient in a pesticide formulation. Exemptions from some or all of the requirements may be granted if it can be determined that the inert ingredient will present minimal or no risk. The Agency has decided that the data normally required to support the proposed tolerance exemption for vinyl acetate-allyl acetate-monomethly maleate copolymer and vinyl acetate-vinyl alcohol-disodium itaconate copolymer will not need to be submitted. The rationale for this decision is described below:

In the case of certain chemical substances which are defined as “polymers,” the Agency has established a set of criteria which identify categories of polymers that present low risk. These criteria (described in 40 CFR 723.250) identify polymers that are relatively unreactive and stable compared to other chemical substances as well as polymers that typically are not readily absorbed. These properties generally limit a polymer’s ability to cause adverse effects. In addition, these criteria exclude polymers about which little is known. The Agency believes that polymers meeting the criteria noted above will present minimal or no risk. Vinyl acetate-allyl acetate-monomethly maleate copolymer and vinyl acetate-vinyl alcohol-disodium itaconate copolymer conform to the definition of a polymer given in 40 CFR 723.250(b)(11) and meet the following criteria which are used to identify low-risk polymers:

1. The minimum average molecular weight of vinyl acetate-allyl acetate-monomethly maleate copolymer is 20,000, and the minimum average molecular weight of vinyl acetate-vinyl alcohol-disodium itaconate copolymer is 50,290. Substances with molecular weights greater than 400 are generally not readily absorbed through the intact skin, and substances with molecular weights greater than 1,000 are generally not absorbed through the intact gastrointestinal (GI) tract. Chemicals not absorbed through the skin or GI tract are generally incapable of eliciting a toxic response.

2. The above-mentioned copolymers are not cationic polymers nor are they reasonably anticipated to become
3. The above-mentioned copolymers do not contain less than 32.0 percent by weight of the atomic element carbon.

4. The above-mentioned copolymers contain as an integral part of their composition the atomic elements carbon, hydrogen, nitrogen, and oxygen.

5. The above-mentioned copolymers do not contain as an integral part of their composition, except as impurities, any elements other than those listed in 40 CFR 723.250(d)(3)(ii).

6. The above-mentioned copolymers are not manufactured from reactants intact.

7. The above-mentioned copolymers do not contain reactive functional groups that are intended or reasonably anticipated to undergo further reaction.

8. The above-mentioned copolymers do not contain reactive functional groups that are intended or reasonably anticipated to undergo further reaction.

9. The above-mentioned copolymers are not designed or reasonably anticipated to substantially degrade, decompose, or depolymerize.

Based upon the above information and review of its use, EPA has found that, when used in accordance with good agricultural practice, these ingredients are useful and tolerances are not necessary to protect the public health. Therefore, EPA proposes that the exemptions from the requirement of a tolerance be established as set forth below.

Any person who has registered or submitted an application for registration of a pesticide, under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended, which contains any of the ingredients listed herein, may request within 30 days after publication of this document in the Federal Register that this rulemaking proposal be referred to an Advisory Committee in accordance with section 408(e) of the Federal Food, Drug, and Cosmetic Act.

Interested persons are invited to submit written comments on the proposed regulation. Comments must bear a notation indicating the document control number, [OPP-300283]. All written comments filed in response to this petition will be available in the Public Response and Program Resources Branch, at the address given above from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

The Office of Management and Budget has exempted this rule from the requirements of section 3 of Executive Order 12291.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-354 Stat. 1164, 5 U.S.C. 601-612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic effect on a substantial number of small entities. A certification statement to this effect was published in the Federal Register of May 4, 1981 (46 FR 24850).

### List of Subjects in 40 CFR Part 180

Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Recording and recordkeeping requirements.


Lawrence E. Culleen,
Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, it is proposed that 40 CFR part 180 be amended as follows:

#### PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:


2. Section 180.1001(d) is amended by adding and alphabetically inserting the inert ingredients, to read as follows:

   §180.1001 Exemptions from the requirement of a tolerance.

   * * * * *

   (d) * * * * *

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### Inert ingredients

<table>
<thead>
<tr>
<th>Limits</th>
<th>Uses</th>
</tr>
</thead>
<tbody>
<tr>
<td>*</td>
<td>*</td>
</tr>
<tr>
<td>Vinyl acetate-allyl acetate-monomethyl maleate copolymer (minimum average molecular weight 20,000).</td>
<td>Component of water-soluble film.</td>
</tr>
</tbody>
</table>

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[FR Doc. 93-10984 Filed 5-11-93; 8:45 am]

BILLING CODE 6560-50-F

40 CFR Part 180

[OPP-300286; FRL-4587-4]

RIN 2070-AC18

Trimethylolpropane; 1-Tetradecanamine, N,N-Dimethyl-, N-oxide; Tall Oil Diesters With Polypropylene Glycol; Glycerol-Polypropylene Oxide Polymer; Tolerance Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: This document proposes that an exemption from the requirement of a tolerance be established for residues of trimethylolpropane; 1-tetradecanamine, N,N dimethyl-, N-oxide; tall oil diesters with polypropylene glycol; and glycerol-polypropylene oxide polymer, when used as inert ingredients (components of water-soluble films) in pesticide formulations applied to growing crops only. This proposed regulation was requested by Chris Craft Industrial Products, Inc.

DATES: Comments, identified by the document control number [OPP-300286], must be received on or before June 11, 1993.

ADDRESSES: By mail, submit written comments to: Public Response and
Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 133.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term "inert" is not intended to imply nontoxicity; the ingredient may or may not be chemically active.

The Agency reviewed the contents of the Chris Craft polyvinyl alcohol films and determined that many of the components did not require establishment of a tolerance exemption because they constituted less than 0.1 percent of the film and therefore would not be detectable in food under reasonable worst-case conditions. However, four components, trimethylolpropane; 1-tetradecanamine, N,N-dimethyl-, N-oxide; tall oil diesters with polypropylene oxide; and glycerol-propylene oxide polymer may leave detectable residues in food.

The Agency has expedited the review of these components in order to ensure that this technology, known to reduce risk of worker exposure to pesticides, can continue to be used with the assurance that the resultant food produced will not be considered adulterated under the Federal Food, Drug and Cosmetic Act (FDCA).

The ingredients and data submitted in the petition and other relevant material have been evaluated. As part of the EPA policy statement on inert ingredients published in the Federal Register of April 22, 1987 (52 FR 13305), the Agency established data requirements which will be used to evaluate the risks posed by the presence of an inert ingredient in a pesticide formulation. Exemptions from some or all of the requirements may be granted if it can be determined that the inert ingredient will present minimal or no risk.

The Agency has decided that the data normally required to support the proposed tolerance exemption for trimethylolpropane; 1-tetradecanamine, N,N-dimethyl-, N-oxide; tall oil diesters with polypropylene oxide; and glycerol-propylene oxide polymeric are not expected to be absorbed by any route based on a review of their chemical structures by the Office of Pollution, Prevention, and Toxics (OPPT) Structure Activity Team, thus eliminating concerns for toxicity including carcinogenicity, mutagenicity, and developmental toxicity.

2. Tall oil diesters with polypropylene glycol are currently used in the compounds approved by the Food and Drug Administration for use as components of adhesives, coatings, paper and paperboard, and animal glues used in packaging, transporting, or holding food under title 21 of the Code of Federal Regulations (CFR), §§ 175.105, 175.210, 175.300, 176.170, 176.180, 176.200, and 176.3120.

3. Trimethylolpropane is approved by the Food and Drug Administration for use as a component of adhesives intended for use in packaging, transporting, or holding food under 21 CFR 175.105.

4. Trimethylolpropane has a reported acute oral LD₅₀ of 14 g/kg or greater in rats, indicating low absorption by the oral route.

5. The OPPT Structure Activity Team indicated a low-to-moderate concern for developmental toxicity for trimethylolpropane. This concern was based on a general concern for developmental toxicity in branched-chain alcohols as a chemical class. Based upon knowledge of the potency of developmental toxicants, in general, and the branched-chain chemical class, in particular, the expected levels of trimethylolpropane in these films and worst-case dietary intake assumptions, the Agency has determined that this chemical will not pose a risk to health under the proposed conditions of use.

Based upon the above information, review of the ingredients' use, and expected low exposure, EPA has found that, when used in accordance with good agricultural practice, these ingredients are useful and tolerances are not necessary to protect the public health. Therefore, EPA proposes that the exemptions from the requirement of a tolerance be established as set forth below.

Any person who has registered or submitted an application for registration of a pesticide, under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended, which contains any of the ingredients listed herein, may request within 30 days after publication of this document in the Federal Register that this rulemaking proposal be referred to an Advisory
the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the Federal Register of May 4, 1981 (46 FR 24950).

List of Subjects in 40 CFR Part 180

Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Recording and recordkeeping requirements.

<table>
<thead>
<tr>
<th>Inert Ingredients</th>
<th>Limits</th>
<th>Uses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glycerol-propylene oxide polymer (CAS Reg. No. 25791-962)</td>
<td>Component in water-soluble film</td>
<td></td>
</tr>
<tr>
<td>Tall oil diesters with polypropylene glycol (CAS Reg. No. 85848-12-4)</td>
<td>Component in water-soluble film</td>
<td></td>
</tr>
<tr>
<td>Trimethylolethane (CAS Reg. No. 7799-6)</td>
<td>Not to exceed 5% of the film</td>
<td>Component in water-soluble film</td>
</tr>
</tbody>
</table>

DATES: Comments must be received on or before June 28, 1993.

ADDRESS: Send comments to: William C. Muir, Environmental Assessment Branch, Environmental Services Division, U.S. Environmental Protection Agency, Region III, 841 Chestnut Building, Philadelphia, PA 19107.

The file supporting this proposed designation is available for public inspection at the following locations: Environmental Protection Agency, Public Information Reference Unit, room 2904 (rear), 401 M Street, SW., Washington, DC 20460.

EPA Region III, 841 Chestnut Street, Philadelphia, PA.

Norfolk District, U.S. Army Corps of Engineers, 803 Front Street, Norfolk, VA.


SUPPLEMENTARY INFORMATION:

A. Background

Section 102(c) of the Marine Protection, Research, and Sanctuaries Act of 1972, as amended, 33 U.S.C. 1401 et seq. ("the Act"), gives the Administrator of EPA the authority to designate sites where ocean dumping may be permitted. On December 23, 1986, the Administrator delegated the authority to designate ocean dumping sites to the Regional Administrator of the Region in which the site is located. This proposed site designation is within Region III and is being made pursuant to that authority. The EPA Ocean Dumping Regulations (40 CFR chapter I, subchapter H, § 228.4) state that ocean dumping sites will be designated by promulgation in this part 228.

B. EIS Development

Section 102(c) of the National Environmental Policy Act of 1969, 42 U.S.C. 4321 et seq. ("NEPA") requires that Federal agencies prepare an Environmental Impact Statement (EIS) on proposals for legislation and other major Federal actions significantly...
Evaluating the Suitability of Ocean Alternatives to the Proposed Action, and Determining Ocean Disposal Site
Part of the Process of Issuing Permits for Ocean Dredged Material Disposal
The Engineering Corps of Engineers, Norfolk District, has requested that EPA designate an Ocean Dredged Material Disposal Site. Such a designation would authorize the disposal of dredged material from the Hampton Roads or Baltimore Inner Harbor system in the lower Chesapeake Bay channels. These channels, the Atlantic Ocean Channel, the Thimble Shoal Channel, the York Spit Channel, and the Hampton Roads Channel, provide critical navigation services for both commercial and military shipping operations. Disposal of dredged material in these channels would be excessively expensive. In addition, this area is proposed for designation as a National Marine Sanctuary under provisions of the Marine Protection, Research and Sanctuaries Act of 1972.

As presented in the EIS, designation of the proposed site for the disposal of dredged material that meets regulatory criteria would give the U.S. Army Corps of Engineers, Norfolk District, adequate long-term capabilities for the disposal of dredged material. The proposed Norfolk Ocean Disposal Site would be one component of a dredged material management plan. Other components of the plan are the continued use of the Craney Island Containment Area, beach replenishment, and the continued use of the Dam Neck Ocean Disposal Site. The Craney Island Containment Area will be used exclusively for the disposal of dredged material that does not meet ocean disposal criteria. Beach replenishment will be limited to material dredged from areas that consist primarily of clean sand. The Dam Neck Ocean Disposal Site will continue to receive primarily fine to medium grained sand and some silts and clays that meet ocean dumping criteria.

C. Proposed Site Designation
The proposed Norfolk Ocean Disposal Site is the primary disposal site for the disposal of suitable material from dredging operations in the lower Chesapeake Bay region. Dredging operations in this region include the maintenance of several navigation channels, the Atlantic Ocean Channel, the Cape Henry Channel, the Thimble Shoal Channel, the York Spit Channel and the Hampton Roads Channel. These channels provide entrance to the ports of Hampton Roads and Baltimore.
Combined these ports provide the largest export tonnage in the country. Maintenance of those ports for navigation is vital to the economy of the region and the United States. Further, the channels provide entrance to the largest naval port in the world, the Naval Shipyard, which is vital to national defense.

On the average, four to five million cubic yards of material is dredged annually by the U.S. Army Corps of Engineers (Norfolk District), the U.S. Navy, and State and private parties. Dredge material is predominately mud, clay, and silt taken primarily from the industrialized Hampton Roads/Elizabeth River area. The remaining dredge material consists of sand, gravel, and shell taken mainly from the Thimble Shoal and Cape Henry channels.

The proposed Norfolk Ocean Disposal Site, which is needed to accommodate current and future disposal requirements of dredged material, is located approximately 17 nautical miles (31 kilometers) west of the mouth of the Chesapeake Bay. The proposed site is delineated by a circle with a radius of 4 nautical miles (7.4 kilometers) centered at 36 degrees, 59 minutes north latitude, and 75 degrees, 39 minutes west longitude. The Norfolk Ocean Disposal Site partially overlaps an area used for dredge material disposal prior to the 1960's. Water depth in the area ranges from 43–85 feet (13.1–26 meters). Extensive characterization and delineation of this site as an acceptable disposal site is presented in the EIS. The proposed site is sufficiently removed from amenities such as beaches, fish havens, environmentally sensitive areas, and shipping lanes so as to minimize impacts. If at any time, however, disposal operations at the site cause unacceptable adverse impacts, further use of the site will be restricted or terminated as per 40 CFR 228.7 through 228.10.

D. Regulatory Requirements

Five general criteria are used in the selection and approval of ocean disposal sites for continuing use. Sites are selected so as to minimize interference with other marine activities, to keep any temporary perturbations from the dumping from causing impacts outside the disposal site, and to permit effective monitoring to detect any adverse impacts at any early stage. Where feasible, locations off the Continental Shelf are preferred. If at any time disposal operations at an interim site cause unacceptable adverse impacts, the use of that site will be terminated as soon as suitable alternate disposal sites can be designated. The general criteria are given in §228.5 of the EPA Ocean Dumping Regulations, and §228.6 lists 11 specific factors used in evaluating a proposed disposal site to assure that the general criteria are met.

The proposed site conforms to the five general criteria. However, there are no existing historically used sites beyond the edge of the Continental Shelf in this area. EPA has determined, based on the information presented in the EIS that a site off the Shelf is not feasible and that no environmental benefit would be obtained by selecting such a site instead of that proposed in this action.

The characteristics of the proposed site are reviewed below in terms of the 11 specific criteria for site selection.

1. Geographical Position, Depth of Water, Bottom Topography, and Distance from Coast (40 CFR 228.6(a)(1))

The proposed Norfolk Ocean Disposal Site is centered at 36 degrees, 59 feet North latitude, and 75 degrees, 39 feet West longitude, and has a radius of four nautical miles (7.4 kilometers). Water depths in the area range from 43 to 85 feet (13 to 26 meters). Water depths near the center of the area range from 65 to 80 feet (19.8 to 24.4 meters). The bottom topography is generally flat with depth contours running parallel to the coastline. The bottom topography slopes from 43 feet (13.1 meters) at the northwest edge of the disposal area to 85 feet (25.9 meters) on the eastern edge of the area. The center of the proposed Norfolk Ocean Disposal Site is located approximately 17 nautical miles (31 kilometers) from the nearest land.

2. Location in Relation to Breeding, Spawning, Nursery, Feeding, or Passage Areas of Lining Resources in Adult or Juvenile Phases (40 CFR 228.6(a)(2))

The Chesapeake Bay, Norfolk Harbor, and adjoining offshore ocean areas support a relatively abundant and diverse biological community. The distribution and abundance of individual species depends on the spawning habits and environmental preferences of the species and the season of the year. Fish and other aquatic organisms (e.g., crabs, plankton) migrate into and out of the Bay throughout the year en route to spawning grounds or juvenile development areas. Several of the fish and shellfish species that inhabit nearshore areas have commercial or recreational importance. Previous studies, however, have shown that the proposed Norfolk Ocean Disposal Site is not an important breeding, spawning, or nursery area for fish because it is located far offshore. No harvestable quantities of fish or shellfish are known to exist in the area.

Studies indicate that disposal activities at the proposed site are unlikely to have substantial adverse effects on aquatic organisms, mainly because organism populations are widely distributed on the continental shelf.

3. Location in Relation to Beaches and Other Amenity Areas (40 CFR 228(a)(3))

The center of the proposed Norfolk Ocean Disposal Site is located 17 nautical miles (31.5 kilometers) from the nearest recreational beach at Virginia Beach, Virginia. Thus, the closest edge of the site is 13 nautical miles (24 kilometers) from the beach. The Triangle Wrecks, a popular sport fishing and diving location, is located 4.8 nautical miles (8.9 kilometers) from the site. Net sediment transport is negligible. Bottom currents are meteorologically controlled and may account for the nonuniform sedimentation rates measured throughout the site. In addition, material with an age less than 10 years was deposited at the site, which indicates that deposition of material occurs at the site. It is unlikely that dredge material disposed at the site would be transported to beaches or other amenity areas.

4. Types and Quantities of Wastes Proposed to be Disposed of, and Proposed Methods of Release, Including Methods of Packing the Wastes, If Any (40 CFR 228.6(a)(4))

The proposed Norfolk Ocean Disposal Site will be used for disposal of new work and maintenance material dredged from the lower Chesapeake Bay. The proposed site could be used for the disposal of appropriate material from the Thimble Shoals, Cape Henry, Atlantic, Hampton Roads, York Spit, and possibly other channels within the lower Chesapeake Bay area. The quantity of material to be placed at the site depends on the quality of the dredged material. Only material that meets ocean dumping criteria will be disposed at the proposed site. This includes unconsolidated fine to medium grain sands, silts, and clays. The Craney Island Containment Area will receive material not suitable for ocean disposal, and the Dam Neck Ocean Disposal Site will receive material for which it has been designated. Dredge material that consists of clean sands will be used for beach replenishment or disposed at the Dam Neck site.
Different dredged material disposal management plans would result in varying amounts of dredge material placed in each of the disposal areas. U.S. Army Corps of Engineers, Norfolk District estimates that 250 million cubic yards of dredged material from Federal, State, and private dredging projects may be disposed at the proposed site over the next 50 years. To dispose of this material at the proposed Norfolk Ocean Disposal Site, the Corps of Engineers will probably employ bucket and scow or hopper dredges of 5,000 to 8,000 cubic yard capacity. The dredges will be either split-hull or bottom-dump design.

The suitability of materials dredged from areas in the lower Chesapeake Bay for ocean disposal has been investigated by several authors. These studies are summarized in the Supplemental Information Report to the final Environmental Impact Statement for the Norfolk Harbor and Channels, Virginia, Deepening and Disposal project prepared by the U.S. Army Corps of Engineers, Norfolk District. These studies, which include the use of bioassays and chemical analysis, conclude that only sediments dredged from the southern branch of the Elizabeth River could not be ocean disposed. In addition, materials dredged from the outer channels (i.e., Thimble Shoal and Atlantic channels) could be used for beach replenishment.

The suitability of dredge material for ocean disposal, however, would have to be determined for each dredging operation. According to section 103 of the MPRSA, any proposed dumping of dredge material into ocean waters must be evaluated through the use of criteria listed in 40 CFR parts 220 through 228. The Corps of Engineers and the EPA have specific guidance for the evaluation of potential environmental impacts of the ocean disposal of dredged material. The suitability for ocean disposal of dredge material is determined through the use of evaluation techniques such as bioassays and bioaccumulation testing.

5. Feasibility of Surveillance and Monitoring (40 CFR 228.6(a)(5))

The U.S. Army Corps of Engineers, Norfolk District, sponsored a monitoring program for the site in the early 1980's. Parameters that were monitored, as identified in the 1982 Final Environmental Impact Statement, include benthic infauna, bioaccumulation in three species of marine organisms, sediment quality, zooplankton, and 20 water quality variables. Investigations that the monitoring data collected by these efforts when combined with statistical models can be used as an effective "early warning system" for major water quality changes that may be associated with disposal activities at the Norfolk Ocean Disposal Site.

During the summer of 1990, sediment and benthic samples were collected by the U.S. EPA, Region III during a site monitoring survey. Results of this sampling effort should be available for incorporation into the final Environmental Impact Statement. Future monitoring efforts will be planned if the site is designated. Monitoring plans should be easily implemented and will be consistent with site management plans.

6. Disposal, Horizontal Transport, and Vertical Mixing Characteristics of the Area, Including Prevailing Current Direction and Velocity, If Any (40 CFR 228.6(a)(6))

Winter currents at the site flow to the south-southwest and velocities that average 10 cm/sec. Summer surface currents flow to the west or northwest and are generally weaker than winter currents. Near-bottom summer currents average about 2 cm/sec and flow to the west. It has been established that a velocity of 35 cm/sec is needed to initiate movement (e.g., erosion) of fine grained sands; however, current velocities of this magnitude occur at the site only during winter storms. Flow in both seasons is highly wind direction dependent. Dispersal of dredged material during dumping operations was evaluated during a test dump during October 1981. No widespread dispersal of dredged material during disposal operations was shown to occur.

7. Existence and Effects of Current and Previous Discharges and Dumping in the Area (Including Cumulative Effects) (40 CFR 228.8(a)(7))

A portion of the proposed Norfolk Ocean Disposal Site overlaps an area used for the disposal of dredged material from the Thimble Shoal and Cape Henry Channels prior to 1971. No cumulative environmental effects of the past dumping activities have been identified; benthic communities at the Norfolk Ocean Disposal Site are similar to those of surrounding areas. In addition, no unacceptable adverse impacts have been identified at the currently used Dem Neck Ocean Disposal Site.

8. Interference with Shipping, Fishing, Recreation, Fish and Shellfish Culture, Areas of Special Scientific Importance and Other Legitimate Uses of the Ocean (40 CFR 228.8(a)(8))

Use of this site is not expected to interfere with known shipping, recreation, mineral extraction, desalination, fish and shellfish activities, or areas of special scientific importance. Some short-term disruption of recreational fishing activities is possible in the immediate area of disposal activities. The proposed Norfolk Ocean Disposal Site is located in an area known to be frequented by herring (Clupea harengus), king mackerel (Scomberomorus cavalla), porgy (Stenotomus chrysops), windowpane flounder (Scophthalmus aquosus), bluefish (Pomatomus saltatrix), summer founder (Paralichthys dentatus) and is in the vicinity of an area known to have harvestable quantities of sea scallop (Placopecten magellanicus). The area is approximately 35 nautical miles (64 kilometers) south of currently harvested Surf Clam (Spisula solidissima) beds. Surveys of the proposed Norfolk Ocean Disposal Site have found no known harvestable quantities of fish or shellfish. Industrial fisheries in the area are spiny dogfish (Squalus acantius), Northern searobin (Prionotus carolinus) and spotted hake (Urophycis regius). No harvesting of industrial fish species is known to occur in this area.

9. The Existing Water Quality and Ecology of the Site as Determined by Available Data or by Trend Assessment or Baseline Surveys (40 CFR 228.6(a)(9))

Previous investigations and baseline surveys show the proposed water and sediment quality and other environmental characteristics of the Norfolk Ocean Disposal Site to be typical of the mid-Atlantic region. Specific information regarding the water quality and ecology of the site is discussed in the EIS. In summary, the proposed site does not possess any unique characteristics that would preclude its designation and use as a disposal site. The designation and use of the Norfolk Ocean Disposal Site would not result in unacceptable environmental impacts on organisms that live near or migrate through the site.

10. Potentiality for the Development or Recruitment of Nuisance Species in the Disposal Site (40 CFR 228.8(a)(10))

Based on information available on the community structure of the proposed site, no change in benthic species...
composition is expected. The communities currently defining the site are characteristic of the mid-Atlantic region. No change in substrate is anticipated if the site is used for dredge material that meets ocean disposal criteria. Past disposal activities adjacent to the proposed site and at the Dam Neck Ocean Disposal Site have not resulted in the development or recruitment of any nuisance species.  

11. Existence at or in Close Proximity to the Site of any Significant Natural or Cultural Features of Historical Importance (40 CFR 228.6(c)(11))

An archeological survey of the area by side-scan sonar was conducted during late 1981. No sites of archeological interest that would be endangered by the proposed disposal operations were found. The survey and subsequent report was coordinated with the State Historical Preservation Officer.

E. Site Management

Site management of the Norfolk ODMDS is the responsibility of the EPA and the COE. The COE issues permits to private applicants for ocean dumping and authorizes Federal navigation dredging and disposal. EPA/Region III assumes overall responsibility for site management.

A Site Management and Monitoring Plan (SMMP) is being developed between the EPA and COE for the site. The plan will provide the framework for both site management and for the monitoring of effects of disposal activities. Site management may include strategically locating and or orienting dredged material within the site boundaries relative to predominate currents. Monitoring could involve sediment mapping of disposed material to determine any movement of material off the site. Determination of the significance of any biological impacts of dredged material outside the ODMDS boundaries would then be appropriate.

F. Proposed Action

The EIS concludes that the proposed site may appropriately be designated for use. The proposed site is compatible with the general criteria and specific factors used for site evaluation. The designation of the Norfolk Ocean Disposal Site as an EPA approved Ocean Dumping Site is being published as proposed rulemaking. Management of this site will be delegated to the Regional Administrator of EPA Region III.

It should be emphasized that, if an ocean dumping site is designated, such a site designation does not constitute or imply EPA's approval of actual disposal of materials at sea. Before ocean dumping of dredged material at the site may commence, other than that already approved under section 103 of the Marine Protection, Research, and Sanctuaries Act, the Corps of Engineers must evaluate a permit application according to EPA's ocean dumping criteria. EPA has the right to disapprove the actual dumping, if it determines that environmental concerns under the Act have not been met.

G. Regulatory Assessments

Under the Regulatory Flexibility Act, EPA is required to perform a Regulatory Flexibility Analysis for all rules which may have a significant impact on a substantial number of small entities. EPA has determined that this action will not have a significant impact on small entities since the site designation will only have the effect of providing a disposal option for dredged material. Consequently, this rule does not necessitate preparation of a Regulatory Flexibility Analysis. Under Executive Order 12291, EPA must judge whether a regulation is "major" and therefore subject to the requirements of a Regulatory Impact Analysis. This action will not result in an annual effect on the economy of $100 million or more or cause any of the other effects which would result in its being classified by the Executive Order as a "major" rule. Consequently, this rule does not necessitate preparation of a Regulatory Impact Analysis.

This proposed rule does not contain any information collection requirements subject to Office of Management and Budget review under the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 et seq.

List of Subjects in 40 CFR Part 228

Water pollution control.

William Bulman,  
Acting Regional Administrator, EPA Region III.

In consideration of the foregoing, subchapter H of chapter I of title 40 is proposed to be amended as set forth below:

PART 228—[AMENDED]  
1. The authority citation for part 228 continues to read as follows:

Authority: 33 U.S.C. 1412 and 1418.

2. Section 228.12 is amended by adding paragraph (b)(94) to read as follows:

§228.12 Delegation of management authority for interim ocean dumping sites.  
(b) * * *  
(94) Norfolk, Virginia, Dredged Material Disposal Site-Region III.  
Location (center point):  
Latitude—36°59'00" N.  
Longitude—75°39'00" W.  
Size: Circular with a radius of 7.4 kilometers (4 nautical miles).  
Depth: Ranges from 13.1-26 meters.  
Primary Use: Dredged material.  
Period of use: Continuing use.  
Restrictions: Site shall be limited to suitable dredged material which passed the criteria for ocean dumping.

[FR Doc. 93–11250 Filed 5–11–93; 8:45 am]

BILLING CODE 6560–50–F

40 CFR Part 721  
[OPPTS–50599; FRL–3999–3]

2,3,5,6-Tetrachloro-2,5-cyclohexadiene-1,4-dione; Proposed Significant New Use of a Chemical Substance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing a significant new use rule (SNUR) under section 5(a)(2) of the Toxic Substances Control Act (TSCA) which would require persons to notify EPA at least 90 days before commencing the manufacture, import, or processing, for any use, of 2,3,5,6-tetrachloro-2,5-cyclohexadiene-1,4-dione (chloranil) containing certain chlorinated dibenzo-p-dioxins (CDDs) and chlorinated dibenzofurans (CDFs) in total combined amounts greater than 20 ppb. The chloranil CDD/CDF concentration would be calculated based on their toxicity equivalence (TEQ) to 2,3,7,8-tetrachlorodibenzo-p-dioxin (2,3,7,8-TCDD or TCDD). The required notice would provide EPA with the opportunity to evaluate the intended use and associated activities, and an opportunity to protect against unreasonable risks, if any, from CDD/CDF exposure that could result from use of chloranil with higher CDD/CDF levels. Certain recordkeeping and certification requirements would also apply to manufacturers, importers, and processors of all chloranil, no matter what the level of CDD/CDF contamination therein.

DATES: Written comments should be received by EPA by June 11, 1993.

ADDRESSES: All comments should be sent in triplicate to: TSCA Document Receipt Office (TS–790), Office of Pollution Prevention and Toxics, U.S. Environmental Protection Agency, 401 M St., SW., rm. E105, Washington, DC
requires EPA to explain in the Federal Register its reasons for not taking action. Persons who intend to export a chemical substance identified in a proposed or final SNUR are subject to the export notification provisions of TSCA section 12(b). The regulations that interpret section 12(b) appear at 40 CFR part 707.

II. Applicability of General Provisions

General regulatory provisions applicable to SNURs are codified at 40 CFR part 721, subpart A. In the Federal Register of August 17, 1988 (53 FR 31252), EPA promulgated a “User Fee Rule” (40 CFR part 700) under the authority of TSCA section 26(b). Provisions requiring persons submitting significant new use notices to submit certain fees to EPA are discussed in detail in that Federal Register document. Interested persons should refer to the CFR and the cited Federal Register notice for further information.

III. Summary of This Proposed Rule

This rule would require persons to submit a significant new use notice to EPA at least 90 days before manufacturing, importing, or processing chloranil for any use if the chloranil contains more than 20 ppb TCDD TEQ of CDDs and CDFs with four to eight chlorine atoms located at least at the 2, 3, 7, and 8 positions on the dioxin or furan molecule. The TCDD TEQ is an additive concentration of all CDD/CDF congeners of concern in which each individual concentration is adjusted according to how its toxicity relates to TCDD, the most toxic congener known of the CDDs/CDFs. EPA has adopted the TEQ system as a way to recognize the possible potential toxicity relationship between TCDD and the other HDD/HDF congeners (including CDDs and CDFs). The TCDD TEQ is determined as follows. A toxicity equivalency factor (TEF) of 1 is assigned to TCDD. The other congeners of concern are assigned fractional TEFs representing how toxic they may be in relationship to TCDD. To find the TCDD TEQ for a particular sample, the concentration of each CDD and CDF congener of concern is determined and multiplied by its TEF. The products are then added to determine the TCDD TEQ.

The TEF concept has been widely accepted and used by the scientific and regulatory community in many parts of the world as an interim method, subject to revision or replacement, for making regulatory decisions in the absence of better scientific evidence. It is recognized that there are shortcomings in the science base supporting this concept, e.g., the extrapolation from short-term to long-term effects and the possible differences in metabolic effects among species, and that the TEF concept should be largely reserved for special situations where the composition of the mixture is not expected to vary much with time, and where the extrapolations are consistent with existing animal data. The TEF values proposed for this rule, which are listed below, are those given in the Interim Procedures for Estimating Risks Associated with Exposures to Mixtures of Chlorinated Dibenzo-p-dioxins and Dibenzoofurans (CDDs and CDFs) and 1989 Update cited above. (See pages 16 and 17 of the Update.) If these TEF values are revised by the Risk Assessment Forum, the updated values will be used in the final rule. However, these TEF values presented below are specific to this rule, and EPA will not make a final determination of the appropriate TEF values to be used generally in regulatory decision making through this rule.

Comment is solicited on the use of TEF values for this rule, which are set forth in the table below. The congeners of concern for this rule and their corresponding TEFs are as follows:

<table>
<thead>
<tr>
<th>Congener</th>
<th>Toxicity Equivalency</th>
</tr>
</thead>
<tbody>
<tr>
<td>2,3,7,8-tetrachlorodibenzo-p-dioxin</td>
<td>1</td>
</tr>
<tr>
<td>1,2,3,7,8-pentachlorodibenzo-p-dioxin</td>
<td>0.5</td>
</tr>
<tr>
<td>1,2,3,4,7,8-hexachlorodibenzo-p-dioxin</td>
<td>0.1</td>
</tr>
<tr>
<td>1,2,3,6,7,8-hexachlorodibenzo-p-dioxin</td>
<td>0.1</td>
</tr>
<tr>
<td>1,2,3,7,8,9-hexachlorodibenzo-p-dioxin</td>
<td>0.1</td>
</tr>
<tr>
<td>1,2,3,4,6,7,8-heptachlorodibenzo-p-dioxin</td>
<td>0.01</td>
</tr>
<tr>
<td>octachlorodibenzo-p-dioxin</td>
<td>0.001</td>
</tr>
<tr>
<td>2,3,7,8-tetrachlorodibenzofuran</td>
<td>0.1</td>
</tr>
<tr>
<td>1,2,3,7,8-pentachlorodibenzofuran</td>
<td>0.05</td>
</tr>
<tr>
<td>2,3,4,7,8-pentachlorodibenzofuran</td>
<td>0.5</td>
</tr>
<tr>
<td>1,2,3,4,7,8-hexachlorodibenzofuran</td>
<td>0.1</td>
</tr>
<tr>
<td>1,2,3,7,8,9-hexachlorodibenzofuran</td>
<td>0.1</td>
</tr>
</tbody>
</table>
EPA is considering providing the following additional instruction for calculating the TCDD TEQ and would like to receive public comment on it: When the concentration of any CDD or CDF congener is below the level of detection, the concentration of that congener would be assigned a value of half the level of detection for purposes of calculating the TCDD TEQ.

EPA realizes that use of chloranil containing CDDs/CDFs in total amounts greater than 20 ppb TCDD TEQ continued until quite recently, when existing stockpiles were depleted. The Agency believes such stockpiles to have been depleted by August 1, 1992, before the publication of this proposed rule.

EPA negotiated agreements with importers and processors to abandon use of this type of chloranil. All chloranil importers except one agreed to abandon import of chloranil containing CDDs/CDFs in combined amounts greater than 20 ppb TCDD TEQ of April 1, 1992. Through a consent agreement with EPA, the company representing the exception has agreed to discontinue import of chloranil containing CDDs/CDFs in combined amounts greater than 20 ppb TCDD TEQ within 30 days of ratification of the consent agreement by EPA’s Environmental Appeals Board (EAB). The EAB ratified the consent agreement on August 17, 1992.

All chloranil processors EPA is aware of agreed to abandon use of chloranil containing CDDs/CDFs in combined amounts greater than 20 ppb TCDD TEQ by September 1, 1992, as long as chloranil with lower levels of CDD/CDF contamination is available. Because most chloranil importers have agreed to abandon import of chloranil containing CDDs/CDFs in combined amounts above 20 ppb TCDD TEQ as of April 1, 1992, chloranil with lower levels of CDD/CDF contamination has been available at least since that date. This rule will not be issued in final form until EPA is satisfied that chloranil containing CDDs and CDFs in total amounts greater than 20 ppb TCDD TEQ is no longer being used in the United States.

The level of CDD/CDF contamination, 20 ppb TCDD TEQ, that is proposed to represent a significant new use of chloranil was determined based on preliminary test data. This SNUR will be promulgated after EPA receives test data for chloranil that is acceptable under the dioxin/furan test rule (40 CFR part 766). Accordingly, the level of CDD/CDF contamination that represents a significant new use may be adjusted before promulgation to reflect the final test data.

This rule would require all manufacturers, importers, and processors of chloranil to maintain the following records, to the extent known to or reasonably ascertainable by the person maintaining the records:

1. Information to demonstrate that each purchase lot or batch of chloranil manufactured, imported, or processed contains CDDs and CDFs in combined amounts equal to or less than 20 ppb TCDD TEQ. Such information shall include:
   a. A statement that the chloranil contains CDDs and CDFs in total amounts equal to or less than 20 ppb TCDD TEQ.
   b. If imported or processed, the company from which the chloranil was purchased.
   c. Any available analytical test data for CDD/CDF contamination in the chloranil.

2. Information on all commercial transactions involving chloranil, including:
   a. Dates of purchases and sales.
   b. The quantities purchased or sold.
   c. Names and addresses of purchasers.

Records would be required to be maintained for a period of 3 years from the date of preparation. All manufacturers, importers, and processors of chloranil who distribute chloranil in commerce would be required to provide certification of the information in item 1, above, excluding item c.i. and any confidential or proprietary information, to each recipient (as defined at 40 CFR 721.3) of chloranil. Such certification would be required for every shipment of chloranil.

Chloranil is known by the same name regardless of the level of CDDs and CDFs it contains, and use of chloranil is expected to continue after this rule is promulgated. For these reasons, it would be difficult for EPA to know whether or not a company is in violation of this rule unless chloranil importers, manufacturers, and processors keep records such as those described above. These recordkeeping requirements are, therefore, necessary for effective enforcement of this rule.

IV. Background Information on Chloranil

On October 22, 1984, the Environmental Defense Fund (EDF) and the National Wildlife Federation (NWF) filed a citizens’ petition under section 21 of TSCA requesting EPA to issue regulations for all media (air, water, commercial chemicals, etc.) that may be contaminated with certain dioxin and furan congeners. The congeners of concern were those containing from four to seven chlorine or bromine atoms substituted at least at the 2, 3, 7, and 8 positions on the dioxin or furan molecule. This group of chemicals, which includes CDDs and CDFs, are referred to as halogenated dibenzofurans (HDFs) and halogenated dibenzodibenzo-p-dioxins (HDDs) and dibenzofurans (HDFs).

HDDs and HDFs have been recognized by EPA as having potential public health and environmental significance because they are structurally related to 2,3,7,8-TCDD. TCDD has caused cancer in animal test systems and may present a risk of cancer to humans. In some species, animal tests show non-cancer effects for TCDD at lower dose levels than for almost all other chemicals.

EPA has adopted the TEQ system as a way to recognize the potential toxicity relationship between TCDD and the other HDD/HDF congeners (including CDDs and CDFs). For further information on TEQ, see Interim Procedures for Estimating Risks Associated With Exposures to Mixtures of Chlorinated Dibenzo-p-dioxins and Dibenzofurans (CDDs and CDFs) and 1989 Update, EPA/625/3/89-016, March 1989, USEPA Risk Assessment Forum. The applicability of the TEQ system to this rule is described in Unit III. of this preamble, Summary of the Rule.

EPA granted the petition filed by EDF and NWF in part by issuing 40 CFR part 766, promulgated in the Federal Register of June 5, 1987 (52 FR 21412). This rule, referred to in the dioxin/furan test rule, requires analytical testing of listed chemicals that may be contaminated with the dioxin and furan congeners of concern. Chloranil is one of the listed chemicals.

EPA denied the remainder of the petition, prompting a lawsuit (EDF v. Thomas, D.C. District Court, Civil Action No. 85-0873). EDF, NWF and EPA reached a settlement and signed a consent decree on July 27, 1988. The consent decree requires EPA to perform a number of activities under its various statutes. One requirement, which has led to this proposed SNUR, is for the Agency to take one of three
possible actions within approximately 6 months after test data are submitted for a chemical under 40 CFR part 766. These actions are to:

1. Commence a risk assessment for that chemical.
2. Determine not to commence a risk assessment and not to take regulatory action with respect to that chemical.
3. Determine that the test data are inadequate to meet the requirements of 40 CFR part 766, in which case EPA must obtain the necessary data within 1 year and then decide whether to take either of the first two actions. Within a year-and-a-half of the commencement of a risk assessment EPA must take one of the following actions:

   a. Publish a proposed rule in the Federal Register controlling dioxin contamination in the chemical.
   b. Determine not to propose a rule.
   c. Determine information is not sufficient, in which case sufficient information must be obtained within a year.

4. Refer the chemical to another Federal agency for consideration.

Chloranil is imported to the United States for use as an intermediate in the production of several dyes and pigments, including Pigment Violet 23, Direct Blues 106 and 108, and Reactive Blues 198 and 293, and as an additive in the manufacture of Vulklor 75, a product used in the manufacture of tires. Since all chloranil used in the United States is imported, all exposures to CDDs/CDFs in chloranil result from the manufacture, processing, and use of chloranil-derived products.

Four companies that were importing chloranil manufactured by methods used at the time the 1987 test rule went into effect submitted test data, but the data were submitted late. Test data were received from the last of the four companies in April of 1990.

As noted above, under the consent decree EPA had to make a decision as to whether to commence a risk assessment within approximately 6 months after receipt of the last test data. A review of the data submitted revealed several inadequacies regarding their quality. A major problem was that the extremely high concentrations of the hepta- and octachlorinated dioxins and furans interfered with the quantitation of the tetra- and pentachlorinated dioxins and furans at the required levels of quantitation. Without further test data, EPA felt it would be difficult to conduct a competent risk assessment for chloranil at that time.

All four importers of chloranil were charged with violation of the 1987 dioxin/furan test rule. Charges against the companies included late submission of letters of intent to test, late submission of test protocols, late submission of test data, and inadequate test data. The Agency initiated enforcement proceedings in response to these violations.

Although EPA did not believe the levels of some of the CDD/CDF congeners were adequately quantified in the test data, the extremely high levels of the hepta- and octachlorinated dioxin and furan congeners gave rise to concern. Based on a preliminary EPA analysis of samples received from the chloranil importers, the Agency estimated the TCDD TEQ of chloranil to be approximately 3,100 ppb. This level was based on estimated concentrations of CDDs/CDFs because the extremely high levels of hepta- and octachlorinated dioxin and furan congeners in the chloranil samples were outside the instrument calibration range and prohibited accurate quantification. Because there were relatively high levels of CDDs/CDFs in chloranil (as confirmed by EPA analysis), the Agency decided it would not be appropriate to delay its regulatory decision while waiting for more precise data. Therefore, in October of 1990, EPA informed EDF and NWIF of its decision to conduct a risk assessment for chloranil.

In February of 1991, EPA became aware of a fifth chloranil importer. This company was subsequently alleged to be in violation of the test rule, and enforcement proceedings were initiated against it.

Through the enforcement proceedings, EPA became aware of alternative processes which, through the use of different feedstocks, produce chloranil with CDD/CDF concentrations that are 2 to 3 orders of magnitude lower than in the chloranil then commonly imported. The conventional chloranil imported before the enforcement proceedings took place is referred to in this rule as high dioxin chloranil or HDC. The new chloranil, referred to as low dioxin chloranil or LDC, contains CDDs/CDFs in amounts equal to or less than 20 ppb TCDD TEQ.

As part of the settlement of the enforcement actions, all five chloranil importers agreed to either begin importing LDC or abandon importation of chloranil. Since that time, a sixth company has begun importing chloranil.

Preliminary results show this chloranil contains CDDs/CDFs in amounts below 20 ppb TCDD TEQ. All chloranil importers EPA is aware of are either currently importing LDC or expect to be importing it by May 1, 1992.

EPA met with several chloranil users groups to encourage them to convert to LDC voluntarily. The industry groups with whom EPA met represent the majority of chloranil processors in the United States and worked with EPA to facilitate agreement from their members to use only LDC or abandon use of chloranil once their existing stockpiles of HDC were depleted. All chloranil processors EPA worked with agreed to discontinue use of HDC by September 1, 1992, assuming LDC is available at that time. Most chloranil importers agreed to abandon HDC and have been importing LDC instead since at least April 1, 1992. LDC has therefore been available to chloranil processors since April 1, 1992. Because of these developments, EPA decided that it was not necessary to obtain further test data for HDC from the chloranil importers that had already submitted data. Instead, the Agency chose to encourage the use of LDC and thereby reduce exposure to the dioxin/ furan contamination. In addition, in view of the industry commitments, EPA decided not to propose a rule under the terms of the consent decree in EDF v. Thomas, and instead has opted to issue a SNUR as discussed further, below.

EPA explained its reasons for not proposing a rule under EDF v. Thomas in a letter to plaintiffs dated May 5, 1992, from EPA Assistant Administrator Linda J. Fisher. This proposed SNUR will serve as a disincentive to any future use of HDC and a means to help ensure that the voluntary industry decision will not be abrogated.

V. Objectives and Rationale for the Proposed Rule

To determine what would constitute a significant new use of chloranil containing CDD/CDFs in combined amounts greater than 20 ppb TCDD TEQ, EPA considered relevant information on the toxicity of the chemical substance, likely exposures associated with possible uses, and the relevant factors listed in section 5(a)(2) of TSCA. Based on these considerations, EPA wishes to achieve the following objectives with regard to the significant new use that is designated in this proposed rule. EPA wants to ensure that:

1. The Agency would receive notice of any company’s intent to manufacture, import, or process chloranil containing CDDs/CDFs in amounts greater than 20 ppb TCDD TEQ for any use before that activity begins.

2. The Agency would have an opportunity to review and evaluate data submitted in a significant new use notice before the notice submitter begins manufacture, importation, or processing.

3. The Agency would be able to regulate prospective manufacturers, importers, or processors of chloranil.
before a significant new use occurs, provided that the degree of potential health and/or environmental risk, or the uncertainty about the risks, is sufficient to warrant such regulation.

Of the four factors listed in section 5(a)(2) of TSCA, factor (c), "the extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance," and factor (d), "the reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance," are especially applicable to chloranil. This is because, as stated in Unit IV of this preamble, the use of different feedstocks has enabled chloranil manufacturers to reduce levels of CDD/CDF contamination in chloranil and subsequent exposures by at least 2 to 3 orders of magnitude.

Consequently, although the form, type, and duration of exposure to CDDs/CDFs may change, through use of different feedstocks and processes the magnitude of exposure to CDDs/CDFs increases dramatically, not gradually in increments, when HDC is used instead of LDC. Because of the availability of LDC, the use of HDC results in unacceptably high worker, consumer, and environmental exposure to CDDs/CDFs.

Preliminary data generated by EPA laboratories shows that CDDs/CDFs in chloranil carry over into Pigment Violet 23, Health and Welfare Canada, the Canadian government health agency, has submitted data to EPA confirming the carry-over of CDDs/CDFs from chloranil into Violet 23 and into Direct Blue Dye 106 and 108, also produced from chloranil.

Using the limited available data, EPA developed risk assessments for human exposure (cancer risk) and environmental exposure (stream concentrations) associated with two different levels of dioxin/furan contamination in chloranil. For most exposure scenarios, the estimated risks associated with chloranil containing CDDs/CDFs in amounts of 25 ppb TCDD TEQ are several orders of magnitude lower than those associated with chloranil containing CDDs/CDFs in amounts of 3,100 ppb TCDD TEQ. EPA decided further verification of risk levels was not needed because the significant new use determination was not based on the level of risk, but on the magnitude of exposure, which is known to increase dramatically when HDC is used instead of LDC. EPA believes that a reduction in exposure of this magnitude is worthwhile regardless of the Agency's ability to verify the risk characterization.

Current technology enables manufacturers to produce chloranil containing CDDs/CDFs in amounts equal to or below 20 ppb TCDD TEQ. This level was measured based on test data available at the time this proposed rule was written and may be adjusted before the rule is promulgated. The data generated on LDC's "under the dioxin/furan test rule will give a more accurate determination of the dioxin levels in LDC. When acceptable data is submitted under the dioxin/furan test rule, the Agency will most likely adopt the dioxin levels shown by that testing as the trigger level for the final SNUR.

To summarize, EPA is proposing to set the level of CDD/CDF contamination that determines a significant new use of chloranil at greater than 20 ppb TCDD TEQ for three reasons: The technology is available to produce chloranil with CDD/CDF contamination below this level; importers and processors have agreed to use LDC instead of HDC; and, if feedstocks are changed to those used for HDC, the resulting increase in exposure would be dramatic and would constitute a significant increase. Since LDC is available, use of HDC would constitute a significant new use of chloranil. If new techniques for producing chloranil are discovered that may increase levels above 20 ppb, not as high as the levels in HDC, they will be reviewed accordingly, after notice is submitted under the SNUR.

VI. Alternatives

Before proposing this SNUR, EPA considered regulating chloranil containing CDDs/CDFs in combined amounts greater than 20 ppb TCDD TEQ under section 6 of TSCA. EPA may regulate under section 6 if there is a reasonable basis to conclude that the manufacture, importation, processing, distribution in commerce, use, or disposal of a chemical substance or mixture "presents or will present" an unreasonable risk of injury to human health or the environment. A finding of unreasonable risk indicates a determination that the reduction of health or environmental risk resulting from a potential regulation outweighs the regulatory burden to society.

In the case of chloranil, EPA decided that a SNUR was more appropriate than, and as effective as, a section 6 rule because chloranil importers and processors have already agreed to eliminate HDC from commerce. This proposed SNUR would serve to discourage any use of HDC without having to engage in a section 6 proceeding, which would be more complicated. Additionally, this proposed SNUR would give EPA advance notice of any intended significant new use and an opportunity to protect against unreasonable risks, if any, from CDD/CDF exposure that could result from the use of HDC.

VII. Use of Engineering and Work Practice Controls

Although it is significantly decreased, exposure to CDDs/CDFs in chloranil is not eliminated through substitution of LDC for HDC. EPA therefore urges chloranil processors to utilize process changes or engineering controls such as local exhaust ventilation to further reduce exposure to CDDs/CDFs in chloranil in the workplace. These are the preferred methods to eliminate or minimize worker contact with chloranil and should be implemented and evaluated before the use of chemical protective clothing. Respiratory and dermal protection equipment could also be utilized, after the previous measures are evaluated, to further reduce exposure.

VIII. Applicability of Proposed Rule to Uses Occurring Before Effective Date of the Final Rule

EPA believes that the intent of section 5(a)(1)(B) is best served by designating a use as a significant new use as of the proposal date of the SNUR rather than as of the effective date of the final rule. If uses initiated during the proposal period of a SNUR were considered ongoing, rather than new, as of the effective date, it would be difficult for EPA to establish SNUR notice requirements, because any person could defeat the SNUR by initiating the proposed significant new use before the rule became final, arguing that the use is no longer new.

As stated above in Unit III, EPA realizes that use of HDC continued until quite recently, when existing stockpiles of HDC were depleted. The Agency believes such stockpiles were depleted by September 1, 1992, before the publication of this proposed rule. Designation of any manufacture, import, or processing of chloranil containing CDDs/CDFs in combined amounts greater than 20 ppb as a significant new use as of the proposal date of this rule is therefore appropriate and consistent with Agency policy.

Persons who begin commercial manufacture, import, or processing of chloranil containing CDDs/CDFs in combined amounts above 20 ppb TCDD TEQ between this proposal and the effective date of the final SNUR may comply with this proposed SNUR before it is promulgated. If a person were to
meet the conditions of advanced compliance as codified at § 721.45(h) (53 FR 28354, July 17, 1988), the person will be considered to have met the requirements of the final SNUR for those activities. If persons who begin commercial manufacture, import, or processing of chloranil containing CDDs/CDFs in excess of 20 ppb TCDD TEQ between proposal and the effective date of the SNUR do not meet the conditions of advance compliance, they must cease that activity before the effective date of the rule. To resume their activities, these persons would have to comply with all applicable SNUR notice requirements and wait until the notice review period, including all extensions, expires.

IX. Test Data and Other Information

EPA recognizes that under TSCA section 5(a)(2), persons are not required to develop any particular test data before submitting a significant new use notice. Rather, persons are required only to submit test data in their possession or control and to describe any other data known to or reasonably ascertainable by them.

However, in light of the potential risks that may be posed by use of HDC, EPA suggests potential SNUR notice submitters consider conducting tests that would permit a reasoned evaluation of the CDD/CDF levels contained in HDC. SNUR notifiers submitted without accompanying test data may increase the likelihood that EPA would take action under section 5(e) of TSCA. EPA encourages persons to consult with EPA before selecting a protocol for testing HDC. As part of this optional prenotice consultation, EPA will discuss the test data it believes are necessary to evaluate use of HDC. Test data should be developed according to dioxin/furan test rule standards at 40 CFR part 766. Failure to do so may lead EPA to find such data to be insufficient to evaluate reasonably the health or environmental effects of HDC.

EPA urges SNUR notice submitters to provide detailed information on human exposure or environmental releases that may result from the use of HDC. In addition, EPA encourages persons to submit information on potential benefits of HDC and information on risks posed by this chemical compared to risks posed by potential substitutes (such as low dioxin chloranil).

X. Economic Analysis

EPA has evaluated the potential costs of establishing SNUR reporting requirements for chloranil. The Agency's complete economic analysis is available in the public record for this rule (OPPTS–50599).

XI. Comments Containing Confidential Business Information

Any person who submits comments claimed as confidential business information must mark the comments as "confidential," "trade secret," or other appropriate designation. Comments not claimed as confidential at the time of submission will be placed in the public file. Any comments marked as confidential will be treated in accordance with the procedures in 40 CFR part 2. Any party submitting confidential comments must prepare and submit a public version of the comments for the EPA public file.

XII. Rulemaking Record

EPA has established a record for this rulemaking (docket control number OPPTS–50599). The record includes the following basic information considered by the Agency in developing this proposed rule:

4. Economic analysis of proposed SNUR for chloranil.
5. Risk characterization of chloranil and chloranil derived products. EPA will consider additional materials for inclusion in the record at any time between this proposal and designation of the complete record.

A public version of the record, without any confidential business information, is available in the TSCA Nonconfidential Information Center (NCIC), also known as TSCA Public Docket Office, from 8 a.m. to 12 noon and 1 p.m. to 4 p.m., Monday through Friday, except legal holidays. NCIC is located in rm. E-G98, 401 M St., SW., Washington, DC, 20460.

XIII. Regulatory Assessment Requirements

A. Executive Order 12291

Under Executive Order 12291, EPA must judge whether a rule is "major" and therefore requires a Regulatory Impact Analysis. EPA has determined that this proposed rule would not be a "major" rule because it would not have an effect on the economy of $100 million or more, and it would not have a significant effect on competition, costs, or prices. While there is no precise way to calculate the total annual cost of compliance with this rule, EPA estimates that the reporting cost for submitting a significant new use notice would be approximately $2,200 to $10,000. Notice submitters would also pay a $2,500 user fee to EPA to partially offset the costs of processing the notice. Firms intending to initiate production of chloranil would also bear costs of approximately $21,000 to test for the level of CDD/CDF contamination in the chloranil. Following chloranil may be subject to the same testing costs if they cannot get information regarding the level of CDD/CDF contamination in their chloranil from their suppliers.

EPA believes that, because of the nature of the rule and the chemical substance (chloranil containing CDDs/CDFs in amounts greater than 20 ppb TCDD TEQ) involved, there would be few, if any, significant new use notices submitted. Furthermore, while the cost of testing, the expense of a notice and the uncertainty of possible EPA regulation may discourage new entrants into the chloranil market, EPA believes that these factors are unlikely to discourage any significant innovations, and also believes that the chloranil market will be competitive.

This rule was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order 12291.

B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act (5 U.S.C. 605(b)), EPA has determined that this rule would not have a significant impact on a substantial number of small businesses. EPA has not determined whether parties affected by this rule would likely be small businesses. However, EPA expects to receive few SNUR notices for chloranil containing CDDs/CDFs in amounts greater than 20 ppb TCDD TEQ. Therefore, EPA believes that the number of small businesses affected by this rule would not be substantial, even if all of the SNUR notice submitters were small firms.

C. Paperwork Reduction Act

OMB has approved the information collection requirements contained in this proposed rule under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 et seq., and has assigned OMB control number 2070–0038. Public reporting burden for this collection of information is estimated to vary from 30 to 170 hours per response, with an
average of 100 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the needed data, and completing and reviewing the collection of information.

Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, and to Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503, marked "Attention: Desk Officer for EPA." The final rule will respond to any OMB or public comments on the information requirements contained in this proposal.

List of Subjects in 40 CFR Part 721

Chemicals, Environmental protection, Hazardous materials. Recordkeeping and reporting requirements, Significant new uses.


Vic Klimas, Acting Assistant Administrator for Prevention, Pesticides and Toxic Substances.

Therefore, it is proposed that 40 CFR part 721 be amended as follows:

PART 721—[AMENDED]

1. The authority citation for part 721 would continue to read as follows:


2. By adding new § 721.2220 to subpart E to read as follows:

§ 721.2220 2,3,5,6-Tetrachloro-2,5-cyclohexadiene-1,4-dione.

(a) Chemical substance and significant new use subject to reporting. (1) The chemical substance, 2,3,5,6-tetrachloro-2,5-cyclohexadiene-1,4-dione (chloranil), CAS No. 118-75-2, containing dibenzop-dioxins and dibenzofurans chlorinated at least at the 2, 3, 7, and 8 positions on the dioxin or furan molecules in total combined amounts greater than 20 ppb 2,3,7,8-tetrachlorodibenzo-p-dioxin (2,3,7,8-TCDD or TCDD) toxicity equivalence (TEQ) is subject to reporting under this section for the significant new use described in paragraph (a)(2) of this section. The TCDD TEQ for chloranil is determined as follows. The actual level of each CDD and CDF congener of concern is determined and multiplied by its toxicity equivalence factor, or TEF. The products are then added to determine the TCDD TEQ. The congeners of concern for this rule and their corresponding TEFs are as follows:

<table>
<thead>
<tr>
<th>Congener</th>
<th>Toxicity Equivalence</th>
</tr>
</thead>
<tbody>
<tr>
<td>2,3,7,8-tetrachlorodibenzo-p-dioxin</td>
<td>1</td>
</tr>
<tr>
<td>1,2,3,7,8-perchlorodibenzo-p-dioxin</td>
<td>0.5</td>
</tr>
<tr>
<td>1,2,3,4,7,8-hexachlorodibenzo-p-dioxin</td>
<td>0.1</td>
</tr>
<tr>
<td>1,2,3,6,7,8-hexachlorodibenzo-p-dioxin</td>
<td>0.1</td>
</tr>
<tr>
<td>1,2,3,7,8,9-hexachlorodibenzo-p-dioxin</td>
<td>0.1</td>
</tr>
<tr>
<td>1,2,3,4,5,6,7,8-heptachlorodibenzo-p-dioxin</td>
<td>0.01</td>
</tr>
<tr>
<td>octachlorodibenzo-p-dioxin</td>
<td>0.001</td>
</tr>
<tr>
<td>2,3,7,8-tetrachlorobenzofuran</td>
<td>1</td>
</tr>
<tr>
<td>1,2,3,7,8-pentachlorodibenzofuran</td>
<td>0.05</td>
</tr>
<tr>
<td>2,3,4,7,8-pentachlorodibenzofuran</td>
<td>0.5</td>
</tr>
<tr>
<td>1,2,3,4,7,8-hexachlorodibenzofuran</td>
<td>0.1</td>
</tr>
<tr>
<td>1,2,3,6,7,8-hexachlorodibenzofuran</td>
<td>0.1</td>
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<tr>
<td>1,2,3,7,8,9-hexachlorodibenzofuran</td>
<td>0.1</td>
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<td>2,3,4,6,7,8-hexachlorodibenzofuran</td>
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<tr>
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</tr>
<tr>
<td>1,2,3,4,7,8,9-heptachlorodibenzofuran</td>
<td>0.01</td>
</tr>
<tr>
<td>octachlorodibenzofuran</td>
<td>0.001</td>
</tr>
</tbody>
</table>

(2) The significant new use is any use.

(b) Specific requirements. The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) Persons who must report. Section 721.5 applies to this section except for § 721.5(a)(2). A person who intends to manufacture, import, or process for commercial purposes a substance identified in paragraph (a)(1) of this section and intends to distribute the substance in commerce must submit a significant new use notice.

(2) Recordkeeping. The following recordkeeping requirements are applicable to all manufacturers, importers, and processors of 2,3,5,6-tetrachloro-2,5-cyclohexadiene-1,4-dione (chloranil) subsequent to the effective date of this section.

(i) Records to be maintained. Records of manufacture, import, or processing of chloranil for a period of 3 years from the date of preparation. The records must include, to the extent that it is known to the person maintaining the records or is reasonably ascertainable, the following:

(A) Information to demonstrate that each purchase lot or batch of the chloranil manufactured, imported, or processed contains CDDs and CDFs in combined amounts equal to or less than 20 ppb TCDD TEQ. Such information shall include:

(1) A statement that the chloranil contains CDDs and CDFs in amounts equal to or less than 20 ppb TCDD TEQ.

(2) If imported or processed, the company from which the chloranil was purchased.

(3) Any available analytical test data for CDD/CDF contamination in the chloranil.

(B) Information on all commercial transactions involving chloranil, including:

(1) Dates of purchases and sales.

(2) The quantities purchased or sold.

(3) Names and addresses of purchasers.

(ii) Submission of and access to records. Persons subject to this paragraph must submit the records listed in paragraph (b)(2)(i) of this section to EPA upon written request by the Director of the Office of Pollution Prevention and Toxics. The records must be provided within 15 working days of receipt of this request. In addition, any person subject to this section must, upon request of any officer or employee of EPA designated by the Administrator, permit such person at all reasonable times to access to and to copy these records.

(3) Certification. Subsequent to the effective date of this section, all manufacturers, importers, and processors of chloranil who distribute chloranil in commerce must provide certification of the information in paragraph (b)(2)(i)(A) of this section, excluding items in paragraph (b)(2)(i)(A)(3) of this section and any confidential or proprietary information, to each recipient (as defined at 40 CFR 721.2) of chloranil. Such certification shall be required for every shipment of chloranil.

(Approved by the Office of Management and Budget under OMB control number 2070-0038)

[FR Doc. 93-11254 Filed 5-11-93; 8:45 am]

BILLING CODE 6560-60-F

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

Endangered and Threatened Wildlife and Plants; 90-day Finding for Petition to List Flatwoods Salamander as Endangered or Threatened and Designate Critical Habitat

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of petition finding.
SUMMARY: The Service announces the 90-day finding on a pending petition to add the flatwoods salamander, Ambystoma cingulatum, to the Lists of Endangered and Threatened Wildlife and Plants. It is the finding of the Service that the petition does not present substantial information indicating that the requested actions may be warranted.

DATES: This finding was made May 6, 1993.

ADDRESSES: Comments and materials concerning this petition should be sent to U.S. Fish and Wildlife Service, 6578 Dogwood View Parkway, suite A, Jackson, MS 39213. The petition, finding, and supporting data are available for public inspection, by appointment, during normal business hours at the above address.

FOR FURTHER INFORMATION CONTACT: Ms. Linda LaClaire or Mr. James Stewart at the above address.

SUPPLEMENTARY INFORMATION: Background

Section 4(b)(3)(A) of the Endangered Species Act of 1973 (Act), as amended in 1982 (16 U.S.C. 1531 et seq.), requires that the Service make a finding on whether a petition to list, delist, or reclassify a species presents substantial scientific or commercial information to demonstrate that the petitioned action may be warranted. To the maximum extent practicable, this finding is to be made within 90 days of the receipt of the petition, and the finding is to be published promptly in the Federal Register. If the finding is positive, the Service is also required to promptly commence a review of the status of the involved species.

The Service has received and made a 90-day finding on a petition from the Biodiversity Legal Foundation and Ms. Elizabeth Carlton to determine the flatwoods salamander, Ambystoma cingulatum, as an endangered or threatened species throughout its historic range and to determine critical habitat. The petition was dated May 8, 1992. The petition lists the historic range as five southeastern States: Alabama, Florida, Georgia, Mississippi, and South Carolina. The petitioners contend that the available evidence indicates that the population of flatwoods salamander has declined precipitously, is in dire straits and requires urgent protective measures.

The Service has reviewed the petition, its supporting data and other available literature, in addition to contacting individuals with knowledge of this species. The petition does not provide any information on this species that was not already available to the Service, and the available data do not provide an adequate basis for judging protection needs under the Act. While declines of this species can be reasonably presumed, based on loss and modification of habitat, much of the range has not been adequately surveyed in recent years.

Information on current status can be briefly summarized as follows. No significant survey work has been conducted in Alabama during the last decade. Surveys conducted in Florida in the winters of 1990–91 and 1991–92 located flatwoods salamanders at a total of 40 sites, mostly within the Apalachicola National Forest. In Georgia, there has apparently been no concerted effort to collect the species in recent years. One adult was captured in South Carolina in early 1992, but recent survey work has been very limited. The lone record for this species in Mississippi is generally considered to be an error by herpetologists. Further details regarding the biological status of the species are contained in the administrative finding. Interested persons may obtain a copy of the finding by contacting the office indicated in the ADDRESSES section of this notice.

The flatwoods salamander has been included in the Service’s comprehensive notices of review for animals published in the Federal Register of December 30, 1982 (47 FR 58454), September 18, 1985 (50 FR 37958), January 6, 1989 (54 FR 554), and November 21, 1991 (56 FR 58804). The flatwoods salamander was included in each of these notices as a category 2 candidate for listing. A category 2 taxon is one for which information in possession of the Service indicates that proposing to list as endangered or threatened is possibly appropriate, but for which conclusive data on biological vulnerability and threat are not currently available to support a proposed rule.

The Service has determined that the petition to list the flatwoods salamander does not present substantial information indicating that the petitioned action may be warranted. A determination of “may be warranted” has, in effect, already been made by the Service through inclusion of the flatwoods salamander as a category 2 species in the various notices of review cited above. The current petition is redundant to ongoing activities, provides no new information and would not trigger the status review process that the Act intends to result from a positive finding. The Service suspects this species is in decline throughout its historic range, and for that reason has contracted for field surveys to better determine current distribution and status. Completion of the status surveys and a decision on protection needs are expected in late 1993. The Service will remain interested in any additional information about population trends for this species as it may become available.

Authors

This notice was prepared by Mr. James Stewart and Ms. Linda LaClaire (see ADDRESSES section).

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.


Dated: May 6, 1993.

Bruce Blanchard, Acting Director, Fish and Wildlife Service.

[FR Doc. 93–11234 Filed 5–11–93; 8:45 am]

BILLING CODE 4310–56–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 625

[Docket No. 930498–3098]

RIN 0648–AE96

Summer Flounder Fishery

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

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS issues this proposed rule to implement the conservation and management measures prescribed in proposed Amendment 3 to the Fishery Management Plan for the Summer Flounder Fishery (FMP). This rule proposes to: (1) Increase from less than 100 pounds (45.4 kg) to less than 200 pounds (90.8 kg) the amount of summer flounder that may be on board an otter trawl vessel from November 1 through April 30 before becoming subject to minimum mesh size requirements; (2) revise the boundary of the seasonal fishing area within which otter trawl vessels may be exempt from minimum mesh size requirements; and (3) implement a framework measure to adjust the boundary and season of the exemption area. The intent of this action is to enhance compliance with and enforcement of minimum mesh size
The first measure proposed by the Council would increase from less than 100 pounds (45.4 kg) to less than 200 pounds (90.8 kg) the amount of summer flounder that otter trawlers permitted in the fishery may land or possess from November 1 through April 30 before being subject to the minimum mesh size requirement of 5.5 inch (14.0 cm) diamond mesh or 6 inch (15.2) square mesh, inside measure, applied throughout the codend (tail bag). Vessels fishing in the exemption area set forth in § 625.24(b)(1) from November 1 through April 30 and possessing an exemption permit under § 625.4(o) would remain exempt from the minimum mesh size requirement.

For the remaining months, May 1 through October 31, vessels possessing 100 or more pounds (45.4 kg) of summer flounder are subject to the mesh requirement and those possessing less than 100 pounds (less than 45.4 kg) would be exempt.

This measure is intended to minimize the waste of legal-sized summer flounder while keeping the discard of undersized summer flounder at a conservative level.

The second proposed measure would revise the boundary of a limited area where vessels may fish from November 1 through April 30 without becoming subject to minimum mesh size requirements. The present boundary of the area extends, roughly, from Pt. Judith, Rhode Island, to and around part of the Southern New England Yellowtail Area (Multispecies FMP), and extends to the outer boundary of the Exclusive Economic Zone (EEZ). A dozen longitude/latitude coordinates are necessary to describe the exemption area specifically.

This boundary has proven to be burdensome because of its complexity and because it bisects an important fishing area, the Hudson Canyon. Fishermen explain that wind velocity and concern for safety dictate which side of the Canyon they will fish on a given day; therefore, the boundary of the area should be revised to grant them this necessary freedom of movement. The Council and ASMFC requested the Secretary of Commerce (Secretary) to modify the boundary by emergency action. This request was approved (57 FR 58150, December 9, 1992) and extended through April 30, 1993 (58 FR 13560, March 12, 1993). The Secretary's action modified the boundary to become a straight line following 72°30’ W. longitude from the U.S. coast to the outer boundary of the EEZ. The new boundary improved compliance with the regulations and simplified enforcement and administration of the minimum mesh size requirements. In addition, the new boundary enabled industry/NMFS sea sampling investigations to occur that may improve information on the size distribution of the catch in the northern range of the resource in the area adjacent to, but formerly outside, the exempted area. Industry has claimed that catches in the area east of 72°30’ W. longitude consist of large summer flounder, negating the need for a minimum mesh size requirement. Industry leaders have pledged their support to accommodate NMFS sea-sampler to document their observations.

This proposed rule would make the boundary revision permanent, and provide a framework mechanism by which the Regional Director may annually adjust the season and boundary of the exemption area to minimize discarding, which may occur as a result of sublegal-sized summer flounder migrating into the exemption area.

**Framework Measure**

The Council proposes to allow the Regional Director to annually adjust the boundary of the exemption area by 30-minute intervals of longitude or latitude and adjustments to the season in 2-week intervals. The goal of the adjustment process would be to achieve a discarding rate in the exemption area of below 10 percent by number. The Summer Flounder Monitoring Committee would review NMFS sea sampling data and winter trawl survey information regarding the size and area distribution of the summer flounder resource as part of the annual review of catch quotas and other restrictions described in § 625.20 of the summer flounder regulations and make adjustment recommendations to the Regional Director.

**Technical Change**

The Council proposes a technical change to the provision governing net modifications to make it consistent with a similar provision in the Northeast Multispecies Fishery Management Plan. The proposed rule would allow nets to have a “bull rope” of the same size as that allowed in the regulations governing the multispecies fishery. This is desirable because many fishermen engage in both fisheries.

**Administrative, Clarifying, and Enforcement Changes**

NMFS proposes some changes to the regulations governing this fishery that are of an administrative or clarifying nature or are necessary for enforcement
purposes. These are: (1) A modification to § 625.8(a)(7) to clarify that nets or netting meeting the requirements of § 625.24 may be carried on board; (2) a modification to the prohibition on purchases of summer flounder (§ 625.8(c)(4)) to clarify that purchases may be made from vessels lawfully fishing in state waters; (3) a clarification to the section authorizing the Regional Director to terminate the small mesh exemption (§ 625.24(b)(1)(ii)) by revising the phrase “the remainder of the year” to “the remainder of the exemption season”, to reflect the fact that the exemption program season does not fall within a single calendar year; (4) a minor change to § 625.24(b)(3)(ii) by changing the phrase “west and south” to “west or south”; and (5) a modification to the prohibition on net modifications in § 625.24(e), to prohibit clearly any net modification that would diminish the size of the mesh, while in use, to a size smaller than the minimum size specified in this part.

Classification

Section 304(a)(1)(D)(ii) of the Magnuson Fishery Conservation and Management Act, as amended (Magnuson Act), requires the Secretary to publish implementing regulations proposed by a Council within 15 days of the receipt of a proposed amendment and proposed regulations. At this time, the Secretary has not determined that the amendment to these rules would implement is consistent with the national standards, other provisions of the Magnuson Act, and other applicable law. The Secretary, in making that determination, will take into account the information, views, and comments received during the comment period.

The Council prepared an environmental assessment (EA) for the amendment and concluded that there will be no significant impact on the environment as a result of this rule. A copy of the EA may be obtained from the Council (see ADDRESSES).

An informal consultation under section 7 of the Endangered Species Act (ESA) was conducted for the proposed amendment that concluded that endangered species interactions and critical habitat issues are not relevant to the amendment, as it is simply designed to fine-tune Amendment 2 and reduce some of the minor regulatory impacts on fishermen. Furthermore, emergency sea turtle conservation measures are currently in effect through the ESA. The biological opinion for the summer flounder FMP, as required by 50 CFR 402.14(a)(1)(ii), calls for promulgation of permanent ESA regulations by the fall of 1993 to provide for long-term protection of sea turtles. The proposed amendment will not affect endangered or threatened species or critical habitat in any way that was not already considered in other consultations (NMFS, 1988, 1991 and 1992).

The Assistant Administrator for Fisheries, NOAA (Assistant Administrator), has determined that this proposed rule is not a “major rule” requiring a regulatory impact analysis under E.O. 12291. This determination is based on the draft RIR that demonstrates positive net short-term and long-term economic benefits to the fishery under the proposed management measures. A copy of the RIR may be obtained from the Council (see ADDRESSES).

The General Counsel of the Department of Commerce certified to the Small Business Administration that this proposed rule, if adopted, will not have a significant economic impact on a substantial number of small entities because of the reasons set forth in the RIR prepared by the Council, a copy of which may be obtained from the Council (see ADDRESSES). As a result, a regulatory flexibility analysis was not prepared.

This rule does not contain a collection-of-information requirement subject to the Paperwork Reduction Act.

The Council determined that this rule will be implemented in a manner that is consistent, to the maximum extent practicable, with the approved coastal zone management programs of Maine, New Hampshire, Massachusetts, Rhode Island, Connecticut, New York, New Jersey, Pennsylvania, Delaware, Maryland, Virginia, and North Carolina. For New Hampshire, the evaluation was that the amendment might affect the coastal zone and was consistent. For Pennsylvania, the Council determined that this rule will not affect the coastal zone. New Hampshire, Rhode Island, Connecticut, New York, and Pennsylvania have concurred with the Council’s opinion. North Carolina disagreed with the Council’s opinion relative to the increase in the possession limit. The other states have not yet responded and consistency is presumed. The Council responded to the State of North Carolina on January 8, 1993, and explained that although Amendment 3 may not be a mirror image of the regulations of all of the states in the management unit because of local differences, the Council is “striving to make Amendment 3 consistent with the Coastal Zone Management Plans of the several coastal states to the maximum extent practicable.”

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

List of Subjects in 50 CFR Part 625

Fisheries, Reporting and recordkeeping requirements.

Dated: May 6, 1993.

Samuel W. McKeen,
Acting Assistant Administrator for Fisheries, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 625 is proposed to be amended to read as follows:

PART 625—SUMMER FLOUNDER FISHERY

1. The authority citation for part 625 continues to read as follows:


2. Section 625.8, paragraphs (a)(3), (a)(7) and (c)(4) are revised to read as follows:

§ 625.8 Prohibitions.

(a)

(3) Possess 100 or more pounds (45.4 or more kg) of summer flounder between May 1 and October 31 or 200 or more pounds (90.7 or more kg) between November 1 and April 30, unless the vessel meets the minimum mesh size requirement specified in § 625.24(a), or is fishing in the exempted area with an exemption permit as specified in § 625.24(b)(1), or is fishing with exempted gear specified in § 625.24(b)(2);

(c)

(4) Purchase or otherwise receive for commercial purposes summer flounder caught by other than a vessel with a moratorium permit not subject to the possession limit in § 625.5 unless the vessel has not been issued a permit under this part and is fishing exclusively within state waters in excess of the bag limit.

§ 625.20 Catch quotas and other restrictions.

(a)
(8) Sea sampling and winter trawl survey data, or, if sea sampling data are unavailable, length frequency information from the winter trawl survey and mesh selectivity analyses;

(b) The exempted area boundary and season specified in §625.24(b)(1) may be adjusted annually by 30-minute and two-week intervals, respectively, based on data specified in paragraphs (a)(8) and (10) of this section to prevent discarding of sublegal sized summer flounder in excess of 10 percent by number.

4. In §625.24, paragraphs (a), (b)(1), and (e) are revised to read as follows:

§625.24 Gear restrictions.
(a) General. Otter trawlers whose owners are issued a permit (including moratorium permit) under §625.4 and that land or possess 100 or more pounds (45.4 or more kg) of summer flounder between May 1 and October 31 or 200 or more pounds (90.8 or more kg) of summer flounder between November 1 and April 30, per trip, must fish with nets that have a minimum mesh size of 51/2 inches (14.0 cm) diamond mesh or 6 inches (15.2 cm) square mesh applied throughout the codend for at least 75 continuous meshes forward of the terminus of the codend or, for codends with less than 75 meshes, the minimum-mesh-size codend must be a minimum of one-third of the net, measured from the terminus of the codend to the head rope, excluding any turtle excluder device extension.

(b) (1) Vessels issued a permit under paragraph §625.4(o) and fishing from November 1 through April 30 in the "exemption area", which is east of a line that follows 72°30.0' W. longitude until it intersects the outer boundary of the EEZ. Vessels fishing with an exemption permit cannot fish west of the foregoing line.

(i) The Regional Director may terminate this exemption if he or she determines, after a review of sea sampling data, that vessels fishing under the exemption are discarding more than 10 percent of their entire catch of summer flounder per trip. If he/she makes such a determination, the Regional Director shall publish a notice in the Federal Register terminating the exemption for the remainder of the exemption season.

(ii) Vessels issued a permit under paragraph §625.4(o) may transit the area west or south of the line described in paragraph (b)(1) of this section if the vessel's fishing gear is stowed in a manner prescribed under 50 CFR 651.20(f) so that it is not "available for immediate use" out side the exempted area.

(e) Net modifications. No vessel subject to this part shall use any device, gear, or material, including, but not limited to nets, net strengtheners, ropes, lines, or chaffing gear, on the top of the regulated portion of a trawl net; except that, one splitting strap and one bull rope (if present), consisting of line or rope no more than 3 inches (7.2 cm) in diameter, may be used if such splitting strap and/or bull rope does not constrict in any manner the top of the regulated portion of the net, and one rope no greater than 0.75 inches (1.9 cm) in diameter extending the length of the net from the belly to the terminus of the cod end along each of the following: the top, bottom, and each side of the net. "Top of the regulated portion of the net" means the 50 percent of the entire regulated portion of the net that (in a hypothetical situation) will not be in contact with the ocean bottom during a tow if the regulated portion of the net were laid flat on the ocean floor. For the purpose of this paragraph, head ropes shall not be considered part of the top of the regulated portion of a trawl net. A vessel shall not use any means or mesh configuration on the top of the regulated portion of the net, as defined in §625.24(e), if it obstructs the meshes of the net or otherwise causes the size of the meshes of the net while in use to diminish to a size smaller than the minimum specified in §625.24(a).
This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE
Forest Service

Southern Region; Exemption From Appeal of the Decisions To Salvage Storm Damaged Timber on the Cherokee National Forest, Hiwassee, Ocoee, and Tellico Ranger Districts, TN

AGENCY: Forest Service, USDA.

ACTION: Notice; exemption of decision from administrative appeal.

SUMMARY: Pursuant to 36 CFR 217.4(a)(11) the Regional Forester for the Southern Region has determined that good cause exists and notice is hereby given to exempt from administrative appeal the six decisions to salvage trees that were damaged by the recent snowstorm affecting the Cherokee National Forest and, where necessary, to rehabilitate the damaged areas. The following decisions, as specified in this exemption, will be exempt from appeal:

(1) Road clearing and salvage of timber in certain named roads and within 100 feet of those roads on the Hiwassee, Ocoee, and Tellico Ranger Districts (a separate Decision Notice or Decision Memo will be issued for each Ranger District);

(2) Salvage of timber in developed recreation areas and organization camps on the Ocoee Ranger District;

(3) Salvage of timber within wildlife openings and the access roads to these openings on the Ocoee Ranger District; and

(4) Salvage of timber in the general forest area on the Tellico Ranger District.

The snow storm caused extensive damage to pine and some hardwood trees resulting in many fallen trees that are blocking forest roads and preventing access for recreation, administration and protection activities. Fallen trees have also caused extensive damage to recreation facilities and are blocking access to important recreation areas. These roads need to be opened quickly to allow access. The Cherokee National Forest proposes to open forest roads, rehabilitate recreation areas, remove damaged trees from permanent wildlife openings, and salvage timber within damaged stands, through the commercial timber sale process. The damaged trees, if not salvaged quickly, will succumb to blue stain fungi and insect damage rendering them unmerchantable as logs that can be processed into wood products. Other negative effects include increased risk to healthy trees from insects and diseases in damaged trees and stands and increased wildfire hazard. Failure to salvage damaged timber within damaged stands also will result in reduced forest health and productivity.

EFFECTIVE DATE: May 12, 1993.

FOR FURTHER INFORMATION CONTACT: Questions about this exemption should be directed to Jean P. Kruglewicz, Appeals and Litigation Group Leader, Southern Region, Forest Service-USDA, 1720 Peachtree Rd. NW., Atlanta, GA 30367 (404) 347-4667.

SUPPLEMENTARY INFORMATION: On March 13-14, 1993, a late-spring snowstorm moved through the Cherokee National Forest. The snow and strong winds caused trees to fall, blocking many forest roads and destroying some recreational facilities. Roads will be opened by clearing the roadways and removing damaged trees within 100 feet of each side of the road. All equipment operations will be limited to the roadway.

Hiwassee Ranger District

166 Miles affected by this exemption. Timber salvage will occur along the following Forest Roads: White Oak Flats, McFarland, Ellis Branch-Starr Mountain, Conasauga, Oswald, Appalachia Tunnel, Smith Mountain, Kinsey Highway, Fingeboard, Shuler Creek, Attic, Ivy Trail, Old 68 Forest developed road (FDR 311), Childers Creek, Spring Creek, Wumble Branch (at Highway 58), Rucker Branch, Tinker Branch, Tellico-Reliance, Duckett Spur, Duckett Ridge, White Cliff, Jones, Hampton Cemetery, Smith Creek, Steer Creek, Dehart Cemetery, Mary's Branch, Lowery Top-Tieskee, and Hiwassee River.

Ocoee Ranger District

109 Miles affected by this exemption. Timber salvage will occur along the following Forest Roads: FDR 77, FDR 185, FDR 62, FDR 67, FDR 99, FDR 65, FDR 1333, FDR 302, FDR 221, FDR 55, FDR 68, FDR 366, FDR 366-A, FDR 366-B, FDR 366-C, FDR 366-D, FDR 45, FDR 102. In addition to salvage along these roads, storm damaged trees will be salvaged in the following recreation areas:

(1) Parksville Lake Campground
(2) Thunder Rock Campground
(3) Wildlife opening access road, immediately north of Rock Creek and within view of Parksville Lake Campground (upper loop) on the south side of Rock Creek, Compartment 311.
(4) King's Slough Boating Site and access road, Compartment 374, off FS 55A, an access road to recreation residences on Parksville Lake.
(5) Camp Ocoee
(6) Camp Cherokee
(7) Charleston Hosiery Recreation Residence

Permanent wildlife openings on the Ocoee Ranger District will have all damaged trees removed from within them to maintain the openings. Short road segments leading to the openings will have damaged trees removed to allow for access for both recreation and administrative purposes. On the Ocoee District, timber on 147 acres of openings and access roads to the openings will be salvaged to remove damaged timber.

Permanent wildlife openings are identified by the following numbers:

301-1; 307-1; 309-1-6; 311-1; 312-1; 313-1; 315-1; 317-1; 321-1-10; 324-1; 325-1-7; 327-2-4; 328-1, 2; 329-1; 330-1; 331-1; 332-1-3; 333-1; 334-1; 335-1-3; 341-1; 342-1; 343-1-4; 344-1, 2; 345-1, 2; 348-1, 2; 351-1, 2; 356-1-4; 359-1; 363-1; 367-1; 373-1; 376-1-3; 377-1; and 378-1.

Tellico Ranger District

14 miles of roads are affected by this exemption. Storm damaged trees will be salvaged along the following road projects:

(1) Toqua Creek Road
(2) Henson Mountain
(3) Young Branch
(4) Barkcamp
(5) Smoky Branch
(6) Little Citico
In addition, the Tellico Ranger District will salvage damaged timber from about 25 acres of stands within the Little Toqua, Lower Wildcat, and Cane Creek Mountain areas.

For areas in the Tellico Districts that require salvage outside road corridors recreation areas, and wildlife openings, damaged trees will be removed by standard logging techniques. The timber stands severely damaged by the storm require restoration through salvage of the merchantable trees and, in some cases, rehabilitation, through site preparation and reforestation.

As temperature begins to climb with the approach of spring, conditions conducive to the onset and rapid spread of blue stain fungi will occur in the recently damaged timber. Blue stain fungi will begin to infect trees within days of the event and will within three months spread to such an extent as to render the trees unmerchantable as sawtimber. Within four or five months, even value as pulpwood will be greatly diminished. Pine bark beetle infestations may also occur in the residual stands and further compound the damage. Fire hazard will increase rapidly as the downed timber dries out in the spring and will continue to be a hazard until decomposition is well advanced. Following salvage of the damaged trees, some areas will need to be reforested. Any planting needed will be accomplished during the winter months. Prior to that time, some sites will need to be prepared for planting. Other stands will require timber stand improvements to allow natural regeneration to become established or to maintain and enhance the residual, remaining stand. Sufficient time will be necessary to complete site preparation and timber stand improvements during the summer months.

Each District's storm damaged salvage will have a documented environmental analysis. These analyses will analyze appropriate methods of harvest, site preparation, timber stand improvements and reforestation. The analyses will include preparation of a biological evaluation and cultural resources inventory, document public involvement, and addres issues raised. Given the present condition of the damaged timber, the need to open roads and recreation areas immediately, the impending onset of higher temperatures in spring and the need to complete site preparation and stand improvements this summer, the need for immediate action is critical. Any delay will result in losses to presently merchantable timber, increase the risk of insect and disease spreading to healthy stands, increase the risk of wildfire, and subsequent rehabilitation efforts will be more difficult. If roads and recreation areas are not opened quickly, the public will lose the use of important recreation facilities this summer. The Forest also will be hindered in responding to emergency conditions, especially wildfire, if roads are not opened quickly.

Dated: May 6, 1993.

Ralph F. Mumme,
Acting Deputy Regional Forester.
[FR Doc 93–11194 Filed 5–11–93; 8:45 am]

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**Apalachicola National Forest Boundary Extension**

AGENCY: Forest Service, USDA.

ACTION: Notice of Apalachicola National Forest Boundary extension.

SUMMARY: On April 7, 1993, the Secretary of Agriculture extended the Apalachicola National Forest boundary. This extension comprises 1,630 acres, more or less, within Liberty County, Florida. A copy of the Secretary's establishment document which includes the legal description of the lands within the boundary extension appears at the end of this notice.

EFFECTIVE DATE: The effective date of this boundary extension was April 7, 1993.

**APPLICA**

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**New World Project (Underground Gold/Copper/Silver Mine), Gallatin National Forest, Park County, MI; Shoshone National Forest, Park County, WY**

AGENCY: Forest Service, USDA.

ACTION: Revised notice; intent to prepare an environmental impact statement.

SUMMARY: The Department of Agriculture, Forest Service, Gallatin National Forest (GNF) and Shoshone National Forest (SNF), in conjunction with Montana's Department of State Lands (DSL), will prepare an environmental impact statement (EIS) for a proposal to permit the development of the New World Project. The New World Project, a gold, copper, and silver mine proposed by Crown Butte Mines, Inc., is located about three miles north of Cooke City, Montana. The proposed plan of operations was submitted on November 15, 1990 pursuant to the Forest Service locatable mineral regulations 36 CFR part 228, chapter II, subpart A, and to the State of Montana Metal Mine Reclamation Act title 82, chapter 4, part 3, MCA. The plan was revised in October of 1992.

ADDRESSES: Send written comments and suggestions concerning the scope of the analysis to David P. Garber, Forest Supervisor, Gallatin National Forest, P.O. Box 130, Bozeman, Montana 59771.

FOR FURTHER INFORMATION CONTACT: Sherrill Solis, Geologist, Gallatin National Forest, P.O. Box 130, Bozeman, Montana 59771, telephone 406-587-6709.
Proposed Plan of Operations, would consist of a 1500-1800 ton-per-day mine and mill complex. The ore would be mined from an underground mine and be crushed and conveyed to a mill in the Fisher Creek drainage. The ore would be ground at the mill and the gold, copper, and silver concentrated by conventional froth flotation and gravity separation methods. Tailings from the mill process would be conveyed through a pipeline to the tailings disposal impoundment located slightly downstream from the mill in Fisher Creek. Some concentrates would be processed at the mill and others would be shipped to a concentrator located slightly downstream from the project area, the Fisher Creek drainage. The proposed project may affect a portion of the Beartooth Roadless Area (1-912).

The project may affect wildlife, including threatened and endangered species such as grizzly bears.

3. The project may affect a portion of the Beartooth Roadless Area (1-912).

4. The project may affect wildlife, including threatened and endangered species such as grizzly bears.

5. The proposed project may have social and economic effects on local communities.

6. Reclamation of high elevation, exposed sites may be difficult. Other issues commonly associated with mineral development include: Effects on cultural resources, soils, and wetlands. This list will be verified, expanded, or modified based on public scoping for this proposal.

The Draft EIS is expected to be filed with the Environmental Protection Agency (EPA) and available for public review in January, 1994. At that time, the EPA will publish a Notice of Availability of the Draft EIS in the Federal Register. The comment period on the Draft EIS will be 45 days from the date the EPA’s notice of availability appears in the Federal Register. A public meeting will be held in conjunction with the issuance of the Draft EIS. The Final EIS is expected to be available in April, 1994.

The Forest Service believes it is important to give reviewers notice at this early stage of several court rulings related to public participation in the environmental review process. First, reviewers of Draft EIS’s must structure their participation in the environmental review of the proposal so that it is meaningful and alerts an agency to the reviewer’s position and contentions. Vermont Yankee Nuclear Power Corp. versus NRDC, 435 U.S. 519, 553 (1978). Also, environmental objections that could be raised at the draft environmental impact stage but that are not raised until after completion of the Final EIS may be waived or dismissed by the courts. City of Angoon versus Hodel, 803 F.2d 1016, 1022 (9th Cir. 1986) and Wisconsin Heritages, Inc. versus Harris, 490 F. Supp. 1334, 1338 (E.D. Wis. 1980). Because of these court rulings, it is very important that those interested in this proposed action.
participate by the close of the 45-day comment period so that substantive comments and objections are made available to the Forest Service at a time when it can meaningfully consider them and respond to them in the Final EIS.

To assist the Forest Service in identifying and considering issues and concerns on the proposed action, comments on the Draft EIS should be as specific as possible. It is also helpful if comments refer to specific pages or chapters of the Draft EIS or the merits of the alternatives formulated and discussed in the statement. Reviewers may wish to refer to the Council on Environmental Quality Regulations for implementing the procedural provisions of the National Environmental Policy Act at 40 CFR 1503.3 in addressing these points.

I am the responsible official for this EIS. My address is Gallatin National Forest, P.O. Box 130, Federal Building, Bozeman, Montana 59771.


David P. Garber,
Forest Supervisor, Gallatin National Forest.

[FR Doc. 93–1176 Filed 5–11–93; 8:45 am]
BILLING CODE 3410–11–M

Proposed Freight Landing Timber Sale
Within the French Creek/Patrick Butte Roadless Area, Payette National Forest, Idaho County, ID

AGENCY: Forest Service, USDA.

ACTION: Revised notice of intent to prepare an environmental impact statement.

SUMMARY: The USDA Forest Service published a notice of intent to prepare an environmental impact statement (EIS) for proposed timber sales in the French Creek roadless area in the Federal Register June 9, 1989 (Vol. 54, No. 110, p. 24725–24726). That notice is hereby revised to show these changes: (1) Prepare separate EIS's for each proposed timber sale, (2) name of the EIS's, and (3) the schedule of the EIS's.

1. This Notice of Intent is for the proposed Freight Landing timber sale which is one of six proposed timber sales within the French Creek/Patrick Butte Roadless Area. All six proposed sales are being analyzed together by one interdisciplinary team.

2. This Notice of Intent covers the proposed Freight Landing timber sale. Separate NOI revisions have been prepared covering the other 5 proposed sales. They include the following proposed timber sales: Fournil, Hazel Helicopter, Jenkins, French Creek, and Lower Elkhorn.

3. Public scoping has included several meetings and written comments. The DEIS is scheduled to be released for public comments in May or June of 1993 and a FEIS released in August or September of 1993.

ADDRESSES: Send written comments to David Alexander, Forest Supervisor, Payette National Forest, P.O. Box 1026, McCall, Idaho 83638.

FOR FURTHER INFORMATION CONTACT: Questions about the proposed action should be directed to Mike Balboni, Team Leader, phone 208–634–0629 or Linda Fitch, District Ranger, phone 208–634–0400.

SUPPLEMENTARY INFORMATION: The USDA Forest Service is proposing to construct roads, harvest and regenerate timber in the Freight Landing timber sale area. This sale lies within the French Creek/Patrick Butte Roadless Area, Idaho County, Idaho. Within the proposed sale area, Fall Creek is the only drainage. Fall Creek is a tributary to the Salmon River.

Preliminary Issues include: roadless characteristics, water quality, biological diversity, forest health, and fisheries habitat.

Preliminary alternatives being considered include: no action, intermediate harvest prescriptions, clearcutting, and road construction.

The Responsible Official is David Alexander, Forest Supervisor, Payette National Forest.

"The comment period on the draft environmental impact statement will be 45 days from the date the Environmental Protection Agency's notice of availability appears in the Federal Register. It is very important that those interested in this proposed action participate at that time. To be the most helpful, comments on the draft environmental impact statement should be as specific as possible and may address the adequacy of the statement or the merits of the alternatives discussed (see The Council on Environmental Quality Regulations for implementing the procedural provisions of the National Environmental Policy Act at 40 CFR 1503.3).

In addition, Federal court decisions have established that reviewers of draft environmental impact statements must structure their participation in the environmental review of the proposal so that it is meaningful and alerts an agency to the reviewers' position and contentions. Vermont Yankee Nuclear Power Corp. v. NRD, 435 U.S. 519, 553 (1978). Environmental objections that could have been raised at the draft stage may be waived if not raised until after completion of the final environmental impact statement. City of Anego v. Hodel, (9th Circuit, 1986) and Wisconsin Heritage, Inc. v. Harris, 490 F. Supp. 1334, 1338 (E.D. Wis. 1980). The reason for this is to ensure that substantive comments and objections are made available to the Forest Service at a time when it can meaningfully consider them and respond to time in the final."


David F. Alexander,
Forest Supervisor.

[FR Doc. 93–1176 Filed 5–11–93; 8:45 am]
BILLING CODE 3410–11–M

COMMISSION ON CIVIL RIGHTS

Agenda and Notice of Public Meeting of the Arkansas Advisory Committee

Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights, that the Arkansas Advisory Committee to the U.S. Commission on Civil Rights will meet on June 10, 1993, from 6 p.m. until 8 p.m. at the Legacy Hotel, 625 West Capitol Avenue, Little Rock, Arkansas 72201. The purpose of the meeting is to plan for future Commission activities.

Persons desiring additional information, or planning a presentation to the Committee, should contact Melvin L. Jenkins, Director of the Central Regional Office, 816–426–5253 (TTY 816–426–5009). Hearing-impaired persons who will attend the meeting and require the services of a sign language interpreter should contact the Regional Office at least five (5) working days before the scheduled date of the meeting.

The meeting will be conducted pursuant to the provisions of the rules and regulations of the Commission.


Carol Lee Hurley,
Chief, Regional Programs Coordination Unit.

[FR Doc. 93–1176 Filed 5–11–93; 8:45 am]
BILLING CODE 6355–01–P

Agenda and Notice of Public Meeting of the Idaho Advisory Committee

Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights, that a meeting of the Idaho Advisory Committee to the Commission will convene at 1 p.m. and adjourn at 4 p.m. on June 3, 1993, at the Shilo Inn, 4111 Broadway Avenue, Boise, Idaho 83705. The purpose of the meeting is to plan activities and programming for the coming year.
Persons desiring additional information, or planning a presentation to the Committee, should contact Committee Chairperson Gladys Esquibel, or Philip Montez, Director of the Western Regional Office, 213–894–3437 (TDD 213–894–0508). Hearing-impaired persons who will attend the meeting and require the services of a sign language interpreter should contact the Regional Office at least five (5) working days before the scheduled date of the meeting.

The meeting will be conducted pursuant to the provisions of the rules and regulations of the Commission.


Carol-Lee Hurley, 
Chief, Regional Programs Coordination Unit.

[FR Doc. 93–11171 Filed 5–11–93; 8:45 am]

BILLING CODE 6335–01–P

DEPARTMENT OF COMMERCE
International Trade Administration

[C–580–818]

Certain Steel Products From Korea; Rescheduling of Public Hearing

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: May 12, 1993.

FOR FURTHER INFORMATION CONTACT: Kris Campbell or Jacqueline Arrowsmith, Office of Antidumping Compliance, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone: (202) 482–4794.

PUBLIC COMMENT: The date of the public hearing in these investigations is rescheduled from the date originally published in the Federal Register on March 8, 1993 (58 FR 12935). The new date is May 13, 1993, at 1:30 p.m., in room 3708.

This notice is published pursuant to section 774(b) of the Tariff Act of 1930, as amended, and 19 CFR 355.38(f) (1992).

Dated: May 7, 1993.

Joseph A. Spettrini, 
Acting Assistant Secretary for Import Administration.

[FR Doc. 93–11416 Filed 5–11–93; 8:45 am]

BILLING CODE 3510–05–P

National Institute of Standards and Technology

[Docket No. 920491–2339]

RIN No. 0693–AB01

Approval of Federal Information Processing Standard (FIPS) 151–2, Portable Operating System Interface (POSIX)—System Application Program Interface [C Language]

AGENCY: National Institute of Standards and Technology (NIST), Commerce.

ACTION: Notice.

SUMMARY: The purpose of this notice is to announce that the Secretary of Commerce has approved a revision of Federal Information Processing Standard (FIPS) 151–1, POSIX: Portable Operating System Interface for Computer Environments, which will be published as FIPS Publication 151–2. This revision adopts International Standard ISO/IEC 9945–1:1990, Information Technology—Portable Operating System Interface (POSIX)—Part 1: System Application Program Interface (API) [C Language], which defines a C programming language source interface to an operating system environment. This revised standard supersedes FIPS 151–1 in its entirety.

On June 9, 1992, notice was published in the Federal Register (57 FR 28829) that a revision of Federal Information Processing Standard Publication (FIPS PUB) 151–1 POSIX, Portable Operating System Interface for Computer Environments, was being prepared for Federal use. The written comments submitted by interested parties and other material available to the Department relevant to this standard were reviewed by NIST. On the basis of this review, NIST recommended that the Secretary approve the revised standard as Federal Information Processing Standards Publication (FIPS PUB) 151–2, and prepared a detailed justification document for the Secretary's review in support of that recommendation.

The detailed justification document which was presented to the Secretary, and which includes an analysis of the written comments received, is part of the public record and is available for inspection and copying in the Department's Central Reference and Records Inspection Facility, room 6020, Herbert C. Hoover Building, 14th Street between Pennsylvania and Constitution Avenue NW., Washington, DC 20230.

This FIPS contains two sections: (1) an announcement section, which provides information concerning the applicability, implementation, and maintenance of the standard; and (2) a specifications section which deals with the technical requirements of the standard. Only the announcement section of the standard is provided in this notice.

EFFECTIVE DATE: This revised standard becomes effective October 15, 1993.

ADDRESSES: Interested parties may purchase copies of this revised standard, including the technical specifications portion, from the National Technical Information Service (NTIS). Specific ordering information from NTIS for this standard is set out in the Where to Obtain Copies Section of the announcement section of the standard.

FOR FURTHER INFORMATION CONTACT: Kris Spetrini, National Institute of Standards and Technology, Gaithersburg, MD 20899, telephone (301) 975–3290.

SUPPLEMENTARY INFORMATION: The suite required for testing conformance of POSIX implementations to FIPS 151–2 is the official NIST–PCTS: 151–2. This test suite is available from the National Institute of Standards and Technology (301–975–3290). After October 15, 1993, NIST will no longer issue Certificates of Validation for FIPS 151–1 implementations. Certification Reports will be processed for FIPS 151–2 implementations that have been validated by POSIX Testing Laboratories accredited by the National Voluntary Laboratory Accreditation Program (NVLAP). See section 8. Related On-Line Information in the FIPS announcement section which follows for information on the POSIX Testing Program.


Raymond Kammer, 
Acting Director.

Federal Information Processing Standards Publications (FIPS PUBS) are issued by the National Institute of Standards and Technology after approval by the Secretary of Commerce pursuant to Section 111(d) of the Federal Property and Administrative Servics Act of 1949 as amended by the Computer Security Act of 1987, Public Law 100–235.


This standard is for use in system and application software development and implementation. This revision supersedes FIPS PUB 151-1 in its entirety.

4. Approving Authority. Secretary of Commerce.


7. Related Documents.
   b. Federal Information Processing Standards Publication 160, C.
   c. ISO/IEC 9899: Information Technology—Programming Languages-C.
   h. NIST POSIX Testing Policy—General Information, April 15, 1993.
   j. Related On-Line Information.
   k. Information on the NIST POSIX Testing Program is available on an electronic mail (email) file server system.
   l. Documents available are:
      Register—a register of accredited laboratories and tested implementations
      Policy—general information on NIST POSIX testing policy
      Required—information on requirements for certificates of validation under NIST POSIX testing policy for FIPS 151

To access the system: You must be able to send and receive email via the Internet. For most email systems, send a message to posix@nist.gov. When the email system responds with “Subject,” you may type anything. The next line should be a basic command for the email server to send you one or more of the documents listed above. For example, to receive a copy of the register file, enter: Send register.

After you issue your send command and carriage return, the next line should signal the end of the email message as required by your email system.

Your email system should signal the end of the email message after the next line and a carriage return, the next line should signal the end of the email message as required by your email system.

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Your email system should signal the end of the email message after the next line and a carriage return, the next line should signal the end of the email message as required by your email system.

These modifications ensure that applications, which choose to use those optional features specified in POSIX.1 and mandated below, are strictly conforming FIPS 151-2 applications (portable to all conforming FIPS 151-2 implementations). For each modification a reference to the associated POSIX text is provided.

a. Implementations claiming conformance to FIPS 151-2 shall provide the functionality specified in FIPS 160 and provide C Standard Language-Dependent System Support.
   (The reference text for FIPS 160 is ISO/IEC 9899: Information Technology—Programming Languages-C [See POSIX.1 Subclause 1.3.3–1.3.3.3 lines 143–158].
   b. Implementations claiming conformance to FIPS 151-2 shall define the POSIX.1 environment variable, HOME, in the environment for the login shell. [See POSIX.1 Subclause 2.6 lines 698–699].
   c. Implementations claiming conformance to FIPS 151-2 shall define the POSIX.1 environment variable, LOGNAME, in the environment for the login shell. [See POSIX.1 Subclause 2.6 lines 698–699].
   d. Implementations claiming conformance to FIPS 151-2 shall support the POSIX.1 option [NGROUPS—MAX] such that the value of [NGROUPS—MAX] is greater than or equal to eight (8) [See POSIX.1 Subclause 2.8.3 lines 1013–1015].
   e. Implementations claiming conformance to FIPS 151-2 shall support a minimum value of 25 for the POSIX.1 variable [CHILID—MAX]. [See POSIX.1 Subclause 2.8.4 lines 1029–1030].
   f. Implementations claiming conformance to FIPS 151-2 shall support a minimum value of 20 for the POSIX.1 variable [OPEN—MAX]. [See POSIX.1 Subclause 2.8.4 lines 1013–1032].
   g. Implementations claiming conformance to FIPS 151-2 shall support the functionality associated with (—POSIX—JOB—CONTROL) being defined in <unistd.h>. [See POSIX.1 Subclause 2.9.3 lines 1117–1118].
   h. Implementations claiming conformance to FIPS 151-2 shall support the functionality associated with (—POSIX—SAVE—IDS) being defined in <unistd.h>. [See POSIX.1 Subclause 2.9.3 lines 1119–1120].
Implementation. This standard becomes effective October 15, 1993. This standard is compulsory and binding for use in all solicitations and contracts for new operating systems where POSIX-like interfaces are required.

a. Acquisition of a Conforming Portable Operating System Environment. Operating system environments which are to be acquired for Federal use after the effective date of this standard and where POSIX-like interfaces are required shall use this FIPS. Conformance to this FIPS shall be considered whether the operating system environments are:

1. Developed internally.
2. Acquired as part of an ADP system procurement.
3. Acquired by separate procurement.
4. Used under an ADP leasing arrangement, or
5. Specified for use in contracts for programming services.

b. Interpretation of the FIPS for Portable Operating System Interface for Computer Environments. NIST provides for the resolution of questions regarding the FIPS specifications and requirements, and issues official interpretations as needed. All questions about the interpretation of this FIPS should be addressed to: Director, Computer Systems Laboratory, Attn: POSIX FIPS Interpretation, National Institute of Standards and Technology, Gaithersburg, MD 20899.

c. Validation of Conforming Operating Systems Environments. NIST has developed cooperatively with industry a validation suite for measuring conformance to this standard. This suite is required for testing conformance of POSIX.1 implementations to FIPS 151-2. The “NIST POSIX Testing Policy, General Information” and the “NIST POSIX Testing Policy, Certificate of Validation Requirements, FIPS 151-2” specify the validation requirements.

14. Waivers. Under certain exceptional circumstances, the heads of Federal departments and agencies may approve waivers to Federal Information Processing Standards (FIPS). The head of such agency may delegate such authority to a senior official designated pursuant to section 3506(b) of Title 44, U.S. Code. Waivers shall be granted only when:

a. Compliance with a standard would adversely affect the accomplishment of the mission of an operator of a Federal computer system, or
b. Cause a major adverse financial impact on the operator which is not offset by Governmentwide savings.

Agency heads may act upon a written waiver request containing the information detailed above. Agency heads may also act without a written waiver request when they determine that conditions for meeting the standard cannot be met. Agency heads may approve waivers only by a written determination which explains the basis on which the agency head made the required finding(s). A copy of each such determination, with procurement sensitive or classified portions clearly identified, shall be sent to: National Institute of Standards and Technology; ATTN: FIPS Waiver Decisions, Technology Building, room B-154; Gaithersburg, MD 20899. In addition, notice of each waiver granted and each delegation of authority to approve waivers shall be sent promptly to the Committee on Government Operations of the House of Representatives and the Committee on Governmental Affairs of the Senate and shall be published promptly in the Federal Register.

When the determination on a waiver applies to the procurement of equipment and/or services, a notice of the waiver determination must be published in the Commerce Business Daily as a part of the notice of solicitation for offers of an acquisition or, if the waiver determination is made after that notice is published, by amendment to such notice.

A copy of the waiver, any supporting documents, the document approving the waiver and any supporting and accompanying documents, with such deletions as the agency is authorized and decides to make under 5 U.S.C. 552(b), shall be part of the procurement documentation and retained by the agency.

14. Where to Obtain Copies. Copies of this publication are for sale by the National Technical Information Service, U.S. Department of Commerce, Springfield, VA 22161. (Sale of the included specifications document is by arrangement with the Institute of Electrical and Electronics Engineers, Incorporated.) When ordering, refer to Federal Information Processing Standards Publication 151-2, (FIPS PUB 151-2), and title. Payment may be made by check, money order, or deposit account.

Appendix A—Application Portability Profile

FIPS 151-2 is the first component of a series of specifications needed for an applications portability profile. POSIX.1 provides the crucial first step by providing a vendor independent interface specification between an application program and an operating system. When fully extended, POSIX.1 will provide the functionality required to support source code portability for a wide range of applications across many different machines and operating systems.
National Oceanic and Atmospheric Administration

Incidental Take of Marine Mammals

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


SUMMARY: NMFS has received a request from ARCO Alaska, Inc., for a Letter of Authorization that would allow a take of marine mammals (by harassment) incidental to exploration activities in the Beaufort Sea during the 1993 open-water season.

DATES: Comments should be received by June 11, 1993.

ADDRESSES: Comments should be sent to William W. Fox, Jr., Ph.D., Director, Office of Protected Resources, 1335 East-West Highway, Silver Spring, MD 20910. A copy of the request may be obtained by writing to this address or by telephoning the contacts listed below.

FOR FURTHER INFORMATION CONTACT: Margaret C. Lorenz, Office of Protected Resources, NMFS, (301) 713-2322 or Ron Morris, Western Alaska Field Office, NMFS, (907) 271-5006.

SUPPLEMENTARY INFORMATION:

Background

Regulations governing the taking of marine mammals incidental to oil and exploration activities in Alaska were published July 18, 1990 (55 FR 29214). The regulations are based on section 101(a)(5) of the Marine Mammal Protection Act and NMFS' determination that the taking of six species of marine mammals (bowhead, gray and beluga whales and bearded, ringed and spotted seals) incidental to exploratory activity in the Beaufort and Chukchi Seas will have a negligible impact on the species or stocks and will not have an unmitigable adverse impact on the availability of the species or stock for subsistence uses. The regulations include permissible methods of taking, and require exploration companies to monitor the effects of their activities on marine mammals and to cooperate with the Alaska native communities to ensure that marine mammals are available for subsistence.

A Letter of Authorization must be requested annually by each group or individual conducting an exploratory activity where there is the likelihood of taking any of the six species of marine mammals identified in the regulations. NMFS grants the Letters based on a determination that the total level of taking by all applicants in any one year is consistent with the estimated level of activity used to make a finding of negligible impact and a finding of no unmitigable adverse impacts on the availability of the species for subsistence hunting.

The regulations require the applicant to submit a request for a Letter of Authorization at least 90 days before the activity is scheduled to begin. NMFS must publish notices of each request in the Federal Register with an opportunity for public comment.

Requests for Letters of Authorization must include a plan of cooperation that identifies what measures have been and will be taken to minimize any adverse effects on the availability of marine mammals for subsistence uses. It must include a description of the activity including the methods to be used, the dates and duration of the activity, and the specific location. Also, it must include a site-specific plan to monitor the effects on marine mammals that are present during exploratory activities.

Summary of Request From ARCO, Alaska, Inc.

On February 10, 1993, NMFS received a request from ARCO Alaska, Inc., for a Letter of Authorization that would allow nonlethal takes of marine mammals incidental to oil and gas exploration activities at its Kuvluim Project in Camden Bay in the Beaufort Sea. The project will be conducted using a floating conical drilling unit that may be accompanied by four support vessels and a helicopter. Seismic activities will be conducted from an ice-strengthened seismic vessel towing an airgun and multiple sensor arrays in an area 10 miles wide and 20 miles long (16 km x 32 km). The project, which is expected to begin about mid-July and continue through October, is located about 45 miles (72 km) northwest of Barter Island, the Kaktovik whaling grounds, and 75 miles (121 km) east of the Cross Island whaling camps of the Nuiqsut whalers. Included in the request is a description of planned contacts with Beaufort Sea whaling communities and ARCO's intended activities to keep the communities informed of its operations.

On April 26, 1993, ARCO submitted a revised monitoring plan which will be conducted to determine the effects of the exploration on marine mammals.

Dated: May 6, 1993.

William W. Fox, Jr.,
Director, Office of Protected Resources.

[FR Doc. 93-11192 Filed 5-11-93; 8:45 am]

BILLING CODE 3510-22-M

COMMODITY FUTURES TRADING COMMISSION

Agricultural Advisory Committee; Fifth Renewal

The Commodity Futures Trading Commission has determined to renew again for a period of two years its advisory committee designated as the “Commodity Futures Trading Commission Agricultural Advisory Committee.” The Commission certifies that the renewal of the advisory committee is in the public interest in connection with duties imposed on the Commission by the Commodity Exchange Act, 7 U.S.C. 1, et seq., as amended.

The objectives and scope of activities of the Agricultural Advisory Committee are to conduct public meetings and submit reports and recommendations on issues affecting agricultural producers, processors, and lenders and others interested in or affected by agricultural commodities markets, and to facilitate communications between the Commission and the diverse agricultural and agriculture-related organizations represented on the committee.

Commissioner Joseph B. Dial serves as Chairman and Designated Federal Official of the Agricultural Advisory Committee. The Committee's membership represents a cross-section of interested and affected groups including representatives of producers, processors, lenders and other interested agricultural groups.

Interested persons may obtain information or make comments by writing to the Commodity Futures Trading Commission, 2033 K Street, NW., Washington, DC 20581.

Issued in Washington, DC, on May 6th, 1993, by the Commission.

Jean A. Webb,
Secretary of the Commission.

[FR Doc. 93-11157 Filed 5-6-93; 8:45 am]

BILLING CODE 3510-01-M
DEPARTMENT OF DEFENSE

Office of the Secretary

Board of Visitors Meeting

AGENCY: Defense Systems Management College, DoD.
ACTION: Board of Visitors meeting.

SUMMARY: A meeting of the Defense Systems Management College (DSMC) Board of Visitors (BOV) will be held at the Fort Belvoir Officers’ Club, Fort Belvoir, Virginia, on Friday, June 25, 1993, from 0830 until 1600. The agenda will include a report on items from the last BOV meeting, and planning issues for the next Policy Guidance Council (PGC) meeting. The meeting is open to the public; however, because of limitations on space available, allocation of seating will be made on a first-come, first-serve basis. Persons desiring to attend the meeting should call Mrs. Joyce Reniere, on (703) 805-4004.

DATED: May 6, 1993.
L.M. Bynum,
Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 93-11164 Filed 5-11-93; 8:45 am]
BILLING CODE 5000-04-M

Department of the Navy

Intent to Prepare a Joint Environmental Impact Statement/Environmental Impact Report for Proposed Disposal and Reuse of Long Beach Naval Hospital, Long Beach, CA

Pursuant to the National Environmental Policy Act (NEPA) as implemented by the Council on Environmental Quality (CEQ) regulations (40 CFR parts 1500-1506), the Department of the Navy, in cooperation with the City of Long Beach (“the City”), announces its intent to prepare a Joint Environmental Impact Statement (EIS)—Environmental Impact Report (EIR) to evaluate the environmental effects of the disposal and reuse of Naval Hospital (NAVHOSP) Long Beach, Long Beach, California.

Pursuant to 40 CFR 1506.2, the City will be a joint lead agency in the preparation of the EIS/EIR, in order to satisfy its requirements for environmental analysis under the California Environmental Quality Act. In accordance with requirements of the 1991 Base Closure and Realignment Commission, the Navy plans to disestablish NAVHOSP Long Beach in April 1994. Operations conducted at NAVHOSP Long Beach are currently relocating to other Naval Hospitals located in the continental United States. The proposed action involves the disposal of land, buildings, and infrastructure of NAVHOSP Long Beach for subsequent reuse. This includes the 65.2 acre NAVHOSP Long Beach site located at 7500 E. Carson Street and generally bounded by Carson Street, Doavy Drive, El Dorado Regional Park, and the 605 Freeway.

The Navy intends to analyze the environmental effects of the disposal of NAVHOSP Long Beach based on the reasonably foreseeable reuse of the property, taking into account uses identified by the City and as determined during the scoping process. It is anticipated that reuse of NAVHOSP Long Beach will include, but not be limited to, demolition of the existing hospital complex and accessary structures and construction of approximately one million square feet of retail, restaurant, and entertainment commercial space. Another alternative being studied is continued use of the existing hospital complex for medical use. In considering the ultimate reuse of NAVHOSP Long Beach, the City is also including: (1) Two parcels of land owned by the City—one on the east side of Dovery Drive and one on the west—generally bounded by El Dorado Regional Park, the San Gabriel River, Carson Street, and NAVHOSP Long Beach; (2) roadways serving NAVHOSP Long Beach and the two City-owned parcels; and (3) the immediate vicinity of these sites and roadways. In accordance with CEQ regulations, the “no action” alternative of Navy retention of NAVHOSP Long Beach land, buildings, and infrastructure in caretaker status will also be addressed in the EIS. However, because of the process mandated by the Base Closure and Realignment Act of 1990, selection of the “no action” alternative would be considered outside the jurisdiction of the Navy.

Major environmental issues that will be addressed in the EIS include, but are not limited to, air quality, water quality, wetlands, endangered species, cultural resources, transportation and socioeconomic impacts.

The Navy and the City will initiate a scoping process for the purpose of determining the scope of issues to be addressed and for identifying the significant issues related to this action. A public scoping meeting is scheduled for Thursday, May 27, 1993, beginning at 9 a.m., at the City Council Chambers, City Hall, 333 West Ocean Boulevard, Long Beach, California. This meeting will be advertised in local newspapers.

A brief presentation will precede request for public comment. Navy representatives will be available at this meeting to receive comments from the public regarding issues of concern to the public. It is important that federal, state, and local agencies and interested individuals take this opportunity to identify environmental concerns that should be addressed during the preparation of the EIS. In the interest of available time, each speaker will be asked to limit their oral comments to five minutes.

Agencies and the public are also invited and encouraged to provide written comment in addition, to, or in lieu of, oral comments at the public meeting. To be most helpful, scoping comments should clearly describe specific issues or topics which the commenter believes the EIS should address. Written statements and or questions regarding the scoping process should be mailed no later than June 28, 1993, to City of Long Beach, Department of Planning and Building, 333 West Ocean Boulevard, Long Beach, California, 90802 (Attn: Mr. Stuart Sunderland, Code 232SS), telephone (619) 532-3624.

DATED May 7, 1993.

Patrick W. Kelley,
Capt, JAGC, USN, Alternate Federal Register Liaison Officer.

[FR Doc. 93-11272 Filed 5-11-93; 8:45 am]
BILLING CODE 3810-AC-M

DEPARTMENT OF EDUCATION

[CFDA No.: 84.246F]

Braille Training Program; Notice Inviting Applications for New Awards for Fiscal Year (FY) 1993

Purpose of Program: To pay all or part of the cost of training in the use of braille for personnel providing vocational rehabilitation services or educational services to youth and adults who are blind. This program will provide support to establish or continue projects that develop braille training materials and provide in-service or pre-service training in the use of braille and methods of teaching braille.

Eligible Applicants: State agencies and public or nonprofit agencies and organizations, including institutions of higher education.

Supplementary Information: The Braille Training Program is authorized

**Deadline for Transmittal of Applications:** July 16, 1993.

**Application Review:** September 14, 1993.

- **Applications Available:** May 14, 1993.
- **Available Funds:** $861,000.
- **Estimated Range of Awards:** $110,000–$120,000.
- **Estimated Average Size of Awards:** $115,000.
- **Estimated Number of Awards:** 3.

**Statutory Requirements**

The statutory requirements in section 302(a), with the exception of the first sentence, sections 302(b) and (c), and paragraphs (1) and (2) of section 302(g) apply to this program. Section 306 statutory requirements also apply.

**Selection Criteria**

In evaluating applications for grants under this competition, the Secretary uses the EDGAR selection criteria in 34 CFR 75.210.

The regulations in 34 CFR 75.210 provide that the Secretary may award up to 100 points for the selection criteria, including a reserved 15 points. For this competition, the Secretary distributes the additional 15 points as follows:

**Plan of operation:** (34 CFR 75.210(b)(3)). Fifteen points are added to this criterion for a possible total of 30 points.

**For Applications:** Telephone (202) 205–9343. Deaf and hearing impaired individuals may call the Federal Information Relay Service at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern time, Monday through Friday.


**Program Authority:** 29 U.S.C. 774.

Dated: May 6, 1993.

**William L. Smith,**

**Acting Assistant Secretary,** Office of Special Education and Rehabilitative Services.

[FR Doc. 93–11208 Filed 5–11–93; 8:45 am]

**BILLING CODE 4000–01–U**

**CFDA No.: 84.129T**

**Distance Learning Through Telecommunications; Inviting Applications for New Awards for Fiscal Year (FY) 1993**

**Purpose of Program:** To support the formation of regional partnerships between institutions of higher education and other public and private entities for the purpose of developing and implementing in-service training programs, including certificate or degree granting programs concerning vocational rehabilitation services and related services, for vocational rehabilitation professionals through the use of telecommunications.

**Supplementary Information:** The Distance Learning Through Telecommunications Training program is authorized under Title VIII of the Rehabilitation Act Amendments of 1992, Public Law 102–569, enacted October 29, 1992.

**Deadline for Transmittal of Applications:** July 16, 1993.

**Application Review:** September 14, 1993.

- **Applications Available:** May 14, 1993.
- **Available Funds:** $861,000.
- **Estimated Range of Awards:** $250,000–$320,000.
- **Estimated Average Size of Awards:** $285,000.
- **Number of Awards:** Under section 306(a)(1) of the Rehabilitation Act of 1973, as amended, the Secretary shall make a minimum of 3 awards.

**Note:** The Department is not bound by any estimates in this notice.

**Project Period:** Up to 36 months.

**Selection Criteria:**

1. A detailed explanation of how the applicant will use interactive audio, video, and computer technologies between distant locations to provide in-service training programs to the region;
2. A description of how the applicant intends to use and build upon existing telecommunications networks within the region to be served;
3. A copy of all agreements governing the division of functions within the partnership, including an assurance that all States within the region will be served;
4. A copy of a binding commitment entered into between the partnership and each entity that is legally permitted to provide, and from which the partnership is to obtain, the telecommunications services and facilities required for the project, that stipulates that if the partnership receives the grant, the entity will provide those telecommunications services and facilities in the area to be served within a reasonable time and at a charge that is in accordance with State law;
5. A description of the curriculum to be provided, frequency of providing service, and sites of service;
6. A description of the need to purchase or lease computer hardware and software, audio and video equipment, telecommunications terminal equipment, or interactive video equipment;
7. An assurance that the partnership will use not less than 75 percent of the amount of the grant for instructional curriculum development and programming; and
8. A description of the means by which the project will be evaluated.

**Selection Criteria:** In evaluating applications for grants under this program competition, the Secretary uses the EDGAR selection criteria in 34 CFR 75.210.

The regulations in 34 CFR 75.210 provide that the Secretary may award up to 100 points for the selection criteria, including a reserved 15 points. For this competition, the Secretary distributes the additional 15 points as follows:

**Plan of operation** (34 CFR 75.210(b)(3)). Fifteen points are added to this criterion for a possible total of 30 points.

**For Applications:** To request an application, telephone (202) 205–9343. Deaf and hearing impaired individuals may call the Federal Information Relay Service at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern time, Monday through Friday.

**For Further Information Contact:** Beverly Brightly, U.S. Department of Education, 400 Maryland Avenue, SW.,
Parent Information and Training Programs Notice Inviting Applications for New Awards for Fiscal Year (FY) 1993

Purpose of Program: To establish programs to provide training and information to enable individuals with disabilities, and the parents, family members, guardians, advocates, or other authorized representatives of the individuals, to participate more effectively with professionals in meeting the vocational and rehabilitation needs of individuals with disabilities.

Eligible Applicants: Private nonprofit organizations.

Supplementary Information: The Parent Information and Training Programs are authorized under Title VIII, section 803(c), of the Rehabilitation Act Amendments of 1992, Public Law 102-569, enacted October 29, 1992.


Available Funds: $569,000.

Estimated Range of Awards: $85,000–$105,000.

Estimated Average Size of Awards: $95,000.

Estimated Number of Awards: 6.

Note: The Department is not bound by any estimates in this notice.

Project Period: Up to 36 months.

Applicable Regulations: The Education Department General Administrative Regulations (EDGAR) in 34 CFR parts 74, 75, 77, 79, 81, 82, 85, and 86.

General Requirements: Each grantee shall assist individuals with disabilities, and the parents, family members, guardians, advocates, or authorized representatives of the individuals to—

(1) Better understand vocational rehabilitation and independent living programs and services;
(2) Provide follow-up support for transition and employment programs;
(3) Communicate more effectively with transition and rehabilitation personnel and other relevant professionals;
(4) Provide support in the development of the individualized written rehabilitation program;
(5) Provide support and expertise in obtaining information about rehabilitation and independent living programs, services, and resources that are appropriate; and
(6) Understand the provisions of the Rehabilitation Act, particularly provisions relating to employment, supported employment, and independent living.

The Secretary distributes grants under this competition geographically to the greatest extent possible throughout all States, and targets awards to individuals with disabilities and the parents, family members, guardians, advocates, or authorized representatives of these individuals, in both urban and rural areas or on a State or regional basis.

Each application submitted under this competition must provide assurances that the grantee—

(1) Has a membership that represents the interests of individuals with disabilities;
(2) Will consult with appropriate agencies that serve or assist individuals with disabilities, and the parents, family members, guardians, advocates, or authorized representatives of the individuals, located in the jurisdiction served by the program; and
(3) Is governed by a board of directors or has established a governing committee, which includes professionals in the field of vocational rehabilitation and on which a majority of members are individuals with disabilities or the parents, family members, guardians, advocates, or authorized representatives of the individuals, or have a membership that represents the interests of individuals with disabilities. The board of directors or governing committee shall meet at least once in each calendar quarter to review the training and information program.

Each application submitted under this competition must also demonstrate the capacity and expertise of the organization to—

(1) Coordinate and work closely with the parent training and information centers established under section 631 of the Individuals with Disabilities Education Act (20 U.S.C. 1431); and
(2) Effectively conduct the training and information activities authorized under this program.

Each applicant for a grant under this competition shall include in its application a description of the manner in which it will address the needs of individuals with disabilities from minority backgrounds.

Each grantee under this competition shall advise recipients of services under its project, or, as appropriate, the parents, family members, guardians, advocates, or authorized representatives of those individuals, of the availability and purposes of the State's Client Assistance Program, including information on seeking assistance from that program.

Selection Criteria: In evaluating applications for grants under this competition, the Secretary uses the EDGAR selection criteria in 34 CFR 75.210.

The regulations in 34 CFR 75.210 provide that the Secretary may award up to 100 points for the selection criteria, including a reserved 15 points. For this competition, the Secretary distributes the additional 15 points as follows:

Plan of operation (34 CFR 75.210(b)(3)). Fifteen points are added to this criterion for a possible total of 30 points.

For Applications: To request an application, telephone (202) 205–9343. Deaf and hearing impaired individuals may call the Federal Information Relay Service at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern time, Monday through Friday.

For Further Information Contact: Beverly Brightly, U.S. Department of Education, 400 Maryland Avenue, SW., Room 3322, Switzer Building, Washington, DC 20202–2649.

Telephone: (202) 205–9561.


Dated: May 6, 1993.

William L. Smith,
Acting Assistant Secretary, Office of Special Education and Rehabilitative Services.

[FR Doc. 93–11206 Filed 5–11–93; 8:45 am]

DEPARTMENT OF ENERGY

Financial Assistance Award; Intent to Award a Cooperative Agreement to Western Interstate Energy Board

AGENCY: Department of Energy.

ACTION: Notice of noncompetitive financial assistance award.

SUMMARY: The Department of Energy (DOE) announces that pursuant to 10 CFR 600.6(a)(5), it is making a discretionary financial assistance award based on the criteria set forth at 10 CFR 600.7(b)(2)(i) (A), (B) and (D) under 10 CFR 600.6.
Cooperative Agreement Number DE–FC01–93WR0282 to the Western Interstate Energy Board to provide a forum between western state representatives and DOE to facilitate the planning and implementation of the transportation system for the disposal of high level nuclear waste and spent fuel under the Nuclear Waste Policy Act of 1982, as amended.

SCOPE: DOE intends to award a five year cooperative agreement at a total projected cost of $725,000 to obtain state participation in regional activities, including collection and analysis of data to be included in nuclear waste transportation reports, analysis of state and regional issues, and meetings to inform state and local officials of the findings of transportation studies. The work also involves developing options for issue resolution or mitigation which will be considered by DOE for implementation in DOE has determined that the circumstances of the proposed award meet the criteria of the Nuclear Waste Policy Act of 1982.

Federal Energy Regulatory Commission
[Docket Nos. ER93–604–000, et al.]
Pennsylvania Power & Light Co., et al;
Electric Rate, Small Power Production, and Interlocking Directorate Filings
May 6, 1993.
Take notice that the following filings have been made with the Commission:

1. Pennsylvania Power & Light Company
[Docket No. ER93–604–000]
Take notice that on April 29, 1993, Pennsylvania Power & Light Company (PP&L) tendered for filing a Supplemental Agreement dated April 13, 1993 to the Interconnection Agreement between PP&L and Public Service Electric and Gas Company (PSE&G). The Supplemental Agreement would allow each company to reimburse the other company for the actual cost of work on interconnection facilities by making either a lump sum payment or periodic progress payments when reimbursement is required by the Agreement. The Agreement currently provides only a carrying charge formula for reimbursements.

PP&L has requested an effective date of June 28, 1993 for the Agreement, which is 60 days from the date of filing. PP&L is not requesting any notice period waivers.

PP&L states that a copy of its filing was served on PSE&G, the Pennsylvania Public Utility Commission, and the New Jersey Board of Regulatory Commissioners.

Comment date: May 20, 1993, in accordance with Standard Paragraph E at the end of this notice.

[Docket No. ER93–605–000]
Take notice that on April 29, 1993, Potomac Electric Power Company and Virginia Power submitted for filing Revision No. 1 to Schedule 3 of their Facilities Agreement dated April 1, 1965 between Virginia Electric and Power Company and Potomac Electric Power Company, providing for relocation of the Virginia Power terminus of the Burches Hill-Ox 500 kV interconnection between the parties from Ox Substation to Possum Point Station.

Comment date: May 20, 1993, in accordance with Standard Paragraph E at the end of this notice.

3. Consolidated Edison Company of New York, Inc.
[Docket No. ER93–618–000]
Take notice that on April 30, 1993, Consolidated Edison Company of New York, Inc. (Con Edison) tendered for filing a Supplement to its Rate Schedule FERC No. 78, an agreement to provide transmission service for the Power Authority of the State of New York (the Authority). The Supplement provides for an increase in the monthly transmission charge from $1.02 to $1.06 per kilowatt per month for transmission of power and energy sold by the Authority to the municipal distribution agencies of Nassau and Suffolk Counties, thus increasing annual revenues under the Rate Schedule by a total of $3,611.04. Con Edison has requested that the increase take effect on July 1, 1993.

Con Edison states that a copy of this filing has been served by mail upon the Authority.

Comment date: June 7, 1993, in accordance with Standard Paragraph E at the end of this notice.

4. PacifiCorp
[Docket No. ER93–629–000]
May 6, 1993.
Take notice that PacifiCorp on May 3, 1993, tendered for filing in accordance with 18 CFR part 35 of the Commission’s Rules and Regulations, various agreements that amend or supplement the Intertie Agreement between PacifiCorp and Bonneville Power Administration (Bonneville), PacifiCorp’s Rate Schedule FERC No. 327.

PacifiCorp requests a waiver of prior notice and that effective dates for the various agreements be assigned that correspond with the dates shown on the agreements.

Copies of this filing were supplied to Bonneville and the Public Utility Commission of Oregon.

Comment date: May 20, 1993, in accordance with Standard Paragraph E at the end of this notice.

5. Consolidated Edison Company of New York, Inc.
[Docket No. ER93–620–000]
Take notice that on April 30, 1993, Consolidated Edison Company of New York, Inc. (Con Edison) tendered for filing a Supplement to its Rate Schedule FERC No. 60, an agreement to provide transmission service for the Power Authority of the State of New York (the Authority). The Supplement provides for an increase in the monthly transmission charge from $1.02 to $1.06 per kilowatt per month for transmission
of power and energy sold by the Authority to Brookhaven National Laboratory, thus increasing annual revenues under the Rate Schedule by a total of $17,807.20. Con Edison has requested that the increase take effect on July 1, 1993.

Con Edison states that a copy of this filing has been served by mail upon the Authority.

Comment date: May 20, 1993, in accordance with Standard Paragraph E at the end of this notice.

6. Turlock Irrigation District v. Pacific Gas & Electric Company

[Docket No. EL93–37–000]

Take notice that on April 29, 1993, Turlock Irrigation District tendered for filing a complaint and request for investigation and reduction of reserved transmission service rates and petition for declaratory order and exemption from fees. The complaint is against Pacific Gas & Electric Company.

Comment date: June 7, 1993, in accordance with Standard Paragraph E at the end of this notice.

7. City of Cleveland, Ohio v. Cleveland Electric Illuminating Company

[Docket No. EL93–35–000]

Take notice that on April 22, 1993, the City of Cleveland Ohio tendered for filing a complaint for order directing Cleveland Electric Illuminating Company to establish physical interconnections, a motion for summary disposition and a complaint for refunds of over-collections.

Comment date: June 7, 1993, in accordance with Standard Paragraph E at the end of this notice.

8. Florida Power Corporation

[Docket No. ER93–627–000]

Take notice that on April 30, 1993, Florida Power Corporation (Florida Power) tendered for filing revisions to the capacity charges, reservation fees and energy adders for various interchange services provided by Florida Power pursuant to interchange contracts as follows:

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<thead>
<tr>
<th>Rate schedule</th>
<th>Customer</th>
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<tr>
<td>80</td>
<td>Tampa Electric Company.</td>
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<td>81</td>
<td>Florida Power &amp; Light Company.</td>
</tr>
<tr>
<td>82</td>
<td>City of Homestead</td>
</tr>
<tr>
<td>86</td>
<td>Orlando Utilities Commission.</td>
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<tr>
<td>88</td>
<td>Gainesville Regional Utility.</td>
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<tr>
<td>90</td>
<td>Sabing Utility Commission.</td>
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<td>91</td>
<td>Jacksonville Electric Authority.</td>
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<tr>
<td>92</td>
<td>City of Lakeland</td>
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<tr>
<td>93</td>
<td>City of Vero Beach</td>
</tr>
<tr>
<td>94</td>
<td>Kissimmee Utility Authority.</td>
</tr>
</tbody>
</table>

The interchange services which are affected by these revisions are (1) Service Schedule A—Emergency, (2) Service Schedule B—Short Term Firm, (3) Service Schedule D—Firm, (4) Service Schedule F—Assured Capacity and Energy, (5) Service Schedule G—Backup Service, (6) Service Schedule H—Resale Service, (7) Service Schedule RE—Replacement Energy, and (8) Contract For Assured Capacity and Energy With Florida Power & Light Company. Florida Power states that the revised capacity charges, reservation fees, and energy adders were developed using the same methodology as approved in its last cost update filing.

Florida Power requests that the amended revised capacity charges, reservation fees and energy adder be made effective on May 1, 1993 and remain effective through April 30, 1994. Florida Power requests waiver of the Commission's sixty-day notice requirement. If waiver is denied, Florida Power requests that the filing be made effective July 1, 1993.

Florida Power also requests confirmation that transactions with Oglethorpe Power Corporation under Service Schedule D of rate schedule FERC No. 139 and with the City of Vero Beach under Service Schedule D of Rate Schedule FERC No. 141 need not be preceded by a timely filing and cost support since the service schedules provide for caps on the charge and the cost support is included in this filing.

Comment date: May 20, 1993, in accordance with Standard Paragraph E at the end of this notice.

9. Public Service Company of Colorado

[Docket No. ER93–580–000]

Take notice that on April 22, 1993, Public Service Company of Colorado (Public Service) filed with the Commission a rate schedule governing peaking power and energy sales to the Platte River Power Authority (PRPA). Public Service submits that the service being provided to PRPA under this agreement is the same as the service being provided to WestPlains Energy, pursuant to Supplement No. 3 to Rate Schedule FERC No. 59. The rates for the peaking power and energy sales under the proposed rate are the same as those for the sale to WestPlains Energy. The rates for service under the proposed agreement generate revenues of $142,080 plus applicable energy revenues. Public Service requests that the rate schedule be effective July 1, 1993.

Copies of the filing have been served on PRPA, the Colorado Public Utilities Commission, and the Colorado Office of Consumer Counsel.

Comment date: May 21, 1993, in accordance with Standard Paragraph E at the end of this notice.

10. Public Service Electric and Gas Company

[Docket No. ER93–586–000]

Take notice that on April 26, 1993, Public Service Electric and Gas Company (PSE&G) tendered for filing an initial Rate Schedule to provide interruptible transmission service to the Long Island Lighting Company (LILCO). The service provides for the delivery of non-firm electric power and associated energy transactions between any investor-owned utility interconnected with the PSE&G system and the Consolidated Edison Company. At the behest of the customer, PSE&G requests a waiver of the Notice Requirements of § 35.3(a) of the Commission's regulations so that the Rate Schedule can be made effective within twenty four (24) hours of the date of this filing.

Comment date: May 21, 1993, in accordance with Standard Paragraph E at the end of this notice.

11. Massachusetts Electric Company and New England Power Company

[Docket No. ER93–628–000]

Take notice that Massachusetts Electric Company (MECo) and New England Power Company (NEP), on May 3, 1993, jointly tendered for filing MECo’s Letter Agreement for its interconnection with Appleton Hydro Trust and NEP’s transmission service agreement for wheeling the output of the Appleton Hydro Trust unit to the Croton [Mass.] Electric Light Department.

Comment date: May 20, 1993, in accordance with Standard Paragraph E at the end of this notice.
12. West Penn Power Company
[Docket No. ER93-515-000]
Take notice that West Penn Power Company, on April 30, 1993, tendered for filing a Second Supplement to proposed changes in its FERC Electric Tariff, First Revised Volume No. 1. The Second Supplement is filed to supply additional information as requested by the Commission's staff. The proposed effective date for the increased rates is June 15, 1993.
Copies of the filing were served upon the jurisdictional customers and the Pennsylvania Public Utility Commission.
Comment date: May 20, 1993, in accordance with Standard Paragraph E at the end of this notice.

13. The Cincinnati Gas & Electric Company
[Docket No. ER93-600-000]
Take notice that The Cincinnati Gas and Electric Company (CG&E) on April 29, 1993, tendered for filing a Short Term Agreement (Agreement) with the City of Hamilton, Ohio. During the term of the Agreement, Hamilton, may reserve up to but not exceeding 30 MW of Service. Service shall be either the provision of (i) short term power and associated energy to be generated by CG&E, or (ii) short term point-to-point transmission service for power and energy to be purchased by Hamilton from a specific third-party source, or any combination thereof not exceeding 30 MW in total.
The reason stated by CG&E for the Agreement is to meet the request and special needs of Hamilton, for the period June 1, 1993 through September 30, 1993.
Copies of the filing were served upon the City of Hamilton, Ohio and the Public Utilities Commission of Ohio.
Comment date: May 20, 1993, in accordance with Standard Paragraph E at the end of this notice.

14. Tampa Electric Company
[Docket No. ER93-601-000]
Take notice that on April 29, 1993, Tampa Electric Company (Tampa Electric) tendered for filing cost support schedules showing recalculation of the Committed Capacity and Short-Term Power Transmission Service rates under Tampa Electric's agreements to provide qualifying facility transmission service for Mulberry Phosphates, Inc. (Mulberry) and Seminole Fertilizer Corporation (Seminole Fertilizer). Tampa Electric states that the recalculated transmission service rates are based on 1992 Form No. 1 data.
Tampa Electric proposes that the recalculated transmission service rates be made effective as of May 1, 1993, and therefore requests waiver of the Commission's notice requirements.
Copies of the filing have been served on Mulberry, Seminole Fertilizer, and the Florida Public Service Commission.
Comment date: May 20, 1993, in accordance with Standard Paragraph E at the end of this notice.

15. Niagara Mohawk Power Corporation
[Docket No. ER93-603-000]
Take notice that on April 29, 1993, Niagara Mohawk Power Corporation (Niagara Mohawk) tendered for filing with the Commission a signed Service Agreement between Niagara Mohawk and the Village of Bergen, New York (Bergen) for sales of system capacity and/or energy under Niagara Mohawk's proposed Power Sales Tariff in Docket No. ER93-313-000. Niagara Mohawk submitted its Power Sales Tariff for filing on January 11, 1993 and requested an effective date of March 13, 1993 for the Tariff. In its April 29, 1993 filing of the proposed Service Agreement with Bergen, Niagara Mohawk requests an effective date for this Service Agreement of April 1, 1993. Actual transactions hereunder are not expected before June 1, 1993.
A copy of this filing has been served upon Bergen and the New York State Public Service Commission.
Comment date: May 20, 1993, in accordance with Standard Paragraph E at the end of this notice.

[Docket No. ER93-619-000]
Take notice that on April 30, 1993, Consolidated Edison Company of New York, Inc. (Con Edison) tendered for filing a Supplement to its Rate Schedule FERC No. 6 an agreement to provide transmission service for the Power Authority of the State of New York (the Authority). The Supplement provides for an increase in the monthly transmission charge from $1.02 to $1.06 per kilowatt per month for transmission of power and energy sold by the Authority to Grumman Corporation, thus increasing annual revenues under the Rate Schedule by a total of $5,059.20. Con Edison has requested that the increase take effect on July 1, 1993.
Con Edison states that a copy of this filing has been served by mail upon the Authority.
Comment date: May 20, 1993, in accordance with Standard Paragraph E at the end of this notice.

17. Niagara Mohawk Power Corporation
[Docket No. ER93-602-000]
Take notice that on April 29, 1993, Niagara Mohawk Power Corporation (Niagara Mohawk) tendered for filing with the Commission a signed Service Agreement between Niagara Mohawk and Consolidated Edison (ConEd) for sales of system capacity and/or energy or resource capacity and/or energy under Niagara Mohawk's proposed Power Sales Tariff in Docket No. ER93-313-000. Niagara Mohawk filed its Power Sales Tariff on January 11, 1993 and requested an effective date of March 13, 1993 for the Tariff. In its April 29, 1993 filing of the proposed Service Agreement with Con Edison, Niagara Mohawk requests an effective date for this Service Agreement of April 20, 1993, the date of the Con Ed signature. A copy of this filing has been served upon Consolidated Edison and the New York State Public Service Commission.
Comment date: May 20, 1993, in accordance with Standard Paragraph E at the end of this notice.

18. Montaup Electric Company
[Docket No. ER93-624-000]
Take notice that on April 30, 1993, Montaup Electric Company filed (1) a firm transmission agreement between itself and MASSPOWER, a Massachusetts General Partnership, (2) an amendment to that agreement and (3) a non-firm transmission agreement between Montaup and Commonwealth Electric Company. Montaup requests that the filing be allowed to become effective as of the commercial operation date, which is expected to occur on or about July 1, 1993.
Comment date: May 20, 1993, in accordance with Standard Paragraph E at the end of this notice.

Standard Paragraphs
E. Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions or protests should be filed on or before the comment date. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding.
Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell, Secretary.

[FR Doc. 93–11280 Filed 5–11–93; 8:45 am]

BILING CODE 6717–01–M

[Docket Nos. CP93–320–000, et al.]

ANR Pipeline Co., et al.; Natural Gas Certificate Filings

May 6, 1993.

Take notice that the following filings have been made with the Commission:

1. ANR Pipeline Company

[Docket No. CP93–320–000]

Take notice that on April 29, 1993, ANR Pipeline Company (ANR), 500 Renaissance Center, Detroit, Michigan 48243, filed in Docket No. CP93–320–000 an application pursuant to section 7(b) of the Natural Gas Act for permission and approval to abandon a natural gas exchange service with Panhandle Eastern Pipe Line Company (Panhandle), all as more fully set forth in the application on file with the Commission and open to public inspection.

ANR (formerly Michigan Wisconsin Pipe Line Company) states that by Commission order issued December 9, 1977, as amended January 4, 1978, in Docket No. CP78–8, et al., (1 FERC ¶ 61,232 and 2 FERC ¶ 61,009) ANR and Panhandle were authorized to exchange up to 100,000 Mcf of natural gas per day, on a best efforts basis, in emergency situations, at a point of interconnection of their facilities in Defiance County, Ohio. Such exchange is made in accordance with a Letter Agreement between ANR and Panhandle dated August 19, 1977 which is currently designated as Rate Schedule X–131 under Original Volume No. 2 of ANR’s FERC Gas Tariff.

ANR states that the Letter Agreement was to remain in effect until terminated by either party upon thirty days’ written notice to the other. In a letter dated October 10, 1992, Panhandle requested termination of the agreement. Accordingly, ANR requests permission to abandon Rate Schedule X–131 under Original Volume No. 2 of ANR’s FERC Gas Tariff. No facilities are proposed to be abandoned.

Comment date: May 27, 1993, in accordance with Standard Paragraph F at the end of this notice.

2. Eastern American Energy Corporation

[Docket No. CP93–326–000]

Take notice that on May 3, 1993, Eastern American Energy Corporation (Eastern American), 501 56th Street, Charleston, West Virginia 25304, filed a petition in Docket No. CP93–326–000, requesting that the Commission declare that facilities to be acquired by Eastern American from Columbia Gas Transmission Corporation (Columbia Gas) are gathering facilities exempt from the Commission’s Regulations pursuant to section 1(b) of the Natural Gas Act (NGA), all as more fully set forth in the petition which is on file with the Commission and open to public inspection.

Eastern American applies for a declaratory order from the Commission confirming that, upon acquisition from Columbia Gas, Line 2, a 56-mile portion of a twelve-inch and eight-inch pipeline and appurtenances located in several counties in West Virginia, would be exempt from the Commission’s jurisdiction under section 1(b) of the Natural Gas Act. In support of its claim that the subject facilities are gathering facilities, Eastern American points out that the Commission determines whether pipelines are nonjurisdictional gathering facilities based upon application of the “primary function test” to the operations and physical characteristics of the facilities. It is indicated that the Commission has explained the factors to be considered in determining the primary function of the facilities in Farmland Industries, Inc., 23 FERC ¶ 61,063 (1983), as modified by a series of subsequent orders. Eastern American states that the facilities to be acquired from Columbia Gas meet all of the gathering criteria as determined by Farmland and later orders.

Eastern American also indicates that, upon its acquisition of the facilities from Columbia Gas, it has agreed to provide certain minimal transportation services to two parties for which Columbia Gas presently transports gas. Eastern American has agreed to continue to provide service presently provided by Columbia Gas to Mountaineer Gas Company (Mountaineer), a West Virginia public utility, so that Mountaineer may continue to serve several individual farm tap customers. Eastern American has also agreed to satisfy Columbia Gas’ limited transportation obligations to Quaker State Oil Refining Company until March 31, 1994, when such obligations would end, if Eastern American acquires the facilities before that date. Eastern American asserts that neither of these transportation services in any way modifies the nonjurisdictional status of Line 2.

Eastern American has filed an application in Docket No. CP93–328–000 to abandon, by sale to Eastern American, its Line 2 and appurtenant facilities.

Comment date: May 27, 1993, in accordance with Standard Paragraph F at the end of this notice.

3. Columbia Gas Transmission Corporation

[Docket No. CP93–328–000]

Take notice that on May 3, 1993, Columbia Gas Transmission Corporation (Columbia Gas), Post Office Box 1273, Charleston, West Virginia 25325, filed in Docket No. CP93–328–000 an application pursuant to section 7(b) of the Natural Gas Act for authorization to abandon facilities and points of delivery to Mountaineer Gas Company (Mountaineer), all as more fully set forth in the application which is on file with the Commission and open to public inspection.

Columbia Gas proposes to implement an agreement dated January 18, 1993, in which Columbia Gas has agreed to sell to Eastern American Energy Corporation (Eastern American) certain jurisdictional and nonjurisdictional facilities located in various counties in West Virginia. It is stated that the jurisdictional facilities include approximately 56 miles of Columbia Gas’ Line 2, consisting primarily of 12-inch pipeline and appurtenances. Columbia Gas also states that the nonjurisdictional facilities include 6.9 miles of gathering lines designated as Lines 18494 and 18497, along with 59 meters used to measure gas delivered into Line 2. It is also stated that currently the jurisdictional facilities are also used to (1) provide mainline gas service to Mountaineer Gas Company for ten residential customers, (2) provide a firm transportation service for Quaker State Corporation (Quaker State) and (3) provide interruptible transportation service for various shippers. In its application, Columbia Gas proposes to abandon by sale to Eastern American the jurisdictional facilities and abandon the ten points of delivery to Mountaineer. It is indicated that the jurisdictional facilities were authorized by a certificate issued to Columbia Gas’ predecessor, Manufactures Light and Heat Company, in Docket No. G–593.

Columbia Gas states that the operation of its system has changes in such a manner that Columbia Gas’ T-System, which is located east of Line 2, provides the majority of the transport service to southwestern Pennsylvania originally.
provided by Line 2. Columbia Gas concludes that Line 2 is no longer an integral part of Columbia Gas’ mainline transmission system.

Columbia Gas states that the agreement provides that Eastern American will pay Columbia Gas $2,137,000 less one-half of the actual revenues paid by Eastern American under Meter No. 631235 for the transportation of natural gas owned by Eastern American through Line 2 from February 1, 1993, to the date of the transfer of properties.

It is indicated that Eastern American intends to use Line 2 to gather and transport its gas for itself and its affiliates. It is stated that, in order to provide continued service to the points of delivery to Mountaineer, Columbia Gas, Eastern American, and Mountaineer have entered into an agreement whereby Eastern American would provide service to Mountaineer. Columbia Gas also states that Columbia Gas and Eastern American have entered into an agreement dated April 29, 1993, whereby Eastern American would provide any alternative service necessary to satisfy Columbia Gas’ firm transportation obligation to Quaker State in the event abandonment authorization is received and the facilities are transferred prior to the March 31, 1994, the expiration date of Quaker State's firm transportation contract with Columbia Gas.

Comment date: May 27, 1993, in accordance with the first subparagraph of Standard Paragraph F at the end of the notice.

4. Arkla Energy Resources Company and ANR Pipeline Company

[Docket No. CP93–317–000]

Take notice that on April 27, 1993, Arkla Energy Resources Company (AER) 525 Milam Street, Shreveport, Louisiana 71101 and ANR Pipeline Company (ANR), 500 Renaissance Center, Detroit, Michigan 48243, filed in Docket No. CP93–317–000, a joint application pursuant to section 7(b) of the Natural Gas Act for permission and approval to abandon a transportation and exchange service provided pursuant to AER’s Rate Schedule XE–44 and ANR’s Rate Schedule X–45, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

It is stated that by orders issued December 18, 1975, in Docket No. CP76–10–000 (AER) and January 15, 1979, in Docket No. CP78–25–000 (ANR), AER, successor-in-interest to Arkansas Louisiana Gas Company and Arkla Energy Resources, a division of Arkla, Inc., and ANR, successor-in-interest to Michigan Wisconsin Pipeline Company were authorized to exchange natural gas pursuant to an agreement dated May 8, 1975. The agreement, it is said, provided for the exchange of natural gas delivered by AER to ANR at a point of interconnection in Guster County, Oklahoma and delivered by ANR to AER at points of interconnection in Caddo County, Oklahoma or Grady County, Oklahoma.

AER and ANR state that this arrangement is no longer necessary or beneficial to the parties and has been terminated pursuant to mutual written agreement of the parties.

No facilities are proposed to be abandoned herein.

Comment date: May 27, 1993, in accordance with the first subparagraph of Standard Paragraph F at the end of the notice.

Standard Paragraphs

F. Any person desiring to be heard or make any protest with reference to said filing shall be served with a copy of the application and the rules and regulations of the commission, on or before the date specified for the filing of protests, as set forth below.

Take further notice that, pursuant to the authority contained in and subject to jurisdiction conferred upon the Federal Energy Regulatory Commission by sections 7 and 15 of the Natural Gas Act and the Commission’s Rules of Practice and Procedure, a hearing will be held without further notice before the Commission or its designee on the filing of a protest if notice is served within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity. If a motion for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for the applicant to appear or be represented at the hearing.

Lois D. Cashell,
Secretary.

[FR Doc. 93–11279 Filed 5–11–93; 8:45 am]
BILING CODE 8117–01–M

[Docket No. JD93–07805T Texas–136]

Texas; NGPA Notice of Determination by Jurisdictional Agency Designating Tight Formation

May 6, 1993.

Take notice that on May 3, 1993, the Railroad Commission of Texas (Texas) submitted the above-referenced notice of determination pursuant to § 271.703(c)(3) of the Commission’s regulations, that a portion of the Austin Chalk Formation, underlying Fayette County, Texas, qualifies as a tight formation under section 107(b) of the Natural Gas Policy Act of 1978. The designated area is in Railroad Commission District No. 3 and is described on the attached appendix.

The notice of determination also contains Texas’ findings that the referenced portion of the Austin Chalk Formation meets the requirements of the Commission’s regulations set forth in 18 CFR part 271.

The application for determination is available for inspection, except for material which is confidential under 18 CFR 275.206, at the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426. Persons objecting to the determination may file a protest, in accordance with 18 CFR 275.203 and 275.204, within 20 days after the date this notice is issued by the Commission.

Lois D. Cashell,
Secretary.

Appendix

The recommended area covers approximately 48,500 Acres and includes all or portions of the following surveys:

Blair, J. A–138
Brown, S.P. A–22
Carson, W.H. A–28
Cartwright, J.H. A–29
Castleman, J. A–31
Castleman, S. A–32
Chriswell, L. A–152
Cottle, S. A–150
Darling, S. A–161
Dibble, Henry A–163
Dickson, A. A–162
Eastland, N. A–173
Eastland, W. A–172
Eblin, John A–42
Fayette Co. School Land A–183
Fayette Co. School Land A–184
Green, James A–189
Green, James A–190
Keller, F. A–220
AES San Nicolas, S.A.; Application for Commission Determination of Exempt Wholesale Generator Status

May 6, 1993.


AES SN intends to operate an electric generating facility with a net power production capacity of approximately 650 MW. The facility, located in San Nicolas, Argentina, is owned by Central Termica San Nicolas, S.A. All of the facility's electric power net of the facility's operating electric power will be purchased at wholesale by one or more public utilities, with the exception of possible future retail sales in Argentina.

Any person desiring to be heard concerning the application for exempt wholesale generator status should file a motion to intervene or comments with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with §§ 385.211 and 385.214 of the Commission's Rules of Practice and Procedure. The Commission will limit its consideration of comments to those that concern the adequacy or accuracy of the application. All such motions and comments should be filed on or before May 26, 1993 and must be served on AES SN. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Lols D. Cashell,
Secretary.

[Citizens filed certain information as required by ordering paragraph (M) of the Commission's August 6, 1989 order in this proceeding, 48 FERC ¶ 61.210 (1989). Copies of Citizens' informational filing are on file with the Commission and are available for public inspection.

Lols D. Cashell,
Secretary.

[FR Doc. 93-11275 Filed 5-11-93; 8:45 am]
BILLING CODE 8717-01-M

[Consolidated Edison Co. of New York, Inc.; Filing

May 6, 1993.

Take notice that on April 30, 1993, Consolidated Edison Company of New York, Inc. (Con Edison) tendered for filing a Supplement to its Rate Schedule FERC No. 78, an agreement to provide transmission service for the Power Authority of the State of New York (the Authority). The Supplement provides for an increase in the monthly transmission charge from $1.02 to $1.96 per kilowatt per month for transmission of power and energy sold by the Authority to the municipal distribution agencies of Nassau and Suffolk Counties, thus increasing annual revenues under the Rate Schedule by a total of $3,611.04. Con Edison has requested that the increase take effect on July 1, 1993.

Con Edison states that a copy of this filing has been served by mail upon the Authority.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure. The Commission will consider its decision concerning the adequacy of the application. All such motions and comments should be filed on or before May 20, 1993 and must be served upon the Authority. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Lols D. Cashell,
Secretary.

[FR Doc. 93-11205 Filed 5-11-93; 8:45 am]
BILLING CODE 8717-01-M
[Docket No. CP93-330-000]

K N Wattenberg Transmission Limited Liability Co.; Request Under Blanket Authorization

May 7, 1993.

Take notice that on May 4, 1993, K N Wattenberg Transmission Limited Liability Company (K N Wattenberg), P.O. Box 281304, Lakewood, Colorado 80228, filed in Docket No. CP93-330-000 a request pursuant to §§157.205(b) and 157.212 of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205(b) and 157.212) for authorization to install a new delivery point for North American Resources Company (NARCO) in Weld County, Colorado, under K N Wattenberg's blanket certificate issued in Docket No. CP92-203-000. This delivery point would be used as a deliver point under an existing transportation agreement with NARCO, all as more fully set forth in the request on file with the Commission and open to public inspection.

K N Wattenberg states that the peak day delivery at the proposed delivery point would be 10,000 Mcf. The cost of the facilities is estimated to be $75,000, and K N Wattenberg would be reimbursed for the actual cost of the facilities by K N Front Range Gathering Company. It is further stated that all volumes of gas delivered to NARCO at the proposed delivery point will be within NARCO's existing entitlements.

Any person or the Commission's staff may, within 45 days after issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and pursuant to §157.205 of the Regulations under the Natural Gas Act (18 CFR 157.205) a protest to the request. If no protest is filed within the time allowed therefor, the proposed activity shall be deemed to be authorized effective the day after the time allowed for filing a protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to section 7 of the Natural Gas Act.

Lois D. Cashell,
Secretary.
[FR Doc. 93-11182 Filed 5-11-93; 8:45 am]
BILLING CODE 6717-01-M

[Project No. 9706-000]

Mechanicville Corp.; Effective Date of Withdrawal of License Application, Amendments, Comments, and All Other Pleadings, Correspondence, and Information In This Proceeding

May 6, 1993.

On December 23, 1985, Mechanicville Corporation (Mechanicville), filed a license application for the Mechanicville Project No. 9706, located on the Hudson River in Saratoga and Rensselaer Counties in New York. On March 30, 1993, Mechanicville filed a notice of withdrawal of its license application, all amendments thereto, including its final amendment, its statement of competing applicant, and all other pleadings, correspondence and supplemental information in this proceeding.

No one filed a motion in opposition to the notice of withdrawal, and the Commission took no action to disallow the withdrawal. Accordingly, pursuant to Rule 216 of the Commission's Rules of Practice and Procedure, the withdrawal became effective on April 14, 1993.

Lois D. Cashell,
Secretary.
[FR Doc. 93-11182 Filed 5-11-93; 8:45 am]
BILLING CODE 6717-01-M

[Project No. ER90-527-007]

Northern States Power Co.; Filing

May 7, 1993.

Take notice that on February 22, 1993, Northern States Power Company (NSP) tendered for filing its compliance filing pursuant to the Commission's order issued on February 6, 1992.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 381, 211 and 18 CFR 385, 214). All such motions or protests should be filed on or before May 17, 1993. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,
Secretary.
[FR Doc. 93-11274 Filed 5-11-93; 8:45 am]
BILLING CODE 6717-01-M

[Project No. RP93-5-000]

Northwest Pipeline Corp.; Informal Settlement Conference

May 6, 1993.

Take notice that an informal settlement conference will be convened in this proceeding on Wednesday, May 19, 1993 at the offices of the Federal Energy Regulatory Commission, 810 First Street, N.E., Washington, DC 20426, for the purpose of exploring the possible settlement of the issues in this proceeding.

Any party, as defined by 18 CFR 385.102(c), or any participant as defined by 18 CFR 385.102(b), is invited to attend. Persons wishing to become a party must move to intervene and receive intervenor status pursuant to the Commission's regulations (18 CFR 385.214).

For additional information, contact Marc G. Denkinger (202) 208-2215 or Kathleen M. Dias (202) 208-0524.

Lois D. Cashell,
Secretary.
[FR Doc. 93-11185 Filed 5-11-93; 8:45 am]
BILLING CODE 6717-01-M

[Project No. ER93-605-000]

Potomac Electric Power Company, et al.; Filing

May 6, 1993.

Take notice that on April 29, 1993, Potomac Electric Power Company and Virginia Power submitted for filing Revision No. 1 to Schedule 3 of their Facilities Agreement dated April 1, 1965 Between Virginia Electric and Power Company and Potomac Electric Power Company, providing for relocation of the Virginia Power terminus of the Burches Hill-Ox 500 kV interconnection between the parties from Ox Substation to Possum Point Station.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 381, 211 and 18 CFR 385, 214). All such motions or protests should be filed on or before May 20, 1993. Protests will be considered by the Commission in
Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,
Secretary.

[FR Doc. 93-11204 Filed 5-11-93; 8:45 am]
BILLING CODE 6717-01-M

[Docket Nos. RP91-203-000 and RP92-132-000]

Tennessee Gas Pipeline Co.; Informal Conference

May 7, 1993.

Take notice that an informal conference in regard to PCBs will be convened in this proceeding on May 20, 1993, at 10 a.m., at the offices of the Federal Energy Regulatory Commission, 810 First Street, NE, Washington, DC as a follow-up to the PCB conference convened on May 8, 1993.

Any party, as defined by 18 CFR 351.102(c), or any participant, as defined by 18 CFR 351.102(b), is invited to attend. Persons wishing to become a party must move to intervene and receive intervener status pursuant to the Commission's regulations (16 CFR 351.214).

For additional information, contact Donald Williams at (202) 208-0743 or Dennis H. Melvin at (202) 208-0042.

Lois D. Cashell,
Secretary.

[FR Doc. 93-11277 Filed 5-11-93; 8:45 am]
BILLING CODE 6717-01-M

[Project No. 1584 Wisconsin]
Wisconsin River Power Co.; Intent to File an Application for a New License

May 7, 1993.

Take notice that Wisconsin River Power Company, the existing licensee for the Petenwell/Castle Rock Hydroelectric Project No. 1984, filed a timely notice of intent to file an application for a new license, pursuant to 18 CFR 16.6 of the Commission's Regulations. The original license for Project No. 1984 was issued effective February 1, 1948, and expires January 31, 1998.

The project is located on the Wisconsin River in Adams, Juneau and Wood Counties, Wisconsin. The principal works of the Petenwell/Castle Rock Project include all of the dams, reservoirs powerhouse, substations and appurtenant facilities associated with the following two developments: Petenwell with an installed capacity of 20,000 kW and Castle Rock with an installed capacity of 15,000 kW for a total installed capacity of 35,000 kW.

Pursuant to 18 CFR 16.7, the licensee is required henceforth to make available certain information to the public. This information is now available from the licensee at 810 High Street, Wisconsin Rapids, WI 54494.

Pursuant to 18 CFR 16.8, 16.9 and 16.10, each application for a new license and any competing license applications must be filed with the Commission at least 24 months prior to the expiration of the existing license.

All applications for license for this project must be filed by January 31, 1996.

Lois D. Cashell,
Secretary.

[FR Doc. 93-11278 Filed 5-11-93; 8:45 am]
BILLING CODE 6717-01-M

Office of Arms Control and Nonproliferation Policy

Proposed Subsequent Arrangement


The subsequent arrangement to be carried out under the above-mentioned agreements involves approval for the following transfer: RTD/AU/EU-68, for the transfer of unirradiated fission chambers and one tube containing approximately 12 grams of uranium enriched to 93 percent in the isotope uranium-235 and 3 milligrams of plutonium-239 from the Federal Republic of Germany to the Atominstitut der Österreichischen Universitaten, Vienna, Austria for research purposes.

In accordance with section 131 of the Atomic Energy Act of 1954, as amended, it has been determined that this subsequent arrangement will not be inimical to the common defense and security.

This subsequent arrangement will take effect no sooner than fifteen days after the date of publication of this notice.

Issued in Washington, DC, on May 6, 1993.

Edward T. Fel,
Acting Director, Office of Nonproliferation Policy.

[FR Doc. 93-11266 Filed 5-11-93; 8:45 am]
BILLING CODE 8420-04-M

Office of Hearings and Appeals

Implementation of Special Refund Procedures

AGENCY: Office of Hearings and Appeals, Department of Energy.
ACTION: Notice of Implementation of Special Refund Procedures.

SUMMARY: The Office of Hearings and Appeals (OHA) of the Department of Energy (DOE) announces the procedures for disbursement of $302,541.89 (plus accrued interest) that Whitaker Oil Company remitted to the DOE pursuant to an Agreed Judgment entered into by the DOE and Whitaker. The OHA has determined that the funds will be distributed in accordance with the DOE's special refund procedures, 10 CFR part 205, subpart V.

DATES AND ADDRESSES: Applications for refund must be filed in duplicate, addressed to "Whitaker Special Refund Proceeding," and sent to: Office of Hearings and Appeals, Department of Energy, 1000 Independence Ave., SW., Washington, DC 20585.

Applications should display a prominent reference to Case Number LEF-0052 and be postmarked no later than August 10, 1993.

FOR FURTHER INFORMATION CONTACT: Richard W. Dugan, Associate Director, Stacy Crowell, Staff Analyst, Office of Hearings and Appeals, 1000 Independence Avenue, SW., Washington, DC 20585, (202) 586-2860 (Dugan); (202) 586-4921 (Crowell).

SUPPLEMENTARY INFORMATION: In accordance with 10 CFR 205.282(c), notice is hereby given of the issuance of the Decision and Order set out below. The Decision and Order sets forth the procedures that the DOE has formulated to distribute monies that have been remitted by Whitaker Oil Company to the DOE to settle possible pricing violations with respect to its sales of diesel fuel, kerosene, toluene, and xylene. The DOE is currently holding $302,541.89 in an interest-bearing escrow account pending distribution.

The OHA has determined to distribute these funds in two stages. In the first stage, we will accept claims from those injured as a result of Whitaker's alleged overcharges. The specific requirements which an applicant must meet in order to receive a refund are set out in section IV of the Decision. A claimant who meets these specific requirements will be eligible to receive a refund based on the number of gallons of diesel fuel, kerosene, and toluene which it purchased from Whitaker during the period from November 1973 through March 1974 and its xylene purchases from November 1973 through January 1974.

If any funds remain after valid claims are paid in the first stage, they will be used for indirect restitution in accordance with the provisions of the Petroleum Overcharge Distribution and Restitution Act of 1986 (PDORDA), 15 U.S.C. 4501-07.

Applications for Refund must be postmarked no later than 90 days after publication of this Decision and Order in the Federal Register. Instructions for the completion of refund applications are set forth in the Decision that immediately follows this notice. Applications should be sent to the address listed at the beginning of this notice.

All submissions, except those containing confidential information, will be made available for public inspection between the hours of 1 p.m. and 5 p.m., Monday through Friday, except federal holidays, in the Public Reference Room of the Office of Hearings and Appeals, located in room 1E-234, 1000 Independence Avenue, SW., Washington, DC 20585.

Dated: May 6, 1993.

George B. Breznay,
Director, Office of Hearings and Appeals.

Decision and Order of the Department of Energy

Special Refund Procedures

Name of Firm: Whitaker Oil Company
Date of Filing: October 1, 1992
Case Number: LEF-0052

In accordance with the procedural regulations of the Department of Energy (DOE), 10 CFR part 205, subpart V, the Economic Regulatory Administration (ERA) of the DOE filed a Petition for the Implementation of Special Refund Procedures with the Office of Hearings and Appeals (OHA) on October 1, 1992. The petition requests that OHA formulate and implement procedures for the distribution of funds received pursuant to an Agreed Judgment entered into by DOE and Whitaker Oil Company of Atlanta, Georgia (Whitaker).

I. Background

Whitaker was a “reseller-retailer” as defined in 6 CFR 150.352 and 10 CFR 212.31. Accordingly, during the period from August 1973 to January 28, 1981, Whitaker was subject to the Mandatory Petroleum Price Regulations, 10 CFR part 212, subpart F, and antecedent regulations at 6 CFR part 150, subpart L. As a result of an ERA audit, the ERA alleged that Whitaker violated the price regulations in sales of motor gasoline, diesel fuel, kerosene, toluene, and xylene during a five month period from November 1973 through March 1974 (the audit period). The auditors determined that, during this period, the firm made sales at prices in excess of the maximum lawful selling price (MLSP) permitted by the price regulations.

Consequently, the ERA issued a Proposed Remedial Order (PRO) to Whitaker on February 24, 1982, alleging pricing violations in the sales of motor gasoline, diesel fuel, kerosene, toluene, and xylene. After considering the firm's Statement of Objections to the PRO, the DOE issued a final Remedial Order on April 10, 1985. Whitaker Oil Co., 13 DOE ¶ 83,004, off’d, 31 FERC ¶ 61,292 (1985). In the Remedial Order, the DOE modified the PRO to take account of retroactive exception relief which Whitaker received with regard to its motor gasoline sales. See Whitaker Oil Co., 12 DOE ¶ 81,024 (1985). The Remedial Order further reduced the alleged overcharges in accordance with the ERA’s position that the equal application rule should not be applied to audits occurring before September 1, 1974, and also found that Whitaker could not be liable for alleged overcharges attributable to the sale of xylene during the months of February and March 1974.

On February 25, 1990, an Agreed Judgment was entered in the U.S. District Court for the Northern District of Georgia with respect to the Remedial Order issued to Whitaker by the DOE. This Judgment settled all claims and liabilities concerning Whitaker’s compliance with the Federal petroleum price and allocation regulations governing the marketing of petroleum products during the period August 18, 1973 to January 28, 1981. Specifically, Whitaker agreed to remit $280,000, plus interest, to the DOE for deposit in an interest bearing escrow account. Whitaker has remitted $302,541.89 to the DOE in full satisfaction of that agreement. In addition, as of March 31, 1993, $22,847.28 in interest had accrued on the amount paid by Whitaker.

II. Jurisdiction

The procedural regulations of the DOE set forth general guidelines by which the Office of Hearings and Appeals may formulate and implement a plan of distribution for funds received as a result of an enforcement proceeding. 10 CFR part 205, subpart V. It is the DOE policy to use the subpart V process to distribute such funds. For a more detailed discussion of subpart V and the authority of the Office of Hearings and Appeals to fashion procedures to distribute refunds obtained as part of settlement agreements, see Office of Enforcement, 9 DOE ¶ 82,597 (1981); Office of Enforcement, 8 DOE ¶ 82,597 (1981) (Vickers). After reviewing the record in the present case, we have concluded that a subpart V proceeding is an appropriate mechanism for distributing the Whitaker settlement fund. In this Decision and Order, we will adopt final refund procedures, set forth the items that must be included in a refund application, and list in the Appendix potential claimants who were identified in the ERA audit files.

III. Refund Procedures

On February 10, 1993, OHA issued a Proposed Decision and Order (PD&O) establishing tentative procedures to distribute the Whitaker settlement fund. That PD&O was published in the Federal Register and a 30-day period was provided for the submission of comments regarding our proposed refund plan. See 58 FR 14,192 (March 17, 1993). More than 30 days have elapsed and the OHA has received no comments concerning the proposed procedures for the distribution of the Whitaker settlement fund. Consequently, the procedures will be adopted as proposed.
A. Refund Claimants

Insofar as possible, the settlement fund should be distributed to those customers of Whitaker who were injured by the alleged overcharges. Those Whitaker customers who purchased products covered by the Final Order during the ERA audit period are the purchasers we have identified as those most likely to have been injured. In this case, the ERA audit files specifically identify Whitaker's customers by name and record the amounts of products purchased by each customer. They do not, however, contain sufficient data which would indicate the dollar amount of the alleged overcharges paid by individual customers of each of the products. We are thus able to use the information contained in the audit files for guidance as to the identity of Whitaker's customers and the volumes of product they purchased, but are unable to apportion the settlement fund based on the specific overcharges incurred by each customer as we have done in some prior refund proceedings. See, e.g., Howard Oil Co., 15 DOE ¶ 85,072 (1986). Consequently, we will use the volumetric approach described below as the mechanism for determining refund amounts.

A list of the customers named in the audit files is set forth in the Appendix to this Decision and Order. We will accept refund applications from customers who can document their monthly purchases of diesel fuel, kerosene, and/or toluene from Whitaker during the period from November 1973 through March 1974. Purchasers of xylene may apply for refunds based on their records through March 1974. If an applicant does not have records to establish a specific gallophone claim, it may elect to rely on information in the ERA audit files regarding its level of purchases. If such information exists for the firm, 1

1. Showing of Injury

As in prior refund proceedings, we will require claimants who were resellers (including retailers and refiners) of refined petroleum products purchased from Whitaker to demonstrate that during the audit period they would have maintained their prices for petroleum products at the same level had the alleged overcharges not occurred. While there are a variety of ways to make this showing, a reseller should generally demonstrate that, at the time it purchased the product from Whitaker, market conditions would not permit it to increase its prices to pass through to its customers the additional costs associated with the alleged overcharges. See Atlantic Richfield Co./Odessa L.P.C. Transport 21 DOE ¶ 85,384 (1991); Gulf Oil Corp./Anderson & Watkins, Inc. 21 DOE ¶ 85,380 (1991). In addition, the reseller will be required to show that it had a "bank" of unrecovered costs in order to demonstrate 2

2 Based on the volumetric refund level established in Part III B, claimants who purchased more than 161,812 gallons of refined petroleum products during the audit period (medium-range claimants) may elect to utilize this presumption.

that it did not recover the increased costs associated with the alleged overcharges by increasing its own prices. The maintenance of a bank does not, however, automatically establish injury in that resellers who purchased relatively small amounts of Whitaker petroleum products. For example, such firms may have limited accounting and data-retrieval capabilities and therefore may be unable to produce the records necessary to prove the existence of banks of unrecovered costs, or that they did not pass on the alleged overcharges to their own customers. We also are concerned that the cost to the applicant and to the government of compiling in their own files is set forth in the Appendix to this Decision and Order. We will accept refund applications from customers who can document their monthly purchases of diesel fuel, kerosene, toluene and/or xylene from Whitaker during the period from November 1973 through March 1974. Purchasers of xylene may apply for refunds based on their records through March 1974. While there are a variety of ways to make this showing, a reseller should

However, if such a firm applies for a refund as both a reseller and an end-user and its total allocable share exceeds $10,000, it cannot take advantage of both the medium-range presumption and the end-user presumption. See Texaco Inc./Union Texas Petroleum Corp., 21 DOE ¶ 85,412 (1991). Instead, its refund will be based upon the presumption that affords it the higher refund (medium-range presumption for all gallons or end-user presumption for only end-use gallons).

4. End-users

We will also adopt the presumption that end-users or ultimate consumers whose businesses are unrelated to the petroleum industry were injured by the alleged overcharges covered by the Agreed Judgment. Unlike regulated firms in the petroleum industry, members of this group were generally not subject to price controls during the audit period, and were not required to keep records which justified selling price increases by reference to cost increases. See, e.g., Marion, Thornton Oil Corp., 12 DOE ¶ 85,312 (1984). For these reasons, an analysis of the impact of the increased cost of petroleum products on the final prices of non-petroleum goods and services would be beyond the scope of this special refund proceeding. See Office of Refiners, 85 DOE ¶ 85,072 (1983); see also Texas Oil & Gas Corp., 12 DOE ¶ 85,069 at 88,209 (1984). Therefore, end-users of Whitaker petroleum products need only document their purchase volumes to make a sufficient showing that they were injured by the alleged overcharges. 4

5. Regulated Firms and Cooperatives

We have determined that, in order to receive a full volumetric refund, a claimant whose prices for goods and services are regulated by a governmental agency, e.g., a public utility, or by terms of a cooperative agreement, needs only to submit documentation of purchases used by itself or, in the case of a cooperative, sold to its members. However, a regulated firm or a cooperative whose allocable share is greater than $10,000 will also be required to certify that it will pass any refund received through

1 We recognize that other parties not identified by the ERA audit may be entitled to a portion of the settlement fund. Such claimants will be required to submit documentation which establishes that they purchased diesel fuels, kerosene, and/or toluene from Whitaker during the period covered by the audit and the volume of those purchases.
to its customers or member-customers on a dollar-for-dollar basis without any deduction, provide us with a full explanation of how it plans to accomplish the restitution, and certify that it will notify the appropriate regulatory body or membership group of the receipt of the refund. See Dorchester Gas Corp., 14 DOE ¶ 85,240 at 88,451 (1986). This requirement is based upon the presumption that, with respect to a regulated firm, any overcharges would have been routinely passed through to its customers. Similarly, any refunds received should be passed through to its customers. With respect to a cooperative, in general, the cooperative agreements which control prices would ensure that the alleged overcharges, and similarly refunds, would be passed through to its member-customers. Accordingly, these firms will not be required to make a detailed demonstration of injury.

6. Spot Purchasers

We have adopted a rebuttable presumption that repeatedly made spot purchases of Whitaker petroleum products suffered no injury. Spot purchasers tend to have considerable discretion in when and to make purchases and therefore would not have made spot purchases of Whitaker's product at prices unless they were able to pass through the full amount of the alleged overcharges to their own customers. See Vickers, 8 DOE at 85,396–97.

Accordingly, any reseller claimant who was a spot purchaser must submit evidence to rebut the spot purchaser presumption and establish the extent to which it was injured by the spot purchase(s). See Saber Energy, Inc./Mobil Oil Corp., 14 DOE ¶ 85,170 (1986).

7. $15 Minimum

We have also established a minimum amount of $15 for refund claims. We have found through our experience in prior refund cases that the cost of processing claims in which refunds are sought for amounts less than $15 outweighs the benefits of restitution in those situations. See Uban Oil Co., 9 DOE ¶ 82,541 (1982); see also 10 CFR 205.286(b).

B. Calculation of Refund Amounts

As stated above, the ERA audit files document Whitaker's customers' names and gallonage of product purchased. The data are not specific enough to permit us to apportion the settlement fund based on the overcharges experienced by each customer. Therefore, we will use a volumetric refund methodology to distribute the settlement fund in this proceeding. The volumetric refund presumption assumes that the alleged overcharges by a firm were spread equally over all gallons of product marketed by that firm. In the absence of better information, this assumption is sound because the DOE price regulations generally required the regulated firm to account for increased costs on a firm-wide basis in determining its prices. This presumption is rebuttable, however. A claimant which believes that it suffered a disproportionate share of the alleged overcharges may submit evidence proving this claim in order to receive a larger refund. SeeAmtel, Inc./Whico, Inc., 19 DOE ¶ 85,319 (1989).\(^3\)

Under the volumetric methodology we will employ, a claimant will be eligible to receive a refund equal to the number of gallons of diesel fuel, kerosene, toluene and/or xylene purchased from Whitaker during the months specified for each of those products in Part III A of this Decision, multiplied by the volumetric factor. The volumetric factor in this case is equal to a base price of 1 gallon.\(^4\) In addition, successful claimants will receive a proportionate share of the accrued interest.

IV. Refund Application Requirements

To apply for a refund from the Whitaker settlement fund, a claimant should submit an Application for Refund containing all of the following information:

1. Identifying information including the claimant's name, address, business address during the refund period, taxpayer identification number,\(^5\) a statement indicating whether the claimant is an individual, corporation, partnership, sole proprietorship, or other business entity, the name, title, and telephone number of a person to contact for any additional information, and the name and address of the person or firm who should receive any refund check.

If the applicant operated under more than one name or under a different name during the price control period, the applicant should specify these names.

2. The applicant's use of the product it purchased from Whitaker: e.g., consumer (end-user), reseller (including retailer or refinery), cooperative, or public utility.

3. A monthly purchase schedule covering the period November 1973 through March 1974 for diesel fuel, kerosene, and toluene and from November 1973 through January 1974 for xylene. The applicant should specify the source of this gallonage information. In calculating its purchase volumes, an applicant should use actual records from the refund period, if available. If these records are not available, the applicant may elect to rely on the gallonage information contained in the ERA audit files, if such information exists.

4. The applicant is a regulated utility or a cooperative whose allocable share exceeds $10,000, a certification that it will pass on the entirety of any refund received to its customers, will notify its state utility commission, other regulatory agency, or membership body of the receipt of any refund, and a brief description as to how the refund will be passed along.

5. A statement as to whether the applicant or a related firm has filed, or has authorized any individual to file on its behalf, any other application in the Whitaker proceeding. If so, an explanation of the circumstances of the other filing or authorization should be submitted.

6. A statement as to whether the applicant is or was affiliated with Whitaker. If the application was in any way affiliated with Whitaker, it should explain this affiliation, including the time period in which it was affiliated. If the applicant was not affiliated with Whitaker, the applicant should submit a statement to that effect.

7. A statement as to whether the ownership of the applicant's firm changed during or since the refund period. If an ownership change occurred, the applicant should list the names, addresses, and telephone numbers of any prior or subsequent owners. The applicant should also provide copies of any relevant Purchase and Sale Agreements, if available. If such written documents are not available, the applicant should submit a description of the ownership change, including the year of the sale and the type of sale (e.g., sale of corporate stock, sale of company assets).

8. A statement as to whether the applicant has ever been a party in a DOE enforcement action or a private Section 210 action. If so, an explanation of the case and copies of relevant documents should also be provided.

9. The following statement signed by the individual applicant or a responsible official of the firm filing the refund application.\(^6\)

I swear (or affirm) that the information contained in this application and its attachments is true and correct to the best of my knowledge and belief. I understand that anyone who is convicted of providing false information to the federal government may be subject to a fine, a jail sentence, or both, pursuant to U.S.C. § 1001. I understand that the information contained in this application is subject to public disclosure. I have enclosed a duplicate of this entire application which will be placed in the OHA Public Reference Room.

\(^3\) In computing the appropriate refund in such a case, we will prorate the alleged overcharge amount by the ratio of the Whitaker settlement amount to the aggregate overcharge amount determined by the Whitaker Remedial Order. See Amtel, Inc./Whico, Inc., 19 DOE at 88,596.

\(^4\) The volumetric factor in the present case is computed by dividing the settlement amount ($302,541.89) by the 4,895,449 gallons of diesel fuel, kerosene, toluene, and xylene which the ERA audit files indicate Whitaker sold during the months of the refund period.

\(^5\) Under the Privacy Act of 1974, the submission of a social security number by an individual applicant is voluntary. An applicant that does not wish to submit a social security number must submit an employer identification number, if one exists. This information will be used in processing refund applications, and is requested pursuant to our authority under the Petroleum Overcharge Distribution and Restitution Act of 1986 and the regulations codified at 10 CFR Part 205, Subpart V. The information may be shared with other Federal agencies for statistical, auditing or archiving purposes, and with law enforcement agencies when information to the federal government may be subject to a fine, a jail sentence, or both, pursuant to U.S.C. § 1001. I understand that the information contained in this application is subject to public disclosure. I have enclosed a duplicate of this entire application which will be placed in the OHA Public Reference Room.

\(^6\) The Temporary Emergency Court of Appeals has recently held that subsidiaries and affiliates of a firm that has settled with the DOE are not entitled to a share of the settlement as a refund would unjustly enrich the settlement firm. Propane Industrial, Inc. v. DOE, 3 Fed. Energy Guidelines ¶ 26.674 (Temp. Emer. Ct. App 1993). See also Good Hope Refineries/Transamerica Natural Gas Corp., 23 DOE ¶ 28012, RF339–13 (March 5, 1993).

The statement must be dated or after the date of this Decision and Order. Any application signed and dated before the date of this Decision will be summarily dismissed.
All applications should be either typed or printed and clearly labeled “Whitaker Special Refund Proceeding, Case No. L.E.F-0052.” Each applicant must submit an original and one copy of the application. If the applicant believes that any of the information in its application is confidential and does not wish for this information to be publicly disclosed, it must submit an original application, clearly designated “confidential,” containing the confidential information, and two copies of the application with the confidential information deleted. All refund applications should be postmarked no later than 90 days from the date this Decision and Order is published in the Federal Register. All refund applications should be sent to: Whitaker Special Refund Proceeding, Office of Hearings and Appeals, Department of Energy, 1000 Independence Ave., SW., Washington, DC 20585.

In those cases where applications are filed by representatives, e.g., filing services or attorneys, we may request information from the representative regarding its solicitation practices and materials and the procedures it uses. Furthermore, each representative that requests that it be a payee of a refund check must file with the OHA if it has not already done so a statement certifying that it maintains a separate escrow account at a bank or other financial institution for the deposit of all refunds received on behalf of applicants, and that its normal business practice is to deposit all Subpart V refund checks in that account within two business days of receipt and to disburse refunds to applicants within 30 calendar days thereafter. Unless such certification is received by the OHA, all refund checks approved will be made payable solely to the applicant. Representatives who have not previously submitted an escrow account certification form to the OHA may obtain a copy of the appropriate form by contacting: Marcia B. Carlson, HG-13, Chief, Docket & Publications Division, Office of Hearings and Appeals, Department of Energy, Washington, D.C. 20585.

V. Distribution of Funds Remaining After First Stage

Any funds that remain after all first stage claims have been decided shall be distributed in accordance with the provisions of the Petroleum Overcharge Distribution and Restitution Act of 1986 (PODRA), 15 U.S.C. 4501-07. PODRA requires that the Secretary of Energy determine annually the amount of oil overcharge funds that will not be required to refund monies to injured parties in Subpart V proceedings and make those funds available to state governments for use in four energy conservation programs. The Secretary has delegated these responsibilities to the OHA, and any funds in the Whitaker settlement fund that the OHA determines will not be needed to effect direct restitution to injured customers will be distributed in accordance with the provisions of PODRA.

It is therefore Ordered That:

(1) Applications for Refund from the funds remitted to the Department of Energy by Whitaker Oil Company pursuant to the Agreed Judgment dated February 25, 1990 may now be filed.

(2) All applications for Refund must be postmarked no later than 90 days after publication of this Decision and Order in the Federal Register.

Dated: May 6, 1993.

George B. Breznay,

Director, Office of Hearings and Appeals.

Appendix—Whitaker Oil Company Customer List

A.B.C. Co. (Atlanta)*
Acousti
Allis Chalmers*
AM Synthetic*
AMCO Transm Service
American Can Co.*
Anchor Continental*
Anderson McGriff*
Andrew Brown
Ansley Golf Course
Arimoc Chemical
Ashland Chemical*
Athena Oil Co.*
Atlanta Boat Works
Atlanta Country Club
Atlanta Refiners
Atlanta Solvents
Atlanta Steel Bldg.
Atlanta Store
Auto Man Transmission
Awnings, Inc.
Barber Oil*
Barron Fabrications
BASF Wyandatte Tucker*
Bates Hardware
Beam Oil Co.
Bellamy Pros. Cont.*
Bender & Thompson Elec.
Bibb Co.*
Branco Inc. (Canton)
Brooks Auto Parts
Browne Steel Contracting
Brown Transport*
Cargill, Inc.*
Centre*
Charter International*
Chem. Manufacturing Co.
Chemical Services
Cities Service Co.*
Clearwater Finishing Co.
Coca Cola*
Coles Auto Transmission
Consolidated Aluminum*
Continental Can Co.*
Corn Bros. Inc.*
Crain Oil Co.*
Crow Pipe & Land Mgmt.
Dewey Almy
Dick Corp
Dunlop Sports Division
E.T. Spell
ECOL, Inc.*
Emory Shell Station
Enterprise Supply
Ethyl Corp.*
EXXON*
Fabrics America Corp.
Ferguson & Son
Firestone*
Fitzgerald*
Florida Solvents*
Ford Motor Co.*
Fountain Oil Corp.*
Freight Del. Serv.
Frito Lay*
Fruit Growers*
G.M. Assembly*
Gate City Oil Equip.
General Metal Wheel
General Oil Co.*
'General Tire'*
Geneva Metal Wheel Co.
Georgia Transports*
Gibson Homans
Gillman Paint & Varnish
Glasgow Indust.
Gildenden Dunke
Gold Shield Solvents
Graniteville Co.*
Guardian Chemical
Guy Hill
Hamilton Bros. Mfg.*
Hardwick Chemical
Hangbrook Oil Co.*
Hayes Auto Serv.
Highview Nursing Home
Hill Green
Hills Aircraft
Hillview Nursing Home
Hugley Oil
Inmont Inc.*
Industrial Refining
Intermodal Serv.
Jim Wallace Oil Co.
Lamar Elliott
Leaseway of Ga.
Lithonia Lighting*
Lockhead*
London Iron & Metal
LIPS Research Lab*
M&T Chemical Co.*
M&J Solvents
Marco Chemical
Marietta Transports
Mark Pope
Mayo Chemical*
McKesson Chemical*
Mead, Thiele, Eigdahl
Milliron Garage
Mobil*
Mobile
Monroe Auto*
Nalco Chemical*
National Cash Register
P&E Contracting
Pascue Steel Corp.
Phillip Beamer*
Pope Assoc. Inc.*
Post Brokerage Co. To
PPG Ind.*
Pride Terminals Inc.*
Print Pack, Inc.
R.C. Hill Co.*
R.G. Reynolds*
Rayloc*
Raymond Cole Auto
RFD Ind.
Reeves Bros. Inc.*
Reliance Varnish Ky.
Rheem Mang.*
Rollins Leasing*
Sammy Nelson*
Sander's Paint
Schneiderorporate Chem.
Selig Chemical
Seydell, Wooley Co.*
Shell Chemical*
Silencer Air Cond.
Southeastern Chemical
Southeastern Elevator
Southeastern Freight*
Southeastern Products
ENVIRONMENTAL PROTECTION AGENCY

[OPPTS-00135; FRL-4586-1]

Agency Information Collection Activities Under OMB Review

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act this notice announces that the Information Collection Request (ICR) abstracted below has been forwarded to the Office of Management and Budget (OMB) for expedited review and comment. The ICR describes the nature of the information collection and its expected cost and burden.

DATES: Comments must be submitted on or before June 11, 1993.

FOR FURTHER INFORMATION CONTACT: Sandy Farmer, Environmental Protection Agency, Information Policy Branch (PM 223Y), 401 M St., SW., Washington, DC 20460, Telephone: (202) 260-2740.

SUPPLEMENTARY INFORMATION: The ICR abstracted below is titled "Special Data Call-In Notice to Certain Pesticide Registrants Requesting Replacement of Craven Laboratory-Generated Data Previously Submitted in Support of Existing Tolerances or Registrations" (EPA No. 1642.01). This ICR is for a new collection of information.

I. Abstract

Notification of the Information Collection

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended (7 U.S.C. 136) requires EPA to register pesticides for distribution and sale within the United States. It also requires registrants to provide EPA with the requisite information (data) needed to assess whether the registration of a pesticide would cause an unreasonable adverse effect on human health or the environment. EPA has a continuing responsibility to assure that registrations do not cause unreasonable adverse effects and that regulatory actions are based on accurate and reliable data. If the Agency at any time needs additional information to make that determination, the Agency under FIFRA section (c)(2)(B) may require that registrants generate and supply the required information.

EPA's Office of Pesticide Programs (OPP), under the Assistant Administrator for Prevention, Pesticides and Toxic Substances, is requiring the submission of new studies/data to replace certain data which were generated by Craven Laboratories Inc. (Craven) of Austin, Texas. This is necessary because the integrity of certain data generated by Craven for pesticide registrants is questionable following allegations of wrongdoing by the laboratory. Additionally, 12 former employees of Craven have admitted that wrongdoing occurred. As a result, Craven data are not considered by the Agency to be reliable or adequate to support continued registration or tolerance levels for certain pesticides which are founded in decisions based upon these data. A criminal investigation ensued which precludes EPA from revealing details of some information on the Craven issue. Since the case has yet to go to trial, the full facts have not yet been made public due to restrictions on disclosure of grand jury materials and to preserve the rights of the defendants.

OPP will issue a data call-in (DCI) to obtain the necessary data under the authority of FIFRA section 3(c)(2)(B). This review request has been expedited because the Agency requires these data to confirm risk assessments. The unnecessary continuance of a registration or tolerance based on a flawed assessment of risk could result in serious public harm. This information collection is a follow-up to two previous Craven-related voluntary information collections. The first was a letter dated February 27, 1991, sent to 262 registrants, requesting that they identify data generated by Craven and submitted to EPA. EPA reviewed its records to identify studies which included Craven data shortly after receiving allegations that some data produced by Craven may be falsified. The Agency became aware that in some cases Craven's contributions were not clearly identified in the studies. Consequently, as part of an ongoing enforcement investigation, the Agency contacted all 262 past submitters of the kinds of data that Craven might have generated.

Companies which had never relied on Craven data were asked to report that fact to EPA. Companies that had submitted Craven data were asked to supply information which:

1. Identified every study submitted to the Agency which reflected any work done by Craven.
2. Identified any other information or data found or gathered by the submitter which might assist the Agency to validate regulatory decisions based on Craven data.
3. Identified what steps the company could take to provide new data if necessary.

The responses were analyzed for completeness and veracity and a data base was designed to store them.

The second was a letter dated June 20, 1991, sent to 13 registrants with Craven-generated data requesting that they provide appropriate existing alternate data to support continuation of established tolerances and registrations. As a result of responses to the first collection, the scope was narrowed from 262 to 13 registrants. In addition, it became clear that alternate data were available in certain cases and that these data should be provided to the Agency for review.

The second voluntary information request had two goals: (1) To provide the Agency with appropriate existing alternate data to determine if existing tolerances and registrations affected by Craven-generated data could be continued until issues surrounding the validity and reliability of these data are resolved or until new replacement data could be generated and (2) to have these existing alternate data available for the public. Qualifying alternate data were not strictly defined in the information request because the Agency was willing to consider any type of reliable, non-Craven data as a possible alternative. All
13 of the affected registrants (BASF, Cheminova, Ciba, DowElanco, du Pont, Hoechst Celanese Corp, Miles, Monsanto, Rhone Poulenc, Rohm Haas, Sandoz, Uniyoyal and Valent U.S.A. Corporation) responded and if alternate, non-Craven data were available, they were submitted. It was found that alternate data were available for a majority of the affected chemicals and crop sites. As a result of the reviews of alternate data, the scope of data needed to replace Craven-generated studies has been reduced and is well defined.

New replacement studies are needed in cases where the Craven data and existing alternate data are not adequate to support existing tolerances and registrations. The alternate data have been evaluated for: (1) Adequacy to provide temporary assurance that tolerances and registrations can continue while replacement data are being generated and; (2) adequacy as replacement data. EPA reviews indicate that alternate data are sufficient to temporarily continue tolerances and registrations while replacement data are being generated where needed. A variety of alternate data types were received including lists of foreign tolerances and monitoring data, test reports, and split sample data (residue analyses redone by the registrant to supplement the Craven conducted portion). The existence of foreign tolerances and monitoring data generally provide interim assurance for the temporary continuation of established U.S. tolerances until new data can be generated. Foreign tolerances and monitoring data, however, are usually not sufficient to be used as replacement data. While foreign studies provide a good indication of residue levels, they are often based on use patterns and rates which are not representative of U.S. labels or agricultural practices and for that reason would not fulfill EPA standards for testing or registration. FDA and CDFA monitoring data may also provide good indications of pesticide residues in foods in channels of trade; however, there is no way of knowing if the monitoring data represent the use rates and pre-harvest intervals required to be tested by EPA residue chemistry protocol for establishing tolerances. In addition, foreign tolerance levels and residues found in monitoring programs may not be representative of the geographic areas needed to fully support the U.S. tolerance.

EPA received Craven-generated data for 43 pesticides over a 15-year time span starting in 1976 and ending in 1990. After reviewing responses to the information request letter for existing alternate data, the Agency determined that 20 of the 43 pesticides have Craven-generated data which support established tolerances and/or registrations and are candidates for a DCI. The 20 pesticides which are DCI candidates and the affected registrants are listed in Table 1. The Craven-generated data for the remaining 23 pesticides do not support current regulatory actions, do not require replacement data, and are not candidates for a DCI. These pesticides do not need replacement data because they either have adequate non-Craven data, have pending actions, have registrations which have been voluntarily withdrawn, or have affected uses withdrawn. The 23 pesticides which have Craven-generated data but are not candidates for a DCI are listed in Table 2.

EPA has not accepted Craven-generated data to support any pending tolerance or registration requests since the allegations against Craven Laboratories have become known.

<p>| Table 1.—Pesticides with Craven-Generated Data Which Require a DCI for Replacement Studies |
|---------------------------------------------|-----------------------------------------------|</p>
<table>
<thead>
<tr>
<th>Pesticide</th>
<th>Affected Registrants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alachlor</td>
<td>Monsanto Agricultural Company</td>
</tr>
<tr>
<td>Ciprylaid</td>
<td>DowElanco</td>
</tr>
<tr>
<td>Dicamba</td>
<td>Sandoz Agro, Inc.</td>
</tr>
<tr>
<td>Dinocap</td>
<td>Rohm &amp; Haas Company</td>
</tr>
<tr>
<td>Diquat</td>
<td>Zeneca, Inc. (transferred from Valent U.S.A.)</td>
</tr>
<tr>
<td>Ethyl parathion</td>
<td>Cheminova Agro A/F</td>
</tr>
<tr>
<td>Fenoxynop-ethyl</td>
<td>Hoechst Celanese Corp</td>
</tr>
<tr>
<td>Glyphosate</td>
<td>Monsanto Agricultural Company</td>
</tr>
<tr>
<td>Linuron</td>
<td>E.I. du Pont de Nemours and Company, Inc.</td>
</tr>
<tr>
<td>MCPA</td>
<td>Industry MCPA Taskforce</td>
</tr>
<tr>
<td>MCPB</td>
<td>Rhone-Poulenc Ag Company</td>
</tr>
<tr>
<td>Methamidophos</td>
<td>Miles Inc.</td>
</tr>
<tr>
<td>Metolachlor</td>
<td>Ciba-Gelgy Corp.</td>
</tr>
<tr>
<td>Methribuzin</td>
<td>Miles Inc.</td>
</tr>
<tr>
<td>Oxydemeton-methyl</td>
<td>Rohm &amp; Haas Company</td>
</tr>
<tr>
<td>Oxynflurufen</td>
<td>Uniroyal Chemical Company, Inc.</td>
</tr>
<tr>
<td>PCNB</td>
<td>DowElanco</td>
</tr>
<tr>
<td>Picloram</td>
<td>Rohm &amp; Haas Company</td>
</tr>
<tr>
<td>Pronamide</td>
<td>BASF Corp.</td>
</tr>
</tbody>
</table>

The Respondents and the Information Requested

EPA has not accepted Craven-generated data to support any pending tolerance or registration requests since the allegations against Craven Laboratories have become known.
Table 2.—Pesticides with Craven-Generated Data which Do Not Require a DCI for Replacement Studies

<table>
<thead>
<tr>
<th>Pesticide</th>
<th>Reason DCI Not Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>2,4-D</td>
<td>Adequate non-Craven data available</td>
</tr>
<tr>
<td>Acetochlor</td>
<td>Pending</td>
</tr>
<tr>
<td>Acifluorfen</td>
<td>Pending</td>
</tr>
<tr>
<td>Anilazine</td>
<td>Adequate non-Craven data available</td>
</tr>
<tr>
<td>Butachlor</td>
<td>Use withdrawn by registrant</td>
</tr>
<tr>
<td>Chlor dane</td>
<td>Use withdrawn by registrant</td>
</tr>
<tr>
<td>Clethodim</td>
<td>Adequate non-Craven data available</td>
</tr>
<tr>
<td>Cyflu thrin</td>
<td>Adequate non-Craven data available</td>
</tr>
<tr>
<td>Demeton</td>
<td>Registration withdrawn by registrant</td>
</tr>
<tr>
<td>Disulfoton</td>
<td>Adequate non-Craven data available</td>
</tr>
<tr>
<td>EBDC/ETU</td>
<td>Adequate non-Craven data available</td>
</tr>
<tr>
<td>Ethiozin</td>
<td>Pending</td>
</tr>
<tr>
<td>Fenamiphos</td>
<td>Adequate non-Craven data available</td>
</tr>
<tr>
<td>Fensulfolin</td>
<td>Registration withdrawn by registrant</td>
</tr>
<tr>
<td>Fluchloralin</td>
<td>Registration withdrawn by registrant</td>
</tr>
<tr>
<td>Heptachlor</td>
<td>Use withdrawn by registrant</td>
</tr>
<tr>
<td>Leptophos</td>
<td>Registration withdrawn by registrant</td>
</tr>
<tr>
<td>Methiocarb</td>
<td>Use withdrawn by registrant</td>
</tr>
<tr>
<td>Myclobutanil</td>
<td>Adequate non-Craven data available</td>
</tr>
<tr>
<td>Oxamyl</td>
<td>Pending</td>
</tr>
<tr>
<td>Propachlor</td>
<td>Adequate non-Craven data available</td>
</tr>
<tr>
<td>Sulprofos</td>
<td>Adequate non-Craven data adequate</td>
</tr>
<tr>
<td>Triadimefon</td>
<td>Uses withdrawn by registrant</td>
</tr>
</tbody>
</table>

Specific replacement data needed are for residue chemistry studies, environmental fate studies and one occupational/residential exposure study. The guideline numbers and names for these studies as listed in 40 CFR part 158 are: Guideline 171–4(k) -- Residue Chemistry Crop Field Trials; Guideline 171–4(j) -- Residue Chemistry Processed Food/Feed Study; Guideline 171–4(e) -- Residue Chemistry Storage Stability Study; Guideline 164–4 – Soil Dissipation Study, Guideline 164–2 -- Aquatic Dissipation Study, and Guideline 165–3 -- Irrigated Crop Study. The occupational/residential exposure replacement study is for a Mixer/Loader/Applicator (M/L/A) exposure study which is not specifically listed in 40 CFR part 158.

The Agency estimates that 293.4 studies will be needed to replace Craven-generated data (see Table 3). The number of replacement studies needed per affected chemical vary depending on the extent to which their various uses are based on Craven-generated data. Consequently, some pesticides will have more replacement data requirements than others.

Table 3.—Estimated Number of Studies Which Need to be Replaced

<table>
<thead>
<tr>
<th>Study Guideline No.</th>
<th>Number of Studies that Need Replacing</th>
</tr>
</thead>
<tbody>
<tr>
<td>164–1</td>
<td>2.4</td>
</tr>
<tr>
<td>164–2</td>
<td>1</td>
</tr>
<tr>
<td>165–3</td>
<td>1</td>
</tr>
<tr>
<td>171–4(k)</td>
<td>268</td>
</tr>
<tr>
<td>171–4(i)</td>
<td>16</td>
</tr>
<tr>
<td>171–4(e)</td>
<td>2</td>
</tr>
<tr>
<td>M/L/A</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>293.4</td>
</tr>
</tbody>
</table>

Some of the affected registrants are voluntarily replacing studies where they feel that their data bases need additional support due to allegations of wrongdoing at Craven (see Table 4). Registrants are voluntarily replacing 103 of the 293.4 studies; however, it takes an average of 2 years to conduct these studies (due to growing season limitations) and they have not been completed yet. Since the Agency does not expect to receive the voluntarily replaced studies until the third fiscal quarter of 1993 at the earliest, the DCI will be issued for all 293.4 studies. Thus, all of the studies will be subject to the Agency’s FIFRA 3(c)(2)(B) authority.

Table 4.—Number of Voluntary Replaced Studies

<table>
<thead>
<tr>
<th>Study Guideline No.</th>
<th>Number of Studies Voluntarily Replaced</th>
</tr>
</thead>
<tbody>
<tr>
<td>164–1</td>
<td>1</td>
</tr>
<tr>
<td>164–2</td>
<td>1</td>
</tr>
<tr>
<td>171–4(k)</td>
<td>85</td>
</tr>
<tr>
<td>171–4(i)</td>
<td>6</td>
</tr>
<tr>
<td>171–4(e)</td>
<td>6</td>
</tr>
<tr>
<td>M/L/A</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>103</td>
</tr>
</tbody>
</table>

II. Public Burden

Public reporting burden for this collection of information is estimated to average 295 hours per response for reporting. This estimate includes the time needed to review instructions, gather the data needed, and review the collection of information.

Respondents: Pesticide registrants.
Estimated number of respondents: 13.
Estimated number of responses per respondent: 1.

Estimated total annual burden on respondents: 86,367 hours.

Frequency of collection: Once. Send comments regarding the burden estimate, or any other aspect of the information collection, including suggestions for reducing the burden to: Sandy Farmer, Environmental Protection Agency, Information Policy Branch (PM 223Y), 401 M St., SW., Washington, DC 20460 and Matthew Mitchell, Office of Management and Budget, Office of Information and Regulatory Affairs, 725 17th St., NW., Washington, DC 20530.

Dated: May 6, 1993.

Jane Stewart,
Acting Director, Regulatory Management Division.

[FR Doc. 93–11255 Filed 5–11–93; 8:45 am]
BILLING CODE 6560–80–F

[FRL–4654–3]

National Academy of Sciences’ Committee on Technical Bases for Yucca Mountain Standards; Meeting

AGENCY: Environmental Protection Agency.

ACTION: Meeting notice.

SUMMARY: The U.S. Environmental Protection Agency (EPA) is giving notice of the first meeting of the Committee on Technical Bases for Yucca Mountain Standards. This committee has been formed by and under the National Academy of Sciences (NAS) in accordance with section 801(a)(2) of the Energy Policy Act of 1992 (Pub. L. 102–486) which directed the EPA to contract with the NAS for this purpose. This meeting is the beginning of a process which will yield findings and recommendations to the EPA on the technical basis of standards for a high-level radioactive waste repository at Yucca Mountain, Nevada.

Most of the sessions during the first and second days of the meeting will be devoted to discussions of the Committee’s charge, with Federal and State officials and representatives of industrial and environmental groups. Time will also be reserved on the afternoon of the second day for observers in the general audience to present their views in brief.

DATES: The meeting will be held on May 27–29, 1993 beginning at 2 p.m. on May 27, 1993.

ADDRESSES: The meeting will be held at the Alexis Park Hotel, 375 East Harmon Avenue, Las Vegas, Nevada.

FOR FURTHER INFORMATION CONTACT: At NAS. For further information about the meeting, to indicate your intention to
attend the meeting, or to register to
speak, contact Lisa Clendening, Board
on Radioactive Waste Management,
National Academy of Sciences, 2101
Constitution Avenue, NW., Washing-
on DC 20416, facsimile transmission
number 202–334–3077. At EPA: For
information on EPA activities in this
area, contact Ray Clark, Criteria and
Standards Division (6602J), Office of
Radiation and Indoor Air, U.S.
Environmental Protection Agency.
Washington, DC 20460–0001, telephone
number 202–233–9310.

Eugene Durman,
Acting Director, Office of Radiation and
Indoor Air.

[FR Doc. 93–11251 Fried 5–11–93; 8:45 am]
BILLING CODE 6560–50–M

[OPP–180893; FRL 4584–7]

Receipt of Application for Emergency
Exemption to use Mancozeb; Solicitation of
Public Comment

AGENCY: Environmental Protection
Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has received a specific
exemption request from the North
Dakota Department of Agriculture
(hereafter referred to as the
"Applicant") for use of the pesticide
mancozeb (CAS 8018–01–7) to control
sunflower rust on up to 75,000 acres of
sunflowers in North Dakota. In
accordance with 40 CFR 166.24, EPA is
soliciting public comment before
making the decision whether or not to
grant the exemption.

DATES: Comments must be received on
or before May 27, 1993.

ADDRESSES: Three copies of written
comments, bearing the identification
notation “OPP–180893,” should be
submitted by mail to: Public Response
and Human Resource Branch, Field
Operations Division (H7506C), Office of
Pesticide Programs, Environmental
Protection Agency, 401 M St., SW.,
Washington, DC 20460. In person, bring
comments to: Rm. 613, Crystal Station 1, 2800
Jefferson Davis Highway, Arlington, VA,
(703–308–8328).

SUPPLEMENTARY INFORMATION: Pursuant
to section 18 of the Federal Insecticide,
Fungicide, and Rodenticide Act (FIFRA)
(7 U.S.C. 136p), the Administrator may,
at his discretion, exempt a State agency
from any registration provision of
FIFRA if he determines that emergency
conditions exist which require such
exemption. The Applicant has requested
the Administrator to issue a specific
exemption for the use of the fungicide,
mancozeb, available as Dithane DF (75
percent dispersible granules) EPA Reg.
No. 707–180; Dithane F–45 (4 pounds/
gallons flowable) EPA Reg. No. 707–156;
Dithane M45 (80 percent wettable
powder) EPA Reg. No. 707–78 from
Rohm and Haas Co., to control
Sunflower rust, caused by Puccinia
helianthi on up to 75,000 acres of
sunflowers in North Dakota. Information
in accordance with 40 CFR part 166
was submitted as part of this request.

According to the Applicant, over the
last few years Races 3 and 4 of
sunflower rust have become common in
North Dakota and Minnesota. Analysis
of isolates collected in 1991 indicated
that there is a greater complexity of
races than previously identified, with
more than races 3 and 4 present; over
half of the newly identified races could
infect all currently available hybrids. No
fungicides are registered for rust control
on sunflowers. Crop rotation would
help reduce the danger of a serious
outbreak, but would not prevent it,
since rust spores are airborne for long
distances. Use of resistant hybrids is not
practical since one fourth of the hybrids
currently available are susceptible to
race 3 of Puccinia helianthi and all are
susceptible to race 4 of Puccinia
helianthi. In addition, the situation is
complicated by the identification of new
races capable of infecting all currently
available hybrids.

Dithane will be applied by air at a
maximum rate of 1.6 pounds of active
ingredient per acre. A maximum of two
applications, a minimum of 10-days
apart, may be made per growing season.
Applications will not be made after
flowering is completed (when flower
rays are wilted).

The Agency initiated a Special Review
of the ethylene
blisithiocarbamate fungicides (EBDCs),
which include mancozeb, on July 17,
1987. A Final Determination Action for
the EBDCs, was issued February 13,
1992. The Agency took this action based
on an assessment of the risks from
exposure to ethylenethiourea (ETU)
present in, or formed as a result of
metabolic conversion from pesticide
products containing the active
ingredient mancozeb. ETU, a potential
human carcinogen, teratogen, and
thyroid toxicant, is present as a
contaminant, degradation product, and
metabolite of all the EBDC pesticides.
The Agency concluded that the
estimated cumulative risk of 10–5 from
current 55 food uses was
unacceptable and, therefore, cancelled
the following food uses of mancozeb:

- apricots, carrots, calery, collards,
- mustard greens, nectarines, peaches,
- rhubarb, spinach, succuleat beans, and
turnips. These cancellations reduce
estimated lifetime dietary risk to 1.6 x
10–6 which the Agency has determined
does not outweigh the benefits of the 45
retained uses.

This notice does not constitute a
decision by EPA on the application
itself. The regulations governing section
18 require that the Agency publish
notice of receipt in the Federal Register
and solicit public comment on an
application for a specific exemption
proposing use of a pesticide which
contains an active ingredient which has
been the subject of a Special Review and
is intended for a use that could pose a
risk similar to the risk posed by any use
of a pesticide which is or has been the
subject of a Special Review (40 CFR
166.24 (a)(3)).

Accordingly, interested persons may
submit written views on this subject to
the Field Operations Division at the
address above. The Agency will review
and consider all comments received
during the comment period in
determining whether to issue the
emergency exemption requested by the
North Dakota Department of
Agriculture.

Lawrence E. Culleen,
Acting Director, Registration Division, Office
of Pesticide Programs.

[FR Doc. 93–10982 Filed 5–11–93; 8:45 am]
BILLING CODE 6560–50–F
Receipt of Notification of Intent to Conduct Small-Scale Field Testing; Nonindigenous Microbial Pesticide

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has received from the Ciba-Geigy Corp., a notification of intent to conduct small-scale field testing on cotton, vegetables, and ornamentals in Florida, Mississippi, California, New York, and Illinois of a strain of Pseudomonas fluorescens isolated from soil in Switzerland.

DATES: Comments must be received on or before May 26, 1993.

ADDRESSES: By mail, submit written comments to: Public Response and Program Resources Branch, Field Operations Division (H7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring comments to: Rm. 1128, Jefferson Davis Hwy., Arlington, VA. 22202. Comments may be disclosed publicly by EPA.

Information submitted and any comment(s) concerning this notice may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment(s) that does not contain CBI must be submitted for inclusion in the public record.

Information not marked confidential may be disclosed publicly by EPA without prior notice to the submitter. Information on the proposed test and any written comments will be available for public inspection in Rm. 246 at the Virginia address given above, from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: Susan T. Lewis, Product Manager (PM-21), Registration Division (H-7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

Office location and telephone number: Rm. 227, CM #2, 1921 Jefferson Davis Hvy., Arlington, VA, (703)-305-6900.

SUPPLEMENTARY INFORMATION: A notification of intent to conduct small-scale field testing pursuant to the EPA's "Statement of Policy; Microbial Products Subject to the Federal Insecticide, Fungicide, and Rodenticide Act and the Toxic Substances Control Act" of June 26, 1986 (51 FR 23313), dated March 22, 1993, has been received from the Ciba-Geigy Corp., Greensboro, NC. The purpose of the proposed testing is to evaluate the efficacy of a nonindigenous Pseudomonas fluorescens, strain MOCG-024, isolated in Switzerland, for the control of soil-borne pathogens of cotton, vegetables, and ornamentals. The proposed field tests would be conducted at Ciba-Geigy research stations in Florida, Mississippi, California, New York, and Illinois. The total area of the proposed test sites is 1.5 acres.


Lawrence E. Culleen,
Acting Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 93-10983 Filed 5-11-93; 8:45 am]

BILLING CODE 6560-50-F

FEDERAL COMMUNICATIONS COMMISSION

Public Information Collection Requirement Submitted to Office of Management and Budget for Review


The Federal Communications Commission has submitted the following information collection requirement to OMB for review and clearance under the Paperwork Reduction Act of 1980 (44 U.S.C. 3507).

Copies of this submission may be purchased from the Commission's copy contractor, International Transcription Service, Inc., 2100 M Street, NW., Suite 140, Washington, DC 20037, (202) 857-3800. For further information on this submission contact Judy Boley, Federal Communications Commission, (202) 632-0276. Persons wishing to comment on this information collection should contact Jonas Neihardt, Office of Management and Budget, Room 3235, NEOB, Washington, DC 20503, (202) 395-4814.

OMB Number: 3060-0411
Title: Sections 1.720-1.735, Formal Complaints Against Common Carriers
Action: Revision of a currently approved collection
Respondents: Individuals or households, state or local governments, federal agencies or employees, non-profit institutions, and businesses or other for-profit (including small businesses)
Frequency of Response: On occasion reporting
Estimated Annual Burden: 760 responses; 10 hours average burden per response; 7,600 hours total annual burden

Needs and Uses: Section 208 of the Communications Act, provides that any person may file a complaint with the FCC regarding acts or omissions of common carriers subject to the Communications Act. This section obligates the FCC to serve such complaints on the affected carrier for response or resolution. Section 208 also obligates the FCC to investigate unsatisfied complaints. Sections 1.720 through 1.735 of the FCC rules were promulgated to implement section 208. The attached Report and Order, CC Docket No. 92-26, amends the FCC rules governing formal complaints to achieve more timely resolution of such actions. Specifically, the revised rules (1) eliminate certain pleading opportunities which do not appear particularly useful or necessary (e.g., routine replies to answers to complaints and replies to oppositions to motions would be discontinued); (2) provide for confidential treatment by opposing parties of certain materials produced through discovery; (3) discontinue the requirement that parties file with the FCC all materials produced through discovery; (4) accord the parties in formal complaint cases an absolute right to file briefs; and (5) authorize the staff to deliver verbal rulings on a variety of interlocutory matters (e.g., objections to discovery, briefing schedules, and submission of other record evidence). The information is used by the FCC to determine the sufficiency of the complaint and to resolve the merits of the dispute between the parties. If the collection of information is not conducted, the FCC will be unable to comply with the Congressional mandate under section 208 of the Communications Act that it provide a forum for the resolution of complaints against carriers.

Federal Communications Commission.

Donna R. Searcy,
Secretary.

[FR Doc. 93-11150 Filed 5-11-93; 8:45 am]

BILLING CODE 7812-01-M

[DA 93-519]

Comments Invited on Kentucky Public Safety Plan


The Commission has received the public safety radio communications plan for Kentucky (Region 17).

In accordance with the Commission's Memorandum Opinion and Order in General Docket 87-112, Region 17 consists of the State of Kentucky.

[DA 93-519]
Federal Communications Commission.
Donna R. Searcy, Secretary.
[FR Doc. 93–11153 Filed 5–11–93; 8:45 am]
BILLING CODE 6712–01–M

[DA 93–516]
Comments Invited on Missouri Public Safety Plan
The Commission has received the public safety radio communications plan for Missouri (Region 24).
In accordance with the Commission's Memorandum Opinion and Order in General Docket No. 87–112, Region 24 consists of the state of Missouri.
In accordance with the Commission's Memorandum Opinion and Order in General Docket 87–112, 3 FCC Rcd 905 (1987), at paragraph 54.
Commenters should send an original and five copies of comments to the Secretary, Federal Communications Commission, Washington, DC 20554 and should clearly identify them as submissions to PR Docket 93–132.
Questions regarding this public notice may be directed to Betty Woolford, Private Radio Bureau, (202) 632–6497 or Ray LaForge, Office of Engineering and Technology, (202) 653–8112.

FEDERAL DEPOSIT INSURANCE CORPORATION

Advertising of Interest and Dividends on Deposits
AGENCY: Federal Deposit Insurance Corporation (FDIC).
ACTION: Notice.
SUMMARY: The FDIC is withdrawing two non-codified documents:

- "Information Regarding Computation of Interest and Dividends on Deposits," and
- General Counsel's Opinion No. 1, "Advertising of Interest or Dividends on Deposits."

These documents were being withdrawn because the regulation which they interpret has been superseded by regulations issued by the Board of Governors of the Federal Reserve System.

EFFECTIVE DATE: June 21, 1993.


SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act
No collections of information pursuant to section 3504(b) of the Paperwork Reduction Act (44 U.S.C. 3501 et seq.) are contained in the notice. Consequently, no information has been submitted to the Office of Management and Budget for review.

Revocation of General Counsel's Opinion and Statement of Policy
The FDIC has therefore amended part 329 of its regulations by means of a final rule to remove § 329.3 upon the effective date of Regulation DD (June 21, 1993). Concomitant with the removal of § 329.3, the FDIC is withdrawing two non-codified interpretative documents:

- "Information Regarding Computation of Interest and Dividends on Deposits," 35 FR 5020 (March 24, 1970), and General Counsel's Opinion No. 1, "Advertising of Interest or Dividends on Deposits," 38 FR 28288 (October 11, 1973), amended at 53 FR 45978 (November 15, 1988). The statement of policy sets forth the FDIC's view of how the prohibition against inaccurate or misleading advertisements, currently found in § 329.3(f), applies to the disclosure of the method of compounding interest on time and savings deposits. General Counsel's Opinion No. 1 provides general guidance on the standards to follow in complying with the requirements of § 329.3. Both these documents will become outdated once § 329.3 is removed.

By order of the Board of Directors.
Dated at Washington, DC, this 4th day of May, 1993.
I do hereby determine the following areas of the State of North Carolina to have been affected adversely by this declared emergency:

The counties of Allegheny, Ashe, Buncombe, Burke, Caldwell, Cherokee, Clay, Cleveland, Davidson, Guilford, Henderson, Iredell, Macon, Madison, McDowell, Polk, Rutherford, Stokes, Surry, Watauga, Wilkes, and Yadkin for debris removal and emergency protective measures. (Already designated for assistance for required emergency measures for a period of five (5) days beginning on March 13 to open critical emergency access on collector roads and streets, and on minor and principal arterials roads for emergency vehicles.) This amendment does not modify the assistance pertaining to snow plowing activities authorized under the snow emergency declaration.

The counties of Beaufort, Brunswick, Carteret, Columbus, Craven, Dare, Davidson, Hyde, Lenoir, New Hanover, Pamlico for debris removal and emergency protective measures.

(Catalog of Federal Domestic Assistance No. 33.516, Disaster Assistance.)

James L. Witt, Director.

[FEDERAL EMERGENCY MANAGEMENT AGENCY (FEMA-987-DR)]

Oklahoma; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the State of Oklahoma (FEMA-987-DR), dated April 26, 1993, and related determinations.

EFFECTIVE DATE: April 26, 1993.

FOR FURTHER INFORMATION CONTACT:


SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated April 26, 1993, the President declared a major disaster under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5121 et seq.), as follows:

I have determined that the damage in certain areas of the State of Oklahoma, resulting from severe storms and tornadoes on April 24, 1993, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act ("the Stafford Act"). I, therefore, declare that such a major disaster exists in the State of Oklahoma.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes, such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Individual Assistance in the designated areas. You may request an amendment to this declaration for Public Assistance, if warranted. Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under the Stafford Act for Public Assistance will be limited to 75 percent of the total eligible costs.

The time period prescribed for the implementation of section 310(a), Priority to Certain Applications for Public Facility and Public Housing Assistance, 42 U.S.C. 5153, shall be for a period not to exceed six months after the date of this declaration.

Notice is hereby given that pursuant to the authority vested in the Director of the Federal Emergency Management Agency under Executive Order 12148, I
hereby appoint Graham Nance of the Federal Emergency Management Agency to act as the Federal Coordinating Officer for this declared disaster.

I do hereby determine the following areas of the State of Oklahoma to have been affected adversely by this declared major disaster:

Rogers County for Individual Assistance.
(Catalog of Federal Domestic Assistance No. 83.516, Disaster Assistance.)

James Lee Witt,
Director.

[FR Doc. 93–11229 Filed 5–11–93; 8:45 am]

BILLING CODE 8710–02–M

FEDERAL MARITIME COMMISSION

Agreement(s) Filed; City and County of San Francisco, et al.

The Federal Maritime Commission hereby gives notice of the filing of the following agreement(s) pursuant to section 5 of the Shipping Act of 1984. Interested parties may inspect and obtain a copy of each agreement at the Washington, DC Office of the Federal Maritime Commission, 800 North Capitol Street, NW., 9th Floor. Interested parties may submit comments on each agreement to the Secretary, Federal Maritime Commission, Washington, DC 20573, within 10 days after the date of the Federal Register in which this notice appears. The requirements for comments are found in §572.603 of title 46 of the Code of Federal Regulations. Interested persons should consult this section before communicating with the Commission regarding a pending agreement.

Agreement No.: 224–200767.

Synopsis: The agreement extends the term of the Agreement through June 30, 1993.

Title: Port of New York and New Jersey/Italia di Navigazione SPA Container Incentive Agreement.

Agreement No.: 224–200768.

Synopsis: The Agreement provides that the Port will pay Italia a container incentive of $20.00 for each import container and $40.00 for each export container moved through the Port’s marine terminals during calendar year 1993, provided each container is shipped by rail to or from points more than 260 miles from the port.

Title: Port of New York and New Jersey/Hanjin Shipping Container Incentive Agreement.

Synopsis: The Agreement provides that the Port will pay Hanjin a container incentive of $20.00 for each import container and $40.00 for each export container moved through the Port’s marine terminals during calendar year 1993, provided each container is shipped by rail to or from points more than 260 miles from the port.

Section 105(a)(2)(B) of the Child Abuse Prevention and Treatment Act of 1988 (the Act), as amended, requires the Department to publish proposed priorities for research on the causes, prevention, identification, treatment and cultural distinctions of child abuse and neglect; on appropriate, effective and culturally sensitive investigative, administrative and judicial procedures with respect to cases of child abuse and neglect; and for demonstration and service programs and projects designed to prevent, identify and treat child abuse and neglect.

Comments on these priorities and suggestions for other topics are invited. The actual solicitation of grant applications will be published separately, at a later date, in the Federal Register. Solicitations for contracts will be announced, at a later date, in the Commerce Business Daily. No proposals, concept papers or other forms of applications should be submitted at this time.

I. Background

The National Center on Child Abuse and Neglect (NCCAN) is located in the Administration on Children, Youth and Families of the Administration for Children and Families. NCCAN conducts activities designed to assist and enhance national, State and community efforts to prevent, identify and treat child abuse and neglect. These activities include: conducting research and demonstrations; supporting service improvement projects; gathering, analyzing and disseminating information through a national
clearinghouse; and providing grants to eligible States for developing, strengthening and carrying out child abuse and neglect prevention and treatment programs and programs relating to the investigation and prosecution of child abuse cases. In addition, the legislatively mandated Advisory Board on Child Abuse and Neglect and the Inter-Agency Task Force on Child Abuse and Neglect produce periodic reports regarding child abuse and neglect activities.

Pursuant to section 105(a)(2)(B) of the Child Abuse Prevention and Treatment Act of 1988 (the Act), as amended, this notice identifies proposed priorities for research on the causes, prevention, identification, treatment and cultural distinctions of child abuse and neglect; on appropriate, effective and culturally sensitive investigative, administrative and judicial procedures with respect to cases of child abuse and neglect; and for demonstration or service programs and projects designed to prevent, identify, and treat child abuse and neglect. It also identifies proposed topics to be discussed in symposia to be convened during fiscal year (FY) 1993. The proposed demonstration and service projects include priorities for innovative programs and other projects which show promise for addressing issues related to child maltreatment. Final research and demonstration priorities and symposia topics will take into consideration the public comments received in response to this Notice. The solicitation for grant applications will be published at a later date in the Federal Register; solicitations for contracts will appear later in the Commerce Business Daily.

In addition to projects funded under priority areas selected as a result of this announcement, NCCAN intends to continue funding for:
- The Clearinghouse on Child Abuse and Neglect Information;
- The National Information Clearinghouse for Infants With Disabilities and Life Threatening Conditions; and
- The implementation of a national data collection and analysis program for collecting data from official State reports on child abuse and neglect, as required by section 105(b) of the Act. Moreover, NCCAN will continue to support a competitively awarded contract to examine the incidence and prevalence of child abuse and neglect. NCCAN is also supporting a competitively awarded contract to plan and conduct the Tenth National Conference on Child Abuse and Neglect, which will take place in FY 1994. Other procurements include an evaluation of the nine NCCAN-funded demonstration projects for community-based prevention of physical child abuse and neglect; and the development and evaluation of training models and educational materials on the prevention of child abuse and neglect for homeless shelter staff and families in these shelters.

NCCAN will continue to support grants awarded in FY 1991 in response to the Federal Register announcement for the Emergency Child Abuse Prevention Services Grant program designed to provide services to children whose parents are substance abusers. Additionally, NCCAN has awarded a contract to provide technical assistance for implementation of these projects.

NCCAN is also actively pursuing Interagency Agreements to address collaborative efforts with members of the Inter-Agency Task Force on Child Abuse and Neglect. Examples of prior Interagency Agreements include those with the Maternal and Child Health Bureau for the development of child protective services infrastructure with the Pacific Basin jurisdictions, and with the Bureau of Indian Affairs for the development of a child protective services curriculum with a multidisciplinary focus on child abuse and neglect in Indian colleges and institutions of higher learning. The Task Force has also provided the information for the report, A Guide to Funding Resources for Child Abuse and Neglect and Family Violence Programs. The report, now in its second edition, is available through the Clearinghouse on Child Abuse and Neglect Information.


II. Recent Research and Demonstration Topics

Recently funded three-year research and demonstration projects supported by NCCAN in FYs 1991 and 1992 have addressed the following topics:

**NCCAN Priority Areas Funded in FY 1991**

- Research Projects:
  - Research on Juvenile Sexual Offenders
  - Graduate Research Fellowships in Child Abuse and Neglect in such areas as:
    - Why Do Some Children Tell? Factors Influencing Children's Disclosure of Intrafamilial Sexual Abuse?
    - Attitudinal Determinants of Juror Decision Making in Cases of Child Sexual Assault;
    - Is Child Maltreatment Reporting a Marker for Mortality Risk in Infants and Young Children;
    - Determinants of Economic Consequences of Child Sexual Abuse in Women;
    - Family Environment, Self-Concept, Motivation, and School Adaptation of Maltreated Children: A Process of Oriented Longitudinal Study;
    - An Exploratory Study of Reframing With Experiencing Abuse and Neglect;
    - The Social Worlds of Maltreated Children: Beyond the Parent-Child Dyad;
    - Child Maltreatment: Modes of Linkage Between Relationship and Disturbance and Psychopathology; and
    - Field Initiated Research on Child Abuse and Neglect in the areas of:
      - Prevention and Identification of Child Maltreatment in Children of Cocaine-Using Mothers;
      - Resilient Peer Training: A Community-Based Treatment to Improve the Social Effectiveness of Maltreating Parents and Preschool Victims;
      - A Longitudinal Study of Child Neglect;
      - Neighborhood Impact of Child Abuse and Neglect;
      - Juvenile and Adult Offending Behavior and Other Outcomes in a Cohort of Sexually Abused Boys: 20 Years Later.

**Demonstration Projects**

- Collaborative Arrangements Between State Child Welfare Agencies and State Title IV–A Agencies to Train Job Opportunity and Basic Skills (JOBS) Participants to Work as Child Protective Services Paraprofessionals; and
- National Resource Centers on Child Abuse and Neglect.

**NCCAN Priority Areas Funded in FY 1992**

- Research Projects:
• Field Initiated Research for Child Abuse and Neglect in the areas of:
  —Intensive Home Visitation: A Randomized Trial, Follow-up and Risk Assessment Study of Hawaii Healthy Start Program;
  —Child Maltreatment Recurrences Among Families Served by Child Protective Services;
  —A Treatment Outcome Study for Sexually Abused Preschool Children;
  —Functional Uses of Anatomical Dolls in Child Sexual Abuse Investigations.
• Graduate Research Fellowships in Child Abuse and Neglect in the areas of:
  —The Effects of a Child Welfare Agency Sibling Policy on Disrupted Placement of Foster Children;
  —The Relationship Between Child Sexual Abuse and Subsequent Parenting Agency as Mediated by Cognitive Factors;
  —Child Rearing Under Stress: An In-depth Analysis of At-risk Poor, Inner-City African-American Mothers Who Participated in Community-Based Child Abuse Prevention Programs;
  —Empowered Parent Education: The Effects of Involving At-Risk Parents in Planning and Implementation;
  —Defining Child Abuse in Frenzally Drug Exposed Infants;
  —Structured Educational Groups for Sexually Abused Children and Non-Offending Parents: A Preliminary Treatment Outcome Study;
  —Research on Hispanic Non-Offending Mothers: Abuse and Victimization;
  —Supportive Response Training for Parents of Sexually Abused Children;
  —Incestuous Offenders’ Maintenance of Child Sexual Abuse;
• Research on the Non-Offending Maternal Parent of Victims of Intrafamilial Child Sexual Abuse; and
• Infrastructure for the Support of Research on Child Abuse and Neglect in the areas of:
  —National Data Archive for Child Abuse and Neglect;
Demonstration Projects:
• New Field-Initiated Demonstrations and Replications of Successful Projects Addressing Child Abuse and Neglect in the areas of:
  —North Carolina Commission of Indian Affairs’ Child Abuse and Neglect Prevention, Intervention and Treatment Project;
  —Don’t Shake the Baby: Replication of a Successful Model.
• Culturally Sensitive Child Maltreatment Prevention Demonstration Programs for Populations of Differing Cultures;
• Model Approaches to Service Delivery to Combat Child Maltreatment in Rural Communities; and
• National Training Program for Effective Models of Child Sexual Abuse Treatment Programs.

NCCAN has also funded grants in earlier fiscal years for five-year periods that are currently ongoing. Examples include the nine demonstration projects for Community-Based Prevention of Physical Child Abuse and Neglect funded in FY 1989; five research projects for empirical evaluations of treatment approaches for child victims of physical or sexual abuse in FY 1990; and the implementation of the Consortium of Longitudinal Studies funded in FYs 1990 and 1991. NCCAN plans to continue support for the Consortium for Longitudinal Studies. More detailed information on prior and continuation projects supported by NCCAN as well as on other studies on child maltreatment are available through the National Data Archive on Child Abuse and Neglect Information, P.O. Box 1182, Washington, DC 20013.

III. Proposed Child Abuse and Neglect Research and Demonstration Priorities For FY 1993

The Administration for Children and Families (ACF) solicits comments and suggestions concerning each of the proposed priorities and symposia topics for FY 1993 described below. We also solicit suggestions for areas not covered in this announcement, but which are timely and relate to specific needs in the field of child abuse and neglect. Any suggestions for new priorities or topics should keep in mind the issues already being addressed in current projects, as listed above. Comments should also build on the current base of knowledge in child abuse and neglect and its prevention, identification, and treatment. Knowledge gained through proposed research and demonstration priorities should lead to improved services for children and families and increase the knowledge in the field. As specified in the proposed priority areas, we intend to pay special attention to issues of ethnic and cultural relevance in the design of research studies and demonstration projects as well as in the development of measures, evaluations and objectives.

All applications for demonstration priority areas are expected to have an evaluation component, as required by the legislation.

All applicants for research priority areas, including those for Graduate Research and Medical Research Fellowships in Child Abuse and Neglect, must provide an Assurance of Human Subjects Protection as specified in the policy described on the HHS Form 596. All applicants will be expected to address ethical issues pertaining to the projects they are proposing.

All successful applicants for both research and demonstration will be expected to follow an NCCAN-suggested format in the preparation of final program reports in order to achieve broader dissemination and successful utilization of findings by policymakers, practitioners, and researchers. Applications that are submitted in response to the final announcement will be subject to peer review.

All applicants should include plans to prepare data sets according to sound documentation practices to ensure the potential of these data sets for subsequent use by other researchers. A manual on The Preparation of Data Sets for Analysis and Dissemination: Technical Standards for Machine-Readable Data can be obtained through the National Data Archive on Child Abuse and Neglect located at Cornell University, Family Life Development Center, E200 MVR Hall, Ithaca, New York 14853-4401 (telephone: 607/255-7794). NCCAN also encourages the use of common data collection instruments across studies where applicable. The Consortium for Longitudinal Studies on Child Abuse and Neglect is developing common batteries of measures for use with children of different age groups. More information can be obtained through the Longitudinal Study Coordinating Center located at the University of North Carolina at Chapel Hill, Department of Social Medicine, CB# 7240, Wing D, Chapel Hill, North Carolina 27599-7240 (telephone: 919/962-1136).

The proposed research and demonstration priority areas have been developed as the result of literature reviews and findings from recently completed studies, information and suggestions received from the field including NCCAN-sponsored and co-sponsored symposia and workshops, the NCCAN Research, Demonstration and State Grants Programs Meetings, hearings convened by the Advisory Board on Child Abuse and Neglect, other Departmental organizations and professional associations.

Since the amount of Federal funds available for new grants in FY 1993 is limited, respondents are encouraged to recommend how proposed issues should be prioritized.

No acknowledgment will be made of the comments submitted in response to this notice, but all comments received by the deadline will be reviewed and
given thoughtful consideration in the preparation of the final funding priorities for child abuse and neglect activities in FY 1993. Copies of the final program announcement will be sent to all persons who comment on these proposed priorities.

A. Proposed Research Priorities

1. Field Initiated Research for Child Abuse and Neglect

The generation of new knowledge that promotes an understanding of critical issues in child abuse and neglect is essential in order to improve prevention, identification and treatment. This priority area proposes to support new research designed to carry out the legislative responsibilities established for the National Center on Child Abuse and Neglect by the Child Abuse Prevention and Treatment Act of 1988, as amended. These responsibilities include the conduct of research on the causes, prevention, identification, treatment and cultural distinctions of child abuse and neglect; and appropriate, effective and culturally sensitive investigative, administrative, and judicial procedures with respect to cases of child abuse and neglect, particularly child sexual abuse and exploitation.

Research areas to be addressed are those that will expand the current knowledge base, build on prior research, contribute to practice and provide insights into new approaches to the prevention and treatment of child maltreatment. The areas include, but are not limited to, the role of neighborhood safety factors in the etiology and reporting of child abuse and neglect; cultural factors in maltreatment; the treatment needs of maltreated children with disabilities and their families and the child protective services' (CPS) system response; and comparative studies on the cost benefits and effectiveness of home visitation programs for differing types of child maltreatment using volunteers or professionals.

The proposed research studies should be designed to address current and emerging issues that have direct application to the field of child abuse and neglect.

2. Graduate Research and Medical Research Fellowships in Child Abuse and Neglect

The research community has highlighted the need to draw new researchers into the field of child abuse and neglect. During FY's 1991 and 1992, NCCAN funded a total of 17 graduate research fellowships for doctoral candidates to complete dissertations addressing critical issues in child abuse and neglect. While many agencies offer research fellowships for a potentially broad spectrum of projects, the NCCAN research fellowship program is the only one whose sole aim is to foster the development of new child abuse and neglect researchers. For FY 1993, NCCAN proposes to expand the graduate research fellowship program to include individual research fellowships to graduate students at the pre-dissertation level as well as to medical students, residents or fellows engaged in empirical research projects.

Examples of the proposed questions to be addressed and issues to be studied for Graduate and Medical Research Fellowships include but are not limited to, the specific topics listed under the priority area on Field Initiated Research for Child Abuse and Neglect, and research on new medical screening and diagnostic techniques or treatments for child abuse and neglect. Applicants will be expected to identify any limitations in carrying out the research (e.g., obtaining the sample) or potential barriers to the completion of the study. Applicants may also propose secondary analyses of existing databases or conduct additional analyses of data within ongoing research projects to address new questions. When the proposed study is to be part of an ongoing research project at the institution, the study must be clearly distinguished from the other research.

Students seeking Graduate or Medical Research Fellowships include but are not limited to, doctoral candidates or medical students, residents or fellows in their sponsoring institutions and provide evidence of their status. All applicants must provide documentation that their faculty sponsor has endorsed the research proposal or project respectively. Proposals submitted by sponsoring institutions must include candidates' resumes outlining education, employment experience, conference presentations, papers and other publications, if any. Relevant information on the academic status of the candidate should also be included. A letter of support from a sponsoring faculty member must be provided for each graduate or medical student, medical resident or fellow seeking this Fellowship. All required assurances and certifications, including Certification of Protection of Human Subjects Assurances, are expected to be part of the application.

While an individual is considered to be the beneficiary of the grant support, awards would be made to eligible institutions on behalf of qualified candidates. Doctoral-level candidates in interdisciplinary programs and special education or early childhood education programs are also encouraged to apply as are medical students, residents or fellows participating in such programs. To be eligible to administer such a grant on behalf of the student, the institution must be fully accredited by one of the regional institutional accrediting commissions recognized by the U.S. Secretary of Education and the Council on Postsecondary Accreditation, the Accreditation Council for Graduate Medical Education, or the Liaison Committee for Medical Education as applicable. Students attending Historically Black Colleges and Universities, Native American institutions of higher learning, and other institutions of higher learning with a history of serving Hispanic and Asian populations would be encouraged to apply. There would be no overhead costs allowed for this program. The full amount of the stipend would go directly to the student, resident or fellow. No more than two awards per institution would be made. Awards would be for a 12-month period and would be used to cover stipends, dependent allowances, university fees and major costs for conducting the proposed project, including any necessary travel.

3. Research on Risk Assessment Systems

Risk assessment systems have been in use by Child Protective Services (CPS) agencies for the past ten years. Several child welfare organizations and nearly all of the State CPS agencies have been involved in the development and/or implementation of such systems. A few States maintain administrative units that conduct research, evaluation and training on risk assessment. At least 14 States are using Child Abuse and Neglect Basic State Grant funds to implement or improve their use of risk assessment systems.

From 1986 to the present, NCCAN has funded eight studies on risk assessment related to such issues as the following: screening decisions in CPS; development of a predictive screening model; improving cultural sensitivity in risk assessment; comparative analyses of risk assessment systems; the impact of investigations; and a study of high risk child abuse and neglect groups. In December 1991, NCCAN sponsored a Symposium on Risk Assessment in Child Protective Services to determine the state of the field and highlight future directions. The extensive background papers are available, and the proceedings are soon to be available from the Clearinghouse on Child Abuse and Neglect Information.
A recent NCCAN-sponsored analysis of State practices indicates that risk assessment is used mainly as a tool for guiding casework practice, for collecting pertinent information about the child and family, for classifying existing risk factors, and for service planning. About one-third of the States reported that they use risk assessment as a predictive tool.

Various risk assessment instruments are being used by CPS agencies across the country. Despite this widespread application of risk assessment in CPS practice and its potential for prediction of maltreatment, further research and development need to be carried out before risk assessment can be used with confidence as a comprehensive approach to effective CPS practice and administration. Under the pressure of high staff turnover, excessive caseloads, and increased reporting of more complex types of maltreatment, some agencies have sought to use these instruments and systems without the adequate preparatory training of staff. Sound protocols and operational procedures will help to address these practice problems. Concerns have also been expressed over the need for culturally sensitive risk assessment systems and the need to include strengths or positive case factors in models. Research on risk assessment should also address such areas as the validation of variables and outcome measures.

NCCAN seeks to build upon the current knowledge base in risk assessment systems to address the need for practice improvements. In this priority area, NCCAN proposes to support projects that would:

- Develop a framework for risk assessment systems which will establish a clear rationale for the use of these systems in child protective services practice based on:
  - A review of those State's statutes, regulations, agency policies, mission statements and philosophies which establish the rationale or govern the use of risk assessment systems; and
  - A determination of how risk assessment is implemented in these States, including a clarification of the purpose for its use and the circumstances under which it is used at the various decision points in CPS case management, and its implications for workload management and resource allocation, supervision and training, program evaluation and use of automation.
- Determine the comparative validity and effectiveness of different risk assessment designs and of specific factors, including family strengths and cultural differences, in predicting the likelihood of future maltreatment.

B. Proposed Demonstration and Service Priorities

Unlike the proposed priority areas for child abuse and neglect published in the Federal Register for FY 1992, NCCAN is not including Field Initiated Demonstration Programs to Address Child Abuse and Neglect as a proposed priority area for FY 1993. Due to limited funding available for FY 1993, NCCAN proposes to provide funding for clusters of grants under specific demonstration and service priority areas that build on prior efforts, are suggested by the legislation, and are already identified by the field. NCCAN plans to include a field-initiated demonstration priority area in future discretionary program announcements.

1. Innovation Approaches To Expand the Use of Volunteers in Child Abuse and Neglect Prevention, Intervention and Treatment Programs

Volunteers continue to be a vital community resource for the prevention and treatment of child abuse and neglect. They have been used extensively in child protection in such support activities as the provision of transportation, clerical assistance, and arranging for food and clothing donations. They have also been worked on effectively in public awareness programs, respite care, and substance abuse prevention and treatment programs. Several approaches for the utilization of volunteers, including those supported by NCCAN, have been piloted and fully implemented by the field. Examples include the use of volunteers in the now established roles of the court-appointed special advocate, guardian ad litem, and parent side.

Given the problem of scarce resources being faced by all levels of government and the nonprofit sector and the increasing needs of the field, NCCAN is interested in promoting the expansion of volunteer opportunities. NCCAN seeks to support this expansion through the development of innovative models which utilize volunteers in settings and activities where they have not previously been used. Collaborative and multidisciplinary approaches are encouraged and may include public-private partnerships.

There is a related need to identify, document and disseminate information on best practices for the recruitment, training and retention of volunteers in order to effectively and efficiently develop this valuable resource. The proposed demonstrations would include an evaluation, plans for the dissemination and utilization of findings through new networks, and manuals for replication of effective approaches in new locations.

2. Model Inter-Agency Collaborative Approaches to Prevent Maltreatment of Children With Disabilities

A number of studies have found that children with mental and physical disabilities are overly-represented in maltreated samples and preliminary studies have found a high incidence of maltreatment among children with disabilities (Ammerman et al., 1988 & 1991). Studies also suggest that many children with disabilities exhibit behaviors that are similar to those of maltreated children who do not have disabilities, indicating that some children with disabilities may be at high risk for child abuse and neglect.

There is a need to identify, develop or adapt model approaches to the prevention of maltreatment of children with disabilities. These approaches should address the unique needs of children with various types of disabilities and their families.

Specifically, the approaches should be sensitive to the severe behavioral problems that some children with disabilities may exhibit. They should also be sensitive to other factors of risk for maltreatment such as disruption in the formation of attachment, stress and frustration associated with the raising of children with disabilities, and the increased vulnerability of many of these children due to communication difficulties in revealing their possible maltreatment to others.

In this priority area, NCCAN proposes to support collaborative efforts for model programs for the prevention of maltreatment of children with disabilities. This would include collaboration with the Education and Training component of the State Protection and Advocacy System created by the Developmental Disabilities Assistance and Bill of Rights Act of 1990, as amended, and the State Interagency Coordinating Council for the early intervention program under Part H of the Individuals with Disabilities Education Act. Examples of products available for use include a training guide for Preventing Maltreatment of Children with Handicaps and Programs to Support Families of Children with Special Needs for Use in Head Start and Public School developed in 1985 and 1986 as a result of an Interagency Agreement between the Department of Education's Special Education Programs, the Administration
on Children, Youth and Families and the Administration on Developmental Disabilities. These demonstration programs may build on such materials developed or adapted from or linked with other community-based programs run by Head Start programs, school systems, University Affiliated Programs under the Developmental Disabilities Assistance and Bill of Rights Act of 1990, as amended, private agencies, hospitals, mental health centers, or Child Protective Services agencies. An evaluation component would be included and the program designed, as appropriate, to:

- Create community awareness and sensitivity to the prevention and intervention needs of children with disabilities who are maltreated through the use of brochures, oral presentations, and the media, including television, radio and newspapers;
- Mobilize local public and private agencies and resources to make provision for the prevention of child maltreatment as part of the systematic screening, early identification and referral of children with single and/or multiple disabilities and their families for appropriate prevention and intervention services;
- Make use of self-instructional training materials for the prevention of child maltreatment for use by families and community service agencies in the provision of early screening, identification, and referral of children with disabilities;
- Adopt a comprehensive and individualized approach to prevention in the assessment and a multi-component intervention strategy;
- Target various intervention strategies to remediate the high risk factors for maltreatment of children with various types of disabilities and parental/family stress and need for supportive services;
- Network with social, medical, mental health, and legal consultants and advocacy groups including State Protection and Advocacy Systems;
- Coordinate maltreatment prevention and intervention services among community-based agencies to meet the needs of children with disabilities and their families;
- Recognize the unique transportation needs of children with disabilities and ensure their accessibility to sites where preventive services are being delivered;
- Recognize the unique needs children with disabilities have for access to and accommodation by the legal system;
- Build on the strengths and community-based support system networks of the individual child and family (e.g., churches, service clubs, extended families, support groups, day programs, respite care, social and recreation facilities);
- Recruit, train and use volunteers and paraprofessionals for home visitation and provision of home-based support services.

These services may be implemented on a multi-county, State or regional basis. The proposed demonstrations would also include plans for the dissemination and utilization of findings through State and local CPS agencies, the State Protection and Advocacy Systems and related networks, and manuals for replication of effective approaches in other locations.


Infants and children with disabilities are particularly vulnerable to abuse and neglect, and many children develop disabilities because of abuse and neglect. The quality of program development, screening and assessment, diagnosis and referral, interagency case management, and services provided to meet the special needs of abused and neglected infants and children with disabilities and their families depends heavily on collaboration and coordination between State and local CPS agencies and State and local agencies that primarily serve children with disabilities.

There is a need to increase the knowledge and expertise of CPS workers and providers of services to children with disabilities in meeting the needs of maltreated infants and children with disabilities. NCCAN proposes to support joint training programs in order to develop such competence and coordination between agencies in addressing the unique needs of this population. The development of these training programs would require collaboration by State and local agencies in the field of child protection and services to children with disabilities. This would include collaboration with the State Protection and Advocacy System authorized by the Developmental Disabilities Assistance and Bill of Rights Act of 1990, as amended. The development of such training programs would be documented and include a strong evaluation component. The training would focus on techniques for the identification, intervention and/or treatment of abuse and neglect of infants and children with disabilities and their families.

The application for the proposed training program would be expected to describe the specific content areas to be addressed, show how these areas are related to the objective of improving coordination between State or local CPS agencies and State and local agencies serving children with disabilities and indicate how such improved coordination would improve the delivery of services to infants and children with disabilities and their families. The proposed demonstrations would also be required to include plans for the dissemination and utilization of the findings through the State and local CPS agencies, the State Protection and Advocacy Systems and related networks, and models for replication of effective training approaches.

4. Model Approaches to Training Professionals on Child Fatality Review Teams

According to the 1991 Annual Fifty State Survey conducted by the National Committee for the Prevention of Child Abuse (NCPCA), 1,383 children were registered as fatal victims of child maltreatment. The actual annual national total may be much higher. A large number of child fatalities are classified as accidents or unexplained deaths, rather than as deaths resulting from maltreatment. Undercounting and lack of knowledge about the circumstances of these deaths undermine prevention efforts.

Many agencies are charged with the investigation of a child’s death and may not recognize the case as suspicious if sufficient information is unavailable. If medical personnel are unfamiliar with signs of child abuse and neglect, the death may be attributed to natural causes. In the absence of an autopsy or an examination by a coroner or medical examiner who is trained in forensic techniques, evidence of maltreatment may go undetected. Further, lack of coordination and sharing of information among agencies and across multiple jurisdictions and concerns over issues of confidentiality often impede the process of correct identification.

A growing number of counties and States have begun to take action to develop strategies for reviewing child deaths in order to more effectively respond to and ultimately prevent child maltreatment fatalities. Currently 26 States have established State and/or local multi-agency teams and half of the remaining States are actively pursuing team development.

The importance of child fatality review is emphasized in the recent
reauthorization of the Child Abuse Prevention and Treatment Act, as amended. Within two years of enactment of the legislation, the Advisory Board on Child Abuse and Neglect must provide a report to Congress with recommendations for a national policy designed to reduce and prevent child maltreatment-related deaths. The Advisory Board has been highlighting the importance of this issue in its recent reports and held a hearing on child fatalities in the Spring of 1992. The law also requires that NCCAN include information on the number of deaths due to child abuse and neglect in its national incidence study and that States, under the basic State grant program, include information on special interagency child fatality review panels in their State program plans. In addition, the purpose of the Children’s Justice Act program has been expanded to require that State task forces address the handling of cases of suspected child maltreatment-related fatalities.

The Department has responded to and initiated other efforts in support of the establishment of child fatality review panels. One of the Healthy People 2000 National Health Promotion and Disease Prevention Objectives is “to extend to at least 45 States implementation of unexplained child death review systems.”

Findings from the Child Maltreatment Fatalities Project, a collaborative effort of the American Bar Association (ABA) and the American Academy of Pediatrics (AAP), funded by the Robert Wood Johnson Foundation, identified two major models of fatality review committees: Intra-agency committees, which may be interdisciplinary, often formed for internal review purposes to identify problems and propose solutions within a single agency; and inter-agency, multi-disciplinary review committees with a broader structure and purpose. Reports from the project are available from the ABA. The National Center for Prosecution of Child Abuse sponsors national conferences, provides basic training, and publishes materials on child maltreatment fatalities. In a recent issue of Update published by that Center, Dr. Michael Durfee, an advocate for multi-agency coordination on suspicious child deaths, reports that the core team members should include the prosecuting attorney, the coroner or medical examiner, representatives of law enforcement, health and child protective services. Additional members may be from the school, preschool, probation, parole, mental health, fire department, emergency room, the emergency medical technician and the child advocate.

In this priority area, NCCAN seeks to encourage efficient and effective child fatality reviews at the local and State levels by supporting the development of model approaches to the training of professionals who are members of interdisciplinary, child fatality review teams. Such training programs would include, but not be limited to, the development of a curriculum on the roles and responsibilities of the members; guidelines and procedures for conducting comprehensive investigations, including internal requirements and interagency protocols and procedures for appropriate sharing of information. The development of these training programs must be documented and include a strong evaluation component. The training program should also include an annotated bibliography and resource manual on relevant forensic issues.

C. Symposia

In addition to the above activities, NCCAN proposes to convene symposia in FY 1993 with selected experts on subject areas of critical concern to the field of child abuse and neglect. The selection of topics for the symposia will focus on issues on which some research and demonstration efforts have occurred, but for which there is no clear direction for further development. The purpose of each symposium is to review what is known to the field, but needs further exploration, and to identify areas about which little is known and which require closer examination. The symposia should result in recommendations for multi-year strategies for further exploring some topics and for identifying new areas for examination. This will be accomplished by bringing together small groups of experts who will assess the major issues and identify trends and problems in the field. Substantive reports of publishable quality will be prepared based upon the discussions during, and findings from, the symposia. Comments are requested on the following symposia topics which NCCAN proposes to address in FY 1993:

- Evaluation of Prevention Programs for Parents of Newborns;
- Recruitment, Background Checks, Training and Retention of Volunteers in Youth-Serving Programs; and
- Findings from Recently Completed Research and Demonstration Grants on Family Functioning of Neglectful Families and Diagnosing and Treating Chronic Neglect.

In addition to those cited above, practitioners and researchers are encouraged to propose other relevant subjects for symposia deliberations.

(Catalog of Federal Domestic Assistance Program Number 93.670, Child Abuse and Neglect Prevention and Treatment.)


Joseph A. Mottola,
Acting Commissioner, Administration on Children, Youth and Families.

[FR Doc. 93–11264 Filed 5–11–93; 8:45 am]
BILIND CODE: 4184–01–M

Health Resources and Services Administration

Availability of Funds for New Community and Migrant Health Centers, Expanded Community and Migrant Health Center Activities and Planning Grants for Future Community Health Centers

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of Availability of Funds.

SUMMARY: The Health Resources and Services Administration (HRSA) announces the availability of discretionary grant funds of approximately $18 million in fiscal year (FY) 1993 under sections 330 and 329 of the Public Health Service (PHS) Act to establish new community health centers (CHCs) and migrant health centers (MHCs), to expand existing C/MHCs, and to award a limited number of planning grants to support future CHCs. For more than twenty-five years, the C/MHC programs have been working toward ensuring the availability and accessibility of essential primary health services to those individuals who have the most limited access to services. The goal of the C/MHC New Start and Expansion strategy is to extend primary health services to a significant portion of the population currently without primary health services by supporting the development and maintenance of systems of care in areas where such systems are lacking or inadequate.

The PHS is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a PHS-led national activity. The health center program directly addresses: the Healthy People 2000 objectives by improving access to preventive and primary care services for underserved populations, especially minority and other disadvantaged populations. Potential applicants may obtain a copy of Healthy People 2000 [Full Report:...

ADDRESSES: The PHS Regional Grants Management Officers (RGMOs) whose names and addresses are provided in the appendix to this document are responsible for distributing application kits and guidance (Form PHS 5161–1 with revised face sheets DHHS Form 424, as approved by the Office of Management and Budget (OMB) under control number 0937–0189), and completed applications must be submitted to them. Potential applicants, either existing or new organizations, should also contact the appropriate RGMO to obtain information about the letter of interest process. Applicants are encouraged to submit a letter of interest. Regional offices will use the letters of interest to assist communities in the development of their applications and to direct these communities to the appropriate and available resources. The RGMO can also provide assistance on business management issues.

DATES: Applications are due June 1, 1993. Applications shall be considered to have met the deadline if they are: (1) Received on or before the deadline date; or (2) postmarked before the deadline date and received in time for orderly processing. Untimely applications will be returned to the applicant. Applicants should obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service or request a legibly dated U.S. Postal Service postmark. Private metered postmarks shall not be accepted as proof of timely mailing. The application deadline for this program was published at 58 FR 19827 on April 19, 1993.

FOR FURTHER INFORMATION CONTACT: For general program information and technical assistance, contact Richard C. Bohrer, Director, Division of Community and Migrant Health, 5600 Fishers Lane, room 7A–55, Rockville, MD 20857 (301) 443–2260.

SUPPLEMENTARY INFORMATION:

1. Community Health Centers

Grant Amounts

Approximately $15.7 million in discretionary grants to establish CHCs in new geographic areas and/or to expand existing CHCs into new or existing geographic areas will be made available under section 330 of the PHS Act (42 U.S.C. 254c). Of the approximately $15.7 million available, approximately half will be directed to new service areas and half will go toward expanding capacity (i.e., increasing the number of new patients served) of existing CHCs within their current service areas. In addition, approximately $500,000 will be made available to support a limited number of planning grants under Section 330(b) of the PHS Act.

Number of Awards

Approximately 40 to 50 Section 330 awards will be made, ranging up to $700,000. Awards will be made for a one year budget period. Project periods for new CHCs will be for up to two years, while expansion grants will have project periods consistent with the ongoing grant. In addition, approximately 10 to 12 planning grants will be awarded, ranging from $25,000 to $40,000. Awards for planning grants will be made for one year and will not, in any way, commit the PHS to support the applicant for additional planning grants or for future operational funding.

Eligible Applicants

Eligible applicants for new CHCs are public or private nonprofit entities whose proposed service areas are not currently being served by a federally funded CHC. The proposed service area must be a defined geographic area or population which is federally designated, in whole or in part, as a medically underserved area (MUA) or medically underserved population (MUP). Applicants must be prepared to provide the comprehensive primary health services required under section 330, and supplemental services necessary to assure that required primary health services are provided effectively.

Eligible applicants for CHC expansions must either be: (1) Current recipients of section 330 funds or (2) recipients of section 329 funds requesting section 330 support for primary health services to other than migrant and seasonal farmworkers and their families. The applicant's proposed delivery system in conjunction with its current delivery capacity must provide the comprehensive primary health services required under section 330, and supplemental services necessary to assure that required primary health care services are provided effectively.

Eligible applicants for CHC planning grants must either be: (1) Current recipients of section 330 funds or (2) recipients of section 329 funds requesting section 330 support for primary health services to other than migrant and seasonal farmworkers and their families. The applicant's proposed delivery system in conjunction with its current delivery capacity must provide the comprehensive primary health services required under section 330, and supplemental services necessary to assure that required primary health care services are provided effectively.

Eligible applicants for CHC planning grants must be a defined geographic area or population which is federally designated, in whole or in part, as a MUA/MUP. If the area/population is not currently designated, the applicant must provide documentation that the request has been submitted to the Bureau of Primary Health Care (must be received, or postmarked, by April 1, 1993 for applicant to be eligible for review). Applicants must provide a detailed plan that demonstrates how the applicant will develop the comprehensive primary health services required under section 330, and the supplemental services necessary to assure that required primary health services are provided effectively.

Criteria for Evaluation

When determining whether Federal support will be made available for new, expansion or planning grants for CHCs, the Department will review the applications for compliance with standard criteria stipulated in the program regulations (42 CFR 51c.305 for operating CHCs and 42 CFR 51c.204 for planning grants). These include:

(a) The relative need of the populations to be served for the services to be provided based on the following indicators:

For Urban Applicants

(1) Percentage of the population with incomes below 200 percent of the official poverty level;
(2) A minority population of 25 percent or more;
(3) A shortage of necessary primary care health professionals to meet the needs of the target population; and
(4) Other documented community health issues such as a high unemployment rate, high percentage of uninsured population, high growth rate of minority/special populations, high teenage pregnancy rate, high mortality rates due to specific diseases, late entry into prenatal care, high percentage geriatric population, high infant mortality rate, high percentage of low birthweight, cultural/language barriers, or excessive travel time/distance to next nearest source of primary care.

For Rural Applicants

(1) Percentage of the population with incomes below 200 percent of the official poverty level; (2) geographic barriers based on average travel time/distance to next nearest source of primary care that is accessible to Medicaid recipients and/or uninsured low income people in need of a sliding fee schedule; (3) shortage of necessary primary care health professionals to meet the needs of the population; and
(4) other documented community health issues such as a high unemployment rate, high percentage of uninsured population, high growth rate of minority/special populations, high teenage pregnancy rate, high morbidity rates due to specific diseases, late entry into prenatal care, high percentage geriatric population, high infant mortality rate, high percentage of low birthweight, cultural/language barriers, or a high percentage minority population; and

(b) The extent to which the applicant's project plan for new starts, expansions or planning grants for CHCs meets the program requirements:

For CHC New Start and Expansions in New Service Areas

(1) The applicant's capability in the following health services/clinical management areas: (i) A health care plan responsive to community needs, i.e., a plan that addresses the priority health problems of the user/service area population; (ii) provision of patient case management and the assurance of continuity of care; (iii) a quality assurance program and an appropriate number and mix of primary care physicians, non-physician primary care providers and clinical support staff; and (iv) provision of translation services—if a substantial number of the individuals in the population served by a center are of limited English-speaking ability, the services of appropriate personnel fluent in the language spoken by a predominant number of such individuals is necessary;

(2) The degree to which the applicant ensures that its governing board is appropriately structured and has by-laws reflecting all its functions and responsibilities. A public entity must be able to meet all governance requirements or have an acceptable coapplicant board (governing boards of public centers by statute are not required to set general policies for the center);

(3) The administrative and management capability of the applicant, particularly the extent to which center operations will emphasize efficiency of operations and sound financial management;

(4) The degree to which the applicant intends to integrate its services with other Federal programs or projects, as well as the degree of collaboration with State and local health departments, health professions training programs, and other health and social services providers; and 3

(5) Whether the proposed expansion will result in new patients being served through a new access point in an MUA/MUP not being served by a Section 329/330 project. If the area/population is not currently designated, applicant must provide documentation that the request has been submitted to the Bureau of Primary Health Care (must be received, or postmarked, by April 1, 1993 for applicant to be eligible for review).

For CHC Expansions in an Existing Service Area

Applicants must demonstrate how the proposed CHC expansion will result in new patients being served. Applicants will be evaluated according to the following criteria:

(1) The extent to which the grantee justifies a patient demand in excess of what is reasonable for the current organization to serve;

(2) The extent to which the clinical component of the proposed expansion plan is responsive to community needs, i.e., plan addresses the priority health problems of the new patients to be served;

(3) The extent to which the proposed expansion plan is a reasonable and cost-effective solution to meet the projected demand; and

(4) The extent to which the budget is reasonable and appropriate and corresponds to the objective of the request for funds.

For CHC Planning Grants

Planning grants are available to provide developmental assistance in such areas as: leadership; strategic and operational plans; and clinical and administrative structures. Although the awarding of a planning grant does not commit the PHS to support the applicant for additional planning grants or for operational funding, the purpose of a planning grant award is to aid a community in the development of a future Section 330 project. Applicants will be evaluated according to the following criteria:

(1) The applicant's capability to develop a plan that addresses the following health services/clinical management areas: (i) A health care plan responsive to community needs, i.e., a plan that addresses the priority health problems of the user/service area population; (ii) provision of patient case management and the assurance of continuity of care; (iii) a quality assurance program and an appropriate number and mix of primary care physicians, non-physician primary care providers and clinical support staff; and (iv) provision of translation services—if a substantial number of the individuals in the population served by a center are of limited English-speaking ability, the services of appropriate personnel fluent in the language spoken by a predominant number of such individuals is necessary;

(2) The degree to which the applicant proposes a plan to ensure that it can develop a governing board that is appropriately structured and has by-laws reflecting all its functions and responsibilities. A public entity must be able to meet all governance requirements or have an acceptable coapplicant board (governing boards of public centers by statute are not required to set general policies for the center);

(3) The applicant provides a plan that demonstrates how the organization will develop its administrative and management capability, particularly the extent to which center operations will emphasize efficiency of operations and sound financial management; and

(4) The degree to which the applicant provides a plan to integrate its services with other Federal programs or projects, as well as the degree of collaboration with State and local health departments, health professions training programs, and other health and social services providers.

The HRSA hopes to achieve a wide geographic dispersion of awards. Contingent upon the outcome of the review process, grant awards will be made in such a manner as to achieve a distribution of resources throughout the country.

2. Migrant Health Centers

Grant Amounts

Approximately $1.8 million in discretionary grants to establish new MH centers or programs and/or to expand the capacity of existing MH centers or programs will be made available under section 329 of the PHS Act (42 U.S.C. 254b). Of the $1.8 million available, approximately half will be directed to new service areas and half will go toward expanding capacity (i.e., increasing the number of new patients served) of existing MH centers or programs within their current service areas.

Number of Awards

A total of approximately 10 awards will be made for new centers, programs and expansions, ranging from $50,000 to $300,000. Awards will be made for a one year budget period, with project periods of up to two years.

Eligible Applicants

Migrant health "centers" and "programs" have different requirements under the authorizing legislation and its implementing regulations. MH
“centers” must offer a full range of specified primary and supplemental services and serve a “high impact area”, i.e., an area having not less than 4,000 migratory agricultural workers and seasonal workers residing in its boundaries for more than two months in any calendar year. (See section 329(d)(1)(A), PHS Act, and 42 CFR part 56, subpart G). On the other hand, MH “programs” may be funded in areas where there is no MH “center” and in which not more than 4,000 migratory agricultural workers and their families reside for more than two months. The range of services which a “program” must provide is more limited than those of a “center”. (See section 329(d)(1)(B), PHS Act, and 42 CFR part 56, subpart F).

Eligible applicants for new starts of MH centers or programs are public or private nonprofit entities whose proposed service area is not currently served by a federally funded MH center or program. For MH centers, applicants must be prepared to provide comprehensive primary health services to migrant and seasonal farmworkers and their families in a defined service area as required under section 329, and supplemental services necessary to assure the effectiveness of required primary health services. For MH programs, applicants must be prepared to make arrangements with existing health care providers to furnish primary health services (although, as noted, the services required of “programs” are more limited).

Eligible applicants for expansions of MH centers or programs must either be: (1) Current recipients of section 329 funds or (2) recipients of section 330 funds requesting section 329 support for primary health services to migrant and seasonal farmworkers and their families. The applicant’s proposed delivery system in conjunction with its current delivery capacity must provide comprehensive primary health services to migrant and seasonal farmworkers and their families as required under section 329, and supplemental services necessary to assure the effectiveness of required primary health services.

**Criteria for Evaluation**

Eligible applicants for new and expansion MH grants will be evaluated in accordance with the standard criteria stipulated in the program regulations (42 CFR 56.303 for MH “centers” and 42 CFR 56.604 for MH “programs”). These include:

(a) The relative need of the population to be served for the services to be provided, specifically: (1) Number of migrant farmworkers and length of stay in the service area (The Atlas Of State Profiles Which Estimate Number of MSFW will be used as the data source). Potential applicants may obtain a copy through the National Clearinghouse for Primary Care Information, 8201 Greensboro Drive, suite 600, McLean, Va. 22102 (Telephone: (703) 621-8955. Ext. 316); (2) number of seasonal farmworkers in the service area (The Atlas Of State Profiles Which Estimate Number of MSFW will be used as the data source.); (3) seasonality of the service area, i.e., the number of migrant farmworkers present in the service area and their length of stay; (4) a shortage of necessary and accessible primary care health professionals to meet the needs of the migrant population; (5) documented increases in the number of migrant and seasonal farmworkers in the service area of 20 percent or more in the last five years; and (6) other documented community health issues such as disparities in health status, environmental health problems, cultural/language barriers, high rate of HIV/STDs, high substance abuse rate, high teen pregnancy rate, high infant mortality rate, high percentage low birthweight, high poverty rate, high rate of dental disease, and high tuberculosis (TB) rate among migrant and seasonal farmworkers in the area as required under section 329, and (7) the extent to which the proposed expansion plan is a reasonable and cost-effective solution to meet the projected demand; and

(b) The extent to which the applicant’s project plan meets the program requirements:

For New Start and Expansions of MH Centers or Programs in New Service Areas

(1) The applicant’s capability in the following health services/clinical management areas: (i) A health care plan responsive to community needs, i.e., a plan that addresses the priority health problems of the user/service area population; (ii) provision of patient case management and the assurance of continuity of care; (iii) a quality assurance program and an appropriate number and mix of primary care physicians, non-physician primary care providers and clinical support staff; and (iv) provision of outreach, health education, health promotion services, environmental health services, translation services—if a substantial number of the individuals in the population served by a center are of limited English-speaking ability, the services of appropriate personnel fluent in the language spoken by a predominant number of such individuals is necessary, and transportation services, if appropriate;

(2) The degree to which the applicant ensures that its governing board is appropriately structured and has by-laws reflecting all its functions and responsibilities. A public entity must meet all governance requirements or have an acceptable co-applicant board (governing boards of public centers by statute are not required to set general policies for the center);

(3) The administrative and management capability of the applicant, particularly the extent to which center operations will emphasize efficiency of operations and sound financial management;

(4) The degree to which the applicant intends to integrate its services with other Federal programs or projects, as well as the degree of collaboration with State and local health departments, health professions training programs, and other health and social services providers; and

(5) Whether the proposed expansion will result in new patients being served through a new geographic access point with 100 percent of the new patients coming from the migrant/seasonal farmworker target population in an area currently not being served.

For Expansions of MH Centers or Programs in an Existing Service Area

Applicants must demonstrate how the proposed expansion will result in new patients being served. Applicants will be evaluated according to the following criteria:

(1) The extent to which the grantee justifies a patient demand in excess of what is reasonable for the current organization to serve;

(2) The extent to which the clinical component of the proposed expansion plan is responsive to community needs, i.e., the plan addresses the priority health problems of the new patients to be served;

(3) The extent to which the proposed expansion plan is a reasonable and cost-effective solution to meet the projected demand; and

(4) The extent to which the budget is reasonable and appropriate and corresponds to the objective of the request for funds.

The HRSA hopes to achieve a wide geographic dispersion of awards. Contingent upon the outcome of the review process, grant awards will be made in such a manner as to achieve a distribution of resources throughout the country.

**Letter(s) of Interest**

All organizations interested in applying for funds under this announcement are encouraged to submit a letter of interest to the appropriate Regional Office with copies forwarded to the appropriate State/Regional Primary Care Association (PCA) and...
State Cooperative Agreement (CA) agency by March 15, 1993. Potential applicants, either existing or new organizations, should contact the appropriate RGMO to obtain information about the letter of interest process. Letters of interest will be used by the Regional Offices to assist communities in the development of their applications and to direct these communities to the appropriate and available resources.

Other Award Information

All grants to be awarded under this notice are subject to the provisions of Executive Order 12372, as implemented by 45 CFR part 100, which allows States the option of setting up a system for reviewing applications from within their States for assistance under certain Federal programs. The application kit will contain a listing of States which have chosen to set up a review system and will identify a State Single Point of Contact (SPOC) in each State for the review. Applicants (other than federally-recognized Indian tribal governments) should contact their SPOCs as early as possible to alert them to the prospective applications and receive any necessary instructions on State process. For proposed projects serving more than one State, the applicant is advised to contact the SPOC of each affected State. State process recommendations should be submitted to the appropriate Regional Office (see Appendix). The due date for State process recommendations is 60 days after the appropriate application deadline date. The Bureau of Primary Health Care does not guarantee that it will accommodate or explain its response to State process recommendations received after this date.

Public Health System Reporting Requirement

These programs are subject to the Public Health System Reporting Requirement, PHS Circular 92.01. Reporting requirements have been approved by the OMB—OFR 92–015. Under this requirement, the community-based nongovernmental applicant must prepare and submit a Public Health System Impact Statement (PHSIS). The PHSIS is intended to provide information to State and local health officials to keep them apportioned of proposed health services grant applications submitted by community-based nongovernmental organizations within their jurisdictions.

Community-based nongovernmental applicants are required to submit the following information to the head of the appropriate State and local health agencies in the area(s) to be impacted no later than the Federal application receipt due date: (1) A copy of the face page of the application (SF 424); and (2) a summary of the project (PHSIS), not to exceed one page, which provides a description of the population to be served, a summary of the services to be provided and a description of the coordination planned with the appropriate State or local health agencies.

In the OMB Catalog of Federal Domestic Assistance, the number for the Community Health Center program is listed as 93.224 and the number for the Migrant Health Center program is listed as 93.246.

Dated: March 26, 1993.

Robert G. Harmon, Administrator.

Appendix—Regional Grants Management Officers

Region I: Mary O'Brien, Grants Management Officer, PHS Regional Office I, John F. Kennedy Federal Building, Boston, MA, 02203, (617) 565–1482

Region II: Steven Wong, Grants Management Officer, PHS Regional Office II, Room 3300, 26 Federal Plaza, New York, NY 10278, (212) 284–4496

Region III: Martin Bree, Acting Grants Management Officer, PHS Regional Office III, P.O. Box 13716, Philadelphia, PA 19101, (215) 596–6653

Region IV: Wayne Cutchens, Grants Management Officer, PHS Regional Office IV, Room 1106, 101 Marietta Tower, Atlanta, GA 30323, (404) 331–2597

Region V: Lawrence Poole, Grants Management Officer, PHS Regional Office V, 105 West Adams Street, 17th Floor, Chicago, IL 60603, (312) 353–8700

Region VI: Joyce Bailey, Grants Management Officer, PHS Regional Office VI, 1200 Main Tower, Dallas, TX 75202, (214) 767–3865

Region VII: Michael Rowland, Grants Management Officer, PHS Regional Office VII, Room 501, 601 East 12th Street, Kansas City, MO 64106, (816) 426–5841

Region VIII: Susan Jaworowski, Grants Management Officer, PHS Regional Office VIII, 1961 Stout Street, Denver, CO 80224, (303) 844–4461

Region IX: Al Tevis, Grants Management Officer, PHS Regional Office IX, 50 United Nations Plaza, San Francisco, CA 94102, (415) 556–2595 Region X: James Tipton, Grants Management Officer, PHS Regional Office X, Mail Stop RX 20, 2291 Sixth Avenue, Seattle, WA 98121, (206) 553–7997

[FR Doc. 93–11199 Filed 5–19–93; 8:45 am]

BILLING CODE 4160–15–P

National Institutes of Health

National Institute on Drug Abuse: Announcement of Intent to Enter a Cooperative Research and Development Agreement (CRADA)

In the matter of Formulation, Preclinical and Clinical Development and New Drug Application Submission for FDA Approval of Buprenorphine and Buprenorphine Combined with Naloxone as Treatment Medications for Opiate Dependence with Reckitt & Colman Pharmaceuticals, Inc.

AGENCY: National Institutes of Health, PHS, DHHS.

ACTION: Notice of intent to award a cooperative research and development agreement and request for comment.

SUMMARY: The National Institute on Drug Abuse, a component of the National Institutes of Health, is contemplating a Cooperative Research and Development Agreement with Reckitt & Colman Pharmaceuticals, Inc., for a collaboration which can effectively pursue the formulation, preclinical and clinical development, and New Drug Application (NDA) submission of multiple, rapidly absorbed, sublingual dosage forms (liquid and/or tablet) containing (1) buprenorphine and naloxone and (2) as medications for the treatment of opiate dependence. The National Institute on Drug Abuse (NIDA) believes that sublingually administered buprenorphine, both in combination with naloxone or alone, may be effective in the treatment of individuals dependent on opiate narcotics.

DATES: In view of the critical need to develop new treatment agents for opiate dependence to opiates, this notice is active until June 11, 1993. Unless within 30 days from the date of publication, the NIH receives written evidence and argument that establishes that the entering into a CRADA with Reckitt & Colman Pharmaceuticals, Inc. would not be consistent with the requirements of the Federal Technology Transfer Act of 1986 and Executive Order 12591 of October 10, 1987 and the selective criteria listed below, NIH will continue to proceed with consideration of this proposal.

ADDRESSES: Questions about this notice may be addressed to Lee Cummings, J.D., or Paul A. Coula, Ph.D., Medications Development Division, NIDA, room 11 A–55, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, (301) 443–1420 from whom further information may be obtained.

SUPPLEMENTARY INFORMATION: The National Institute on Drug Abuse has
received a proposal for collaboration for the development of the above described products from Reckitt Colman Pharmaceuticals, Inc. Buprenorphine is a novel compound which has shown promise in the treatment of persons dependent on heroin and other opiates. Inasmuch as buprenorphine and buprenorphine combined with naloxone have not been approved for the treatment of opiate dependence, the Government seeks to complete the formulation, preclinical and clinical development, and NDA submission(s) for FDA approval of a sublingual formulation for that indication. In this regard, the completion of the formulation, preclinical and clinical development of buprenorphine in combination with naloxone, and of buprenorphine alone are dual requirements to be addressed by the collaborator.

Buprenorphine is currently approved for marketing in the United States solely as a parenteral analgesic (at doses substantially lower than those needed for the treatment of opiate dependence) and in Europe and elsewhere as both a sublingually and parenterally administered analgesic. Substantial research and development activities must be undertaken by the Collaborator and NIDA to bring buprenorphine and buprenorphine with naloxone to marketable status in the United States for the indication of treatment of opiate dependence.

Selection factors of importance to NIDA include:

1. Access to a proprietary database covering the long-term pre-clinical toxicity (including lifetime animal studies) for buprenorphine at dose levels relevant to the indication for treatment of opiate dependence. Access or permission to cross-reference an existing data base from Reckitt Colman Pharmaceuticals, Inc. may be prerequisite for the conduct of long term clinical trials.

2. Agreement to bear the financial and organizational costs of formulating and supplying appropriate buprenorphine and buprenorphine combined with naloxone dosage forms and matching placebo as necessary to allow NIDA to complete those trials deemed necessary for regulatory approval for the indication of opiate dependence.

3. Agreement to bear a significant portion of the financial and organizational costs of analysis, report writing and assembly of relevant data (whether derived from company studies or NIDA clinical trials) as necessary to secure regulatory approval for these dosage forms for this indication in the United States. No NIH funding may be provided to a collaborator under a CRADA, therefore, the collaborator will bear the financial and organizational costs of assembling all necessary NDA(s), including those requirements of items (1) and (2), above.

4. Agreement to follow applicable NIH CRADA policies.

Based on the present record, NIDA believes that it is in the best interest of the public to enter into a CRADA with Reckitt Colman Pharmaceuticals, Inc. for the indicated study. NIDA is providing, via this notice, the opportunity for other potential collaborators to comment upon this course of action and to propose alternative collaborations which could be considered more advantageous to NIDA.

Dated: May 6, 1993.

Reid G. Adler,
Director, Office of Technology Transfer
[FR Doc. 93-11129 Filed 5-11-93; 8:45 am]
BILLING CODE 4160-29-M

Social Security Administration

Statement of Organization, Functions and Delegations of Authority

Part S of the Statement of Organization, Functions and Delegations of Authority for the Department of Health and Human Services covers the Social Security Administration. Chapter S2 covers the Office of the Deputy Commissioner, Operations; Subchapter S2H covers the Office of Disability and International Operations (ODIO). Notice is given of the following changes in ODIO. In the Office of Disability Operations (ODO), the number of Process Divisions is decreased from five to four. Subchapter S2H is changed as follows:

Section S2H.19 The Office of Disability and International Operations—Organization:

D. The Office of Disability Operations (S2HA). Delete the comma and number 5 to leave:

1. The Process Divisions (S2HA1,2,3,4).

Section S2H.20 The Office of Disability and International Operations—Functions:

D. The Office of Disability Operations (ODO) (S2HA). Delete the comma and number 5 to leave:

1. The Process Divisions (S2HA1,2,3,4).


Ruth A. Pierce,
Deputy Commissioner for Human Resources.
[FR Doc. 93-11149 Filed 5-11-93; 8:45 am]
BILLING CODE 4160-29-M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management
[MT-070-4333-04]

Implementation of Federal Fees at Log Gulch and Departure Point Recreation Sites, Holter Lake, Headwaters Resource Area, MT

AGENCY: Butte District Office, Bureau of Land Management, DOI.

ACTION: Imposition of federal recreation fees to be charged at Log Gulch and Departure Point sites.

SUMMARY: Effective May 8, 1993, federal fees will be charged to all visitors at Log Gulch and Departure Point Recreation Sites at Holter Lake in Lewis and Clark County, Montana. Fees at both sites are as follows:

- Day-use=$2.00/vehicle
- Camping=$6.00/vehicle (includes day-use fee)
- Seasonal Day-use Pass = $25.00/vehicle
- Group Picnic Reservation = $25.00/group plus $2.00/vehicle
- Individuals possessing a Golden Age or Golden Access Passport will be given a fifty-percent discount.


FOR FURTHER INFORMATION CONTACT: Bradley Rixford, Bureau of Land Management, P.O. Box 3388, Butte, Montana 59702, telephone 406-494-5059.

James R. Owings,
District Manager.
[FR Doc. 93-11173 Filed 5-11-93; 8:45 am]
BILLING CODE 4310-DN-M

[NV-930-03-4210-05; N-54237]

Realty Action Lease Purchase for Recreation and Public Purposes Clark County, NV

The following described public land in Las Vegas, Clark County, Nevada has been identified and examined and will be classified as suitable for lease/
be offered for lease/purchase until at least 60 days after the date of publication of this notice in the Federal Register.

Mount Diablo Meridian, Nevada

T. 21 S., R. 60 E., Sec. 17: W\(^2\)SE\(^2\)NE\(^4\)W\(^4\)
Aggregating 5.00 acres (gross)

The Twin Lakes Baptist Church intends to use the land for a church facility. The lease and/or patent, when issued, will be subject to the provisions of the Recreation and Public Purposes Act and applicable regulations of the Secretary of the Interior, and will contain the following reservations to the United States:


All minerals shall be reserved to the United States, together with the right to prospect for, mine and remove such deposits from the same under applicable law and such regulations as the Secretary of the Interior may prescribe.

and will be subject to:

An easement for streets, roads, public utilities and flood control purposes in favor of Clark County to include the following: A 50.00 foot wide easement on the north, a 30.00 foot wide easement with a 20.00 foot spandrel on the west, and a 30.00 foot wide easement with a 15.00 foot spandrel on the south.

Those rights for telephone line purposes which have been granted to the Las Vegas Valley Water District by Permit No. N-29217 under the Act of October 21, 1976.

Those rights for water line purposes which have been granted to Las Vegas Valley Water District by Permit No. N-29217 under the Act of October 21, 1976.

The land is not required for any federal purpose. The lease/purchase is consistent with the Bureau's planning for this area.

Detailed information concerning this action is available for review at the office of the Bureau of Land Management, Las Vegas District, 4765 W. Vegas Drive, Las Vegas, Nevada.

Upon publication of this notice in the Federal Register, the above described land will be segregated from all forms of appropriation under the public land laws, including the general mining laws except for recreation and public purposes, leasing under the mineral leasing laws and disposals of mineral materials.

For a period of 45 days from the date of publication of this notice in the Federal Register, interested parties may submit comments to the District Manager, Las Vegas District, P.O. Box 26569, Las Vegas, Nevada 89126. Any adverse comments will be reviewed by the State Director. In the absence of any adverse comments, the classification of the land described in this Notice will become effective 60 days from the date of publication in the Federal Register.


Ben F. Collins,
District Manager, Las Vegas, NV

[FR Doc. 93-11167 Filed 5-11-93; 8:45 am]

BILLING CODE 4310-DC-1

[UT-09-4910-10-4174; UTU-63982]

Realty Action; Utah

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of realty action; exchange of public lands in Utah County, UT.

SUMMARY: Notice is given that the following described public lands have been examined and found to be suitable for disposal by exchange under section 206 of the Federal Land Policy and Management Act of 1976 (80 Stat. 2755, 43 U.S.C. 1716).

In exchange for the public lands, the United States would acquire the following described public lands:

T. 1 S., R. 24 E., Salt Lake Meridian, Utah
Sec. 15, W\(^4\)N\(^4\)W\(^4\).

Comprising 280 acres of public lands.

In exchange for these lands the United States would acquire a right-of-way thereon for ditches and canals constructed under the authority of the United States, Act of August 30, 1890, 43 U.S.C. 945.

(2) Compliance by the exchange proponent with applicable Federal or State law and compliance with State and local land use plans, relevant to floodplain and riparian area management restrictions.

COMMENTS: Interested parties may submit comments to the Vernal District Office, Bureau of Land Management, 170 South 500 East, Vernal, Utah 84076 on or before June 28, 1993. Objections will be reviewed by the Utah State Director who may sustain, vacate, or modify this realty action. In the absence of any objections, this realty action will become the final determination of the Department of the Interior.

SUPPLEMENTARY INFORMATION: Detailed information concerning this exchange, including the environmental assessment and plan amendment for the Diamond Mountain Management Framework Plan, is available for review at the Vernal District Office or can be obtained by contacting Joy Wehking, Realty Specialist, 801-789-1362.


David E. Little,
Vernal District Manager

[FR Doc. 93-11175 Filed 5-11-93; 8:45 am]

BILLING CODE 4310-DQ-H
Bureau of Reclamation

Proposed Water Service Contract, El Dorado County, California

AGENCY: Bureau of Reclamation (Interior).

ACTION: Notice of intent to prepare a draft environmental impact statement/environmental impact report and notice of scoping meetings for proposed water service contracts to El Dorado County Water Agency from the Central Valley Project, California.

SUMMARY: Pursuant to Public Law 101-514 (104 Stat. 2087), Section 102(2)(C) of the National Environmental Policy Act (NEPA) of 1969, as amended, and section 21002 of the California Environmental Quality Act (CEQA), the Bureau of Reclamation (Reclamation) and El Dorado County Water Agency (Agency) intended to prepare a joint environmental impact statement/environmental impact report (EIS/EIR) for a water service contract from the Central Valley Project, California.

The proposed project consists of a water supply contract for El Dorado County Water Agency. The El Dorado County Water Agency has entered into discussions with Reclamation to negotiate long-term water supply contracts from the American River Division, Central Valley Project (CVP).

DATES: Comments are requested concerning the scope of analysis of the draft EIS/EIR. Input concerning issues related to the proposed water service contract should be received by June 11, 1993. Two public scoping meetings for this project will be held: Date: Wednesday, May 26, 1993. Times: 3 p.m. and 7 p.m.

ADDRESSES: Location of meetings: El Dorado County Board of Supervisors Chambers, 330 Fair Lane, Placerville, California.

FOR FURTHER INFORMATION CONTACT: Please address scoping comments or information requests to Robert J. Reeb, General Manager, El Dorado County Water Agency, 330 Fair Lane, Placerville, CA 95667, telephone: (916) 621-5392. Reclamation’s environmental representative is James Frederick, Environmental Specialist, Bureau of Reclamation, Mid-Pacific Region, 2800 Cottage Way, Sacramento, CA 95825-1898, telephone: (916) 978-5134.

SUPPLEMENTARY INFORMATION: The contract to be negotiated has been authored and directed by the United States Congress as part of Public Law 101-514. This contract has been excluded from the prohibition on new contracting found in Public Law 102-575.

Public Law 101-514 directs the Secretary of the Interior (Secretary) to enter into long-term municipal and industrial water supply contracts to meet the immediate water needs of El Dorado and Sacramento Counties. This law directs the Secretary to enter into contracts for up to 22,000 acre-feet annually with Sacramento County, 13,000 acre-feet annually with San Juan Suburban Water District, and 15,000 acre-feet annually with El Dorado County Water Agency. These water service contracts are intended as the first phase of a contracting program to meet the long-term water supply needs of El Dorado and Sacramento Counties.

El Dorado County Water Agency water service contract is not part of the Sacramento County water service contract project. Sacramento County Water Agency and San Juan Suburban Water District have initiated negotiations with Reclamation on a water service contract under Public Law 101-514, and they are preparing NEPA/CEQA environmental documentation under a separate notice of intent.

El Dorado County is currently considering plans for long-term water supplies. An environmental impact report (EIR) has been prepared which analyzes several combinations of actions designed to satisfy the county’s long-term water needs. One element of several proposed alternatives is the water service contract with Reclamation. The element is the Folsom Reservoir Water Supply Contract. Folsom Reservoir water would be used in the western service area, which includes the most urbanized areas of the county. It is proposed that the contract water would be diverted at Folsom Reservoir or upstream from the American River or its tributaries.

The EIS/EIR will focus on impacts to the physical environment from diversion, distribution, and use of the contracted water. The documentation will include analysis of the potential impacts to the natural environment, i.e., aquatic, wetland, and riparian communities, including any effect on special status species. Secondary growth impacts associated with the water delivery and secondary impacts associated with the construction of water delivery facilities are considered. Folsom Reservoir water will be investigated.

The draft EIS/EIR is expected to be completed and available for review and comment in the winter of 1994-95.

Scoping

One element of the EIS/EIR process is scoping. Scoping activities are initiated early in the process to identify reasonable alternatives that should be evaluated in the draft EIS/EIR, to identify significant environmental issues related to the proposed projects, to determine the depth of analysis for issues associated with the documentation, and to identify resource issues that are not important and that do not require detailed study. Scoping meetings have been scheduled to solicit public input to help identify issues and possible alternative actions within the framework for delivery and use of the contracted water.

Fish and Wildlife Service

Endangered and Threatened Species: Policy on Candidate Categories Relative to Petition Findings

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice.

SUMMARY: Under the Endangered Species Act of 1973 (Act), as amended, the Fish and Wildlife Service (Service) evaluates petitions for listing animal and plant species. Within 1 year after receiving a listing petition (if substantial information is presented), the Service is required under the Act to make one of the following findings on the merits of the petition: " warranted," " not warranted," or " warranted but precluded." The Service has a separate, but related, administrative process to identify candidate species for listing under the Act. These two processes have not been formally linked in the past. This notice states the Service’s current policy regarding the treatment of petition findings relative to the candidate categorization process.

DATES: The policy announced in this notice has been in effect since December 15, 1992.

ADDRESSES: Please send any correspondence concerning this notice to the Director (AES), Mail Stop 3024, U.S. Fish and Wildlife Service, Washington, DC 20240.
FOR FURTHER INFORMATION CONTACT: Dr. John Fay, Chief, Branch of Listing and Candidate Assessment, Division of Endangered Species, U.S. Fish and Wildlife Service (452 ARLSQ), Arlington, VA, telephone (703) 358-2171.

SUPPLEMENTARY INFORMATION: The purpose of this notice is to announce the Service’s current policy on the proper classification of candidate species that have received “warranted but precluded” petition findings. Under this policy, any candidate species that has received a “warranted but precluded” finding petitions will be classified as either a “Category 1” species and assigned a listing priority number. Species that receive a “not warranted” finding will be classified as either “Category 2” or “Category 3,” as defined below. 

Background

Under section 4 of the Act (16 U.S.C. 1533), the Service evaluates petitions for listing plants and animals as either endangered or threatened. The Service must first make a finding within 90 days of receipt whether substantial information is available to indicate that the requested action may be warranted. If that finding is positive, a second finding must be made within 1 year of receipt of the petition. Based upon the merits of the information assembled during those 12 months, that latter finding must be one of the following: “warranted,” “not warranted,” or “warranted but precluded.” (50 CFR 424.14)

Periodically the Service publishes notices of review that indicate what species are currently being considered for listing and those that are no longer active candidates. Species are placed in one of three “Categories” as follows: 

Category 1—Species for which sufficient information is currently available to the Service to support a proposed listing rule to classify them as endangered or threatened. An immediate proposal to list is preceded by other ongoing listing activities. Species in this category are assigned a listing priority in order to assist the Service in determining which species are most in need of immediate protection.

Category 2—Species for which sufficient information is not currently available to decide whether a proposal to list could be made or that the species should not be listed; there is sufficient information that these species are possibly under threat to their continued existence. Further field studies are required before final determinations can be made.

Category 3—Species for which sufficient information is currently available to conclude that they no longer warrant further consideration to classify them as endangered or threatened. A species in this category may be considered extinct, not an entity that meets the definition of “species” under the Act, or sufficiently common and not at risk to the degree that requires protection under the Act at this time.

In previous years, the Service had been including some candidate species with “warranted but precluded” findings in Category 2 on the basis that further action was precluded until sufficient information became available. In other cases, some species were being placed in Category 2 following a “not warranted” finding.

Policy

The previous discretionary practice of finding the list of a petitioned species “warranted but precluded” when additional information was still required to support a proposed listing rule (i.e., for Category 2 species) has been terminated. The Service will no longer place candidate species that have received “warranted but precluded” petition findings in Category 2; all such species will be assigned to Category 1.

Effect of Policy

In a future notice the Service will have completed a review of all Category 2 species that have previously had a “warranted but precluded” finding. The Service will either keep such species in Category 2 (i.e., sufficient information is still lacking to determine whether listing is appropriate) and make a final “not warranted” finding on that petition, or the Service will retain the “warranted but precluded” finding, move the species to Category 1, and assign it a listing priority number (i.e., sufficient information is available to support a proposed listing rule).

This notice is issued under the authority of the Endangered Species Act, 16 U.S.C. 1531–1544.


Bruce Blanchard,
Director, U.S. Fish and Wildlife Service.

Minerals Management Service (MMS)

Information Collection Submitted to the Office of Management and Budget (OMB) for Review under the Paperwork Reduction Act

The proposal for the collection of information listed below has been submitted to OMB for approval under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35). Copies of the proposed collections of information and related forms may be obtained by contacting the Bureau's Clearance Officer at the telephone number listed below. Comments and suggestions on the proposal should be made directly to the Bureau Clearance Officer and to the Office of Management and Budget; Paperwork Reduction Project (1010–0058); Washington, DC 20503, telephone (202) 395–7340, with copies to Chief, Engineering and Standards Branch; Engineering and Technology Division; Main Stop 4700; Minerals Management Service; 381 Elden Street; Herndon, Virginia 22070–4817.

Title: 30 CFR part 250, subpart I, Platforms and Structures.

OMB approval number: 1010–0058.

Abstract: Respondents submit this information to MMS’s regional offices so they can determine the structural integrity of offshore structures and ensure that such integrity will be maintained throughout the useful life of the structures.

Bureau form number: None.

Frequency: Varies.

Description of respondents: Federal Outer Continental Shelf oil and gas lessees.

Estimated completion time: 23.4 hours.

Annual responses: 526.

Annual recordkeeping hours: 1,000.

Annual burden hours: 12,324 (rounded).

Bureau Clearance Officer: Arthur Quintana, (703) 787–1238.

Dated: April 21, 1993.

Henry G. Bartholomew,
Deputy Associate Director for Operations and Safety Management.
[FR Doc. 93–11198 Filed 5–11–93; 8:45 am]
BILLING CODE 4310–55–M
INTERNATIONAL TRADE COMMISSION

[Investigation 337-TA-348]

Certain In-Line Roller Skates With Ventilated Boots and In-Line Roller Skates with Axle Aperture Plugs and Component Parts Thereof; Initial Determination Terminating Respondent on the Basis of Settlement Agreement


ACTION: Notice is hereby given that the Commission has received an initial determination from the presiding officer in the above captioned investigation terminating the following respondents on the basis of a settlement agreement: Key Fitness Products, Inc.

SUPPLEMENTARY INFORMATION: This investigation is being conducted pursuant to section 337 of the Tariff Act of 1930 (19 U.S.C. 1337). Under the Commission’s rules, the presiding officer’s initial determination will become the determination of the Commission thirty (30) days after the date of its service upon the parties, unless the Commission orders review of the initial determination. The initial determination in this matter was served upon parties on April 30, 1993.

Copies of the initial determination, the settlement agreement, and all other nonconfidential documents filed in connection with the investigation are available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone (202) 205-2000. Hearing impaired individuals are advised that information on this matter can be obtained by contacting the Commission’s TDD terminal on (202) 205-1810.

WRITTEN COMMENTS: Interested persons may file written comments with the Commission concerning termination of the aforementioned respondents. The original and 14 copies of all such documents must be filed with the Secretary to the Commission, 500 E Street, SW., Washington, DC 20436, no later than 10 days after publication of this notice in the Federal Register. Any person desiring to submit a document (or portions thereof) to the Commission in confidence must request confidential treatment.
The applications are governed by 49 CFR part 1182, as revised in Pur. Merger & Cont.—Motor Passenger & Water Carriers, 5 I.C.C.2d 786 (1989). The findings for these applications are set forth at 49 CFR 1182.18. Persons wishing to oppose an application must follow the rules under 49 CFR part 1182, subpart B. If no one timely opposes the application, this publication automatically will become the final action of the Commission.

USTS, Inc.—CONTROL—TRANSPORTATION SYSTEMS CORP. Dba WESTCHESTER TRANSPORTATION SYSTEMS. Applicants’ representative: Arthur Wagner, 342 Madison Ave., Suite 1002, New York, NY 10173. U.S. Transportation Systems, Inc. (USTS), a motor common and contract carrier of passengers (MC-188174), controls transportation systems (Westchester), a noncarrier, which is seeking its initial grant of motor common and contract passenger authority in No. MC-258021.

As a condition to the use of this exemption, any employees adversely affected by the trackage rights will be protected pursuant to Norfolk and Western Ry. Co.—Trackage Rights—BN, 354 I.C.C. 605 (1978), as modified in Mendocino Coast Ry. Inc.—Lease and Operate, 360 I.C.C. 653 (1980).

Decided: May 6, 1993.

By the Commission, David M. Koschknik, Director, Office of Proceedings.

Secretary.

[FR Doc. 93–11269 Filed 5–11–93; 8:45 am]

BILLING CODE 7035·01·M

DEPARTMENT OF JUSTICE

Lodging of Consent Decree Pursuant to the Clean Water Act

In accordance with Departmental policy, 28 CFR 50.7, notice is hereby given that on March 22, 1993, a proposed Consent Decree as to Defendant Puerto Rico Industrial Development Company ("PRIDCO") ("Consent Decree") in United States v. Puerto Rico Industrial Development Company, Civil Action No. 90–2079 (PG), was lodged with the United States District Court for the District of Puerto Rico. The proposed Consent Decree concerns the failure of four facilities owned and operated by PRIDCO to comply with their discharge permits in violation of the Clean Water Act.

Under the terms of the Consent Decree, PRIDCO will pay a civil penalty of $1,000,000 for its past violations, and must construct connections between three of its facilities and the treatment facilities of the Puerto Rico Aqueduct and Sewer Authority of the Puerto Rico Industrial Development Company.
Commonwealth of Puerto Rico. By July 1, 1994, the three PRIDCO facilities must cease discharging pollutants to the navigable waters of the United States. (The fourth facility named in the complaint has already ceased discharging.) PRIDCO must also comply with interim discharge limits until their discharge ceases, and also comply with certain monitoring and reporting requirements. The Consent Decree provides for stipulated penalties in the event that PRIDCO violates the terms of the Consent Decree.

The Department of Justice will receive comments for a period of thirty (30) days from the date of this publication. Comments should be addressed to the Assistant Attorney General for the Environment and Natural Resources Division, Department of Justice, Washington, DC 20530, and should refer to United States v. Puerto Rico Industrial Development Company D.J. Ref. 90–5–1–1–3348.

The proposed Consent Decree may be examined at the office of the United States Attorney, District of Puerto Rico, Federal Office Building, rm. 101, Carlos E. Chardon Avenue Hato Rey, Puerto Rico, 00918, and at the Region II Office of the Environmental Protection Agency, 841 Chestnut Building, Philadelphia, Pennsylvania 19107; and at the Consent Decree Library, 1120 G Street, NW., 4th Floor, Washington, DC 20005. In requesting a copy, please enclose a check in the amount of $22.75 (25 cents per page reproduction costs) payable to “Consent Decree Library.” Myles E. Flint, Acting Assistant Attorney General, Environment and Natural Resources Division.

Drug Enforcement Administration

Fred G. Constant, M.D.; Revocation of Registration

On February 11, 1993, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause for Fred G. Constant, M.D., of Rosendale, New York, proposing to revoke his DEA Certificate of Registration, AC3271343, and deny any pending applications for registration as a practitioner. The statutory basis for the Order to Show Cause was that Dr. Constant was no longer authorized by State law to handle controlled substances and thus was ineligible for DEA registration as set forth in 21 U.S.C. 823(f).

The Order to Show Cause was sent by registered mail to Dr. Constant at his registered location in Rosendale. The letter was returned to the DEA on March 16, 1993, with the notation that the letter was unclaimed. On March 16, 1993, the Order to Show Cause was resent to Dr. Constant by regular first class mail. No response was received from Dr. Constant or anyone purporting to represent him.

Pursuant to 21 CFR 1301.54(d), the Administrator finds that Dr. Constant has waived his opportunity for a hearing. The Administrator has carefully considered the investigative file in this matter, and enters his final order under the provisions of 21 CFR 1301.57.

The Administrator finds that on November 5, 1990, the New York State Board of Regents revoked Dr. Constant’s medical license, based on findings that...
he practiced while impaired due to mental instability, practiced with negligence and incompetence, and committed unprofessional conduct. Therefore, Dr. Constant is not authorized to administer, dispense, prescribe, or otherwise handle controlled substances under the laws of the state in which he is registered with DEA.

DEA has consistently held that termination of a registrant’s state authority to handle controlled substances requires that DEA revoke the registrant’s DEA Certificate of Registration. Sam S. Misasi, D.O., 50 FR 11469 (1985); George P. Gotsis, M.D., 49 FR 33750 (1984); Henry Weiss, M.D., 46 FR 3458 (1981).

Based on the foregoing, the Administrator concludes that Dr. Constant’s registration must be revoked. 21 U.S.C. 823(f) and 824(a)(3). Accordingly, the Administrator of the Drug Enforcement Administration, pursuant to the authority vested in him by 21 U.S.C. 823 and 824 and 28 CFR 0.100(b), hereby orders that DEA Certificate of Registration, AC9271343, previously issued to Fred G. Constant, M.D., be, and it hereby is, revoked, and that any pending applications for registration, be, and they hereby are, denied. This order is effective May 12, 1993.

Dated: May 6, 1993.

Robert C. Bonner,
Administrator of Drug Enforcement.

DEPARTMENT OF LABOR
Employment Standards Administration
Wage and Hour Division
Minimum Wages for Federal and Federally Assisted Construction;
General Wage Determination Decisions

General wage determination decisions of the Secretary of Labor are issued in accordance with applicable law and are based on the information obtained by the Department of Labor from its study of local wage conditions and data made available from other sources. They specify the prevailing hourly wage rates and fringe benefits which are determined to be prevailing for the described classes of laborers and mechanics employed on construction projects of a similar character and in the localities specified therein.

The determinations in these decisions of prevailing rates and fringe benefits have been made in accordance with 29 CFR part 1, by authority of the Secretary of Labor pursuant to the provisions of the Davis-Bacon Act of March 3, 1931, as amended (46 Stat. 1494, as amended, 40 U.S.C. 276a) and of other Federal statutes referred to in 29 CFR part 1, appendix, as well as such additional statutes as may from time to time be enacted containing provisions for the payment of wages determined to be prevailing by the Secretary of Labor in accordance with the Davis-Bacon Act. The prevailing rates and fringe benefits determined in these decisions shall, in accordance with the provisions of the foregoing statutes, constitute the minimum wages payable on Federal and federally assisted construction projects to laborers and mechanics of the specified classes engaged on contract work of the character and in the localities described therein.

Good cause is hereby found for not utilizing notice and public comment procedure thereon prior to the issuance of these determinations as prescribed in 5 U.S.C. 553 and not providing for delay in the effective date as prescribed in that section, because the necessity to issue current construction industry wage determinations frequently and in large volume causes procedures to be impractical and contrary to the public interest.

General wage determination decisions, and modifications and superseded decisions thereto, contain no expiration dates and are effective from their date of notice in the Federal Register, or on the date written notice is received by the agency, whichever is earlier. These decisions are to be used in accordance with the provisions of 29 CFR parts 1 and 5. Accordingly, the applicable decision, together with any modifications issued, must be made a part of every contract for performance of the described work within the geographic area indicated as required by applicable Federal prevailing wage law and 29 CFR part 5. The wage rates and fringe benefits, notice of which is published herein, and which are contained in the Government Printing Office (GPO) document entitled "General Wage Determinations Issued Under The Davis-Bacon And Related Acts," shall be the minimum paid by contractors and subcontractors to laborers and mechanics.

Any person, organization, or governmental agency having an interest in the rates determined as prevailing is encouraged to submit wage rate and fringe benefit information for consideration by the Department. Further Information and self-explanatory forms for the purpose of submitting this data may be obtained by writing to the U.S. Department of Labor, Employment Standards Administration, Wage and Hour Division, Division of Wage Determinations, 200 Constitution Avenue, NW., room S–3014, Washington, DC 20210.

New General Wage Determination Decisions

The numbers of the decisions added to the Government Printing Office document entitled "General Wage Determinations Issued Under the Davis-Bacon and Related Acts" are listed by Volume and State.

**Volume I**

- Rhode Island
  - RI93-2 (May 14, 1993)
  - RI93-3 (May 14, 1993)
  - RI93-4 (May 14, 1993)

- Virginia
  - VA93-84 (May 14, 1993)

**Modification to General Wage Determination Decisions**

The number of decisions listed in the Government Printing Office document entitled "General Wage Determinations Issued Under the Davis-Bacon and Related Acts" being modified are listed by Volume and State. Dates of publication in the Federal Register are in parentheses following the decisions being modified.

**Volume 1**

- Connecticut
  - CT93-1 (Feb. 19, 1993)
  - CT93-3 (Feb. 19, 1993)
  - CT93-4 (Feb. 19, 1993)
  - CT93-5 (Feb. 19, 1993)

- District of Columbia
  - DC93-1 (Feb. 19, 1993)

- Florida
  - FL93-1 (Feb. 19, 1993)
  - FL93-9 (Feb. 19, 1993)
  - FL93-15 (Feb. 19, 1993)
  - FL93-36 (Feb. 19, 1993)
  - FL93-37 (Feb. 19, 1993)
  - FL93-40 (Feb. 19, 1993)
  - FL93-44 (Feb. 19, 1993)

- Massachusetts
  - MA93-5 (Feb. 19, 1993)
  - MA93-10 (Feb. 19, 1993)

- New Jersey
  - NJ93-2 (Feb. 19, 1993)
  - NJ93-3 (Feb. 19, 1993)
  - NJ93-4 (Feb. 19, 1993)
  - NJ93-7 (Feb. 19, 1993)

- New York
  - NY93-2 (Feb. 19, 1993)
  - NY93-8 (Feb. 19, 1993)
  - NY93-21 (Feb. 19, 1993)
  - NY93-22 (Feb. 19, 1993)
  - NY93-26 (Feb. 19, 1993)

- Pennsylvania
  - PA93-4 (Feb. 19, 1993)

- Rhode Island
  - RI93-1 (Feb. 19, 1993)

- Tennessee
  - TN93-1 (Feb. 19, 1993)

- Virginia
  - VA93-3 (Feb. 19, 1993)
The investigation reveals Douglas Aircraft Company (DAC) had decreasing sales, production and employment at the above locations during the relevant period 1990 through September 1992. In addition, the Department conducted a survey of the major potential customers of DAC for their purchases imported commercial transport aircraft. The results of the survey revealed that a major potential customer increased its orders for imported commercial transport aircraft in the relevant survey period, 1991 through September 1992.

U.S. imports of civilian passenger aircraft, unladen weight over 15,000 kilograms increased absolutely in the latest twelve-month period, September 1991 through August 1992, compared to the previous twelve-month period, September 1990 through August 1991.
Conclusion

After careful review of the facts obtained in the investigation, I conclude that increases of imports of articles like or directly competitive with commercial transport aircraft and their component parts produced at Douglas Aircraft Company’s facilities in Salt Lake City, Utah (TA-W-27,850), Long Beach, California (TA-W-27,872), Columbus, Ohio (TA-W-28,097), Monrovia, California (TA-W-28,202) and Huntington Beach, California (TA-W-28,203) contributed importantly to the decline in sales or production and to the total or partial separation of workers of that firm. In accordance with the provisions of the Act, I make the following certifications:

“All workers of Douglas Aircraft Company’s facilities in Salt Lake City, Utah (TA-W-27,850) engaged in activities related to the production of commercial transport aircraft component parts who became totally or partially separated from employment on or after September 14, 1991 are eligible to apply for adjustment assistance under section 223 of the Trade Act of 1974.”

“All workers of Douglas Aircraft Company, Long Beach, California (TA-W-27,872) engaged in activities related to the production of commercial transport aircraft who became totally or partially separated from employment on or after September 14, 1991 are eligible to apply for adjustment assistance under section 223 of the Trade Act of 1974.”

“All workers of Douglas Aircraft Company, Columbus, Ohio (TA-W-28,097) engaged in activities related to the production of commercial transport aircraft component parts who became totally or partially separated from employment on or after September 25, 1991 are eligible to apply for adjustment assistance under section 223 of the Trade Act of 1974.”

“All workers of Douglas Aircraft Company, Monrovia, California (TA-W-28,202) and Huntington Beach, California (TA-W-28,203) engaged in activities related to the production of commercial transport aircraft component parts who became totally or partially separated from employment on or after December 4, 1991 are eligible to apply for adjustment assistance under section 223 of the Trade Act of 1974.”

“All workers of Douglas Aircraft Company, Monrovia, California (TA-W-28,202) and Huntington Beach, California (TA-W-28,203) contributed importantly to the production of commercial transport aircraft component parts produced at Douglas Aircraft Company’s facilities in Salt Lake City, Utah and Long Beach, California (TA-W-28,203) contributed importantly to the decline in sales or production and to the total or partial separation of workers of that firm.”

After careful review of the facts obtained in the investigation, I conclude that increases of imports of articles like or directly competitive with commercial transport aircraft and their component parts produced at Douglas Aircraft Company’s facilities in Salt Lake City, Utah (TA-W-27,850), Long Beach, California (TA-W-27,872), Columbus, Ohio (TA-W-28,097), Monrovia, California (TA-W-28,202) and Huntington Beach, California (TA-W-28,203) contributed importantly to the decline in sales or production and to the total or partial separation of workers of that firm. In accordance with the provisions of the Act, I make the following certifications:

“All workers of Douglas Aircraft Company’s facilities in Salt Lake City, Utah (TA-W-27,850) engaged in activities related to the production of commercial transport aircraft component parts who became totally or partially separated from employment on or after September 14, 1991 are eligible to apply for adjustment assistance under section 223 of the Trade Act of 1974.”

“All workers of Douglas Aircraft Company, Long Beach, California (TA-W-27,872) engaged in activities related to the production of commercial transport aircraft who became totally or partially separated from employment on or after September 14, 1991 are eligible to apply for adjustment assistance under section 223 of the Trade Act of 1974.”

“All workers of Douglas Aircraft Company, Columbus, Ohio (TA-W-28,097) engaged in activities related to the production of commercial transport aircraft component parts who became totally or partially separated from employment on or after September 25, 1991 are eligible to apply for adjustment assistance under section 223 of the Trade Act of 1974.”

“All workers of Douglas Aircraft Company, Monrovia, California (TA-W-28,202) and Huntington Beach, California (TA-W-28,203) engaged in activities related to the production of commercial transport aircraft component parts who became totally or partially separated from employment on or after December 4, 1991 are eligible to apply for adjustment assistance under section 223 of the Trade Act of 1974.”

“All workers of Douglas Aircraft Company, Monrovia, California (TA-W-28,202) and Huntington Beach, California (TA-W-28,203) contributed importantly to the production of commercial transport aircraft component parts produced at Douglas Aircraft Company’s facilities in Salt Lake City, Utah and Long Beach, California (TA-W-28,203) contributed importantly to the decline in sales or production and to the total or partial separation of workers of that firm.”

The results from the Department’s customer survey of the firm’s major declining customers of safety glass lenses, sunglass lenses, precision optical components and display lenses shows that none of the respondents increased their purchases of imports while decreasing their purchases from the subject firm during the relevant period. Imported components for reading glasses (hinges, screws, metal templates and plastic lenses) were purchased parts and were not produced at Reading in the period relevant to the Petition.

Further, a domestic transfer of production to Dallas, Texas would not provide a basis for a worker group certification.

Conclusion

After review of the application and investigative findings, I conclude that there has been no error or misinterpretation of the law or of the facts which would justify reconsideration of the Department of Labor’s prior decision. Accordingly, the application is denied.

Signed at Washington, DC this 4th day of May 1993.

Stephen A. Wandrei,
Deputy Director, Office of Legislation & Actuarial Service, Unemployment Insurance Service.

Mine Safety and Health Administration

Summary of Decisions Granting in Whole or in Part Petitions for Modification

AGENCY: Mine Safety and Health Administration (MSHA), Labor.

ACTION: Notice of affirmative decisions issued by the Administrators for Coal Mine Safety and Health and Metal and Nonmetal Mine Safety and Health on petitions for modification of the application of mandatory safety standards.

SUMMARY: Under section 101(c) of the Federal Mine Safety and Health Act of 1977, the Secretary of Labor may modify the application of a mandatory safety standard to a mine if the Secretary determines either that an alternate method exists at a specific mine that will guarantee no less protection for the miners affected than that provided by the standard, or that the application of the standard at a specific mine will result in a diminution of safety to the affected miners.
Summaries of petitions received by the Secretary appear periodically in the Federal Register. Final decisions on these petitions are based upon the petitioner's statements, comments and information submitted by interested persons and a field investigation of the conditions at the mine. MSHA has granted or partially granted the requests for modification submitted by the petitioners listed below. In some instances the decisions are conditioned upon compliance with stipulations stated in the decision.

FOR FURTHER INFORMATION: Petitions and copies of the final decisions are available for examination by the public in the Office of Standards, Regulations and Variances, MSHA, Room 627, 4015 Wilson Boulevard, Arlington, Virginia 22203.

Patricia W. Silvey,
Director, Office of Standards, Regulations and Variances.

Affirmative Decisions on Petitions for Modification.

Docket No.: M–87–301–C.
FR Notice: 53 FR 4789.
Petitioner: Tunnelton Mining Company.
Reg Affected: 30 CFR 75.305.
Summary of Findings: Petitioner's proposal to establish bleeder evaluation points and air monitoring stations where methane and air readings would be made by a certified person weekly considered acceptable alternate method. Granted with conditions.

Docket No.: M–91–131–C.
FR Notice: 57 FR 3220.
Petitioner: Peabody Coal Company.
Reg Affected: 30 CFR 75.1105.
Summary of Findings: Petitioner's proposal to enclose electrical equipment in a monitored fireproof structure instead of ventilating directly into the return considered acceptable alternate method. Granted with conditions.

Docket No.: M–92–14–C.
FR Notice: 57 FR 10044.
Petitioner: Double M Coal Company, Inc.
Reg Affected: 30 CFR 75.1710.
Summary of Findings: Petitioner's request to operate electric face equipment without canopies due to rises and dips in the mine's roof and floor considered acceptable alternate method. Granted with conditions.

Docket No.: M–92–48–C.
FR Notice: 57 FR 22493.
Petitioner: Kermit Coal Company.
Reg Affected: 30 CFR 75.800.
Summary of Findings: Petitioner's proposal to use contactors to obtain undervoltage protection on specific three-phase alternating current circuits in conveyor belt power centers considered acceptable alternate method. Granted with conditions for the high-voltage belt drive installations.

Docket No.: M–92–53–C.
FR Notice: 57 FR 22494.
Petitioner: Cyprus Shoshone Coal Corporation.
Reg Affected: 30 CFR 75.804(a).
Summary of Findings: Petitioner's proposal to install a SHD+GC, Number 16 A.W.G type cable as an internal ground check conductor for the ground continuity circuit considered acceptable alternate method. Granted with conditions for the 2,400 volt high-voltage longwall systems.

Docket No.: M–92–54–C.
FR Notice: 57 FR 22494.
Petitioner: Florence Coal Company.
Reg Affected: 30 CFR 75.305.
Summary of Findings: Petitioner's proposal to ventilate the fall area with return air and evaluate the fall area with an intake evaluation point and bleeder evaluation point instead of traveling the return aircourse in its entirety considered acceptable alternate method. Granted with conditions for the right side return aircourse of D-Parallels.

Docket No.: M–92–55–C.
FR Notice: 57 FR 22494.
Petitioner: Twentymile Coal Company.
Reg Affected: 30 CFR 75.804(a).
Summary of Findings: Petitioner's proposal to install a type SHD+GC, Number 16 A.W.G type cable on longwall face equipment as an internal ground check conductor for ground continuity circuit considered acceptable alternate method. Granted with conditions for the 2,400 volt high-voltage longwall systems.

Docket No.: M–92–61–C.
FR Notice: 57 FR 28882.
Petitioner: Sunnyside Coal Company.
Reg Affected: 30 CFR 75.507.
Summary of Findings: Petitioner's proposal to install a nonpermissible deep-well pump in return air considered acceptable alternate method. Granted with conditions.

Docket No.: M–92–66–C.
FR Notice: 57 FR 28882.
Petitioner: Consol Pennsylvania Coal Company.
Reg Affected: 30 CFR 75.503.
Summary of Findings: Petitioner's proposal to increase the maximum lengths of certain trailing cables supplying equipment from 480-volt alternating current systems to 800 feet considered acceptable alternate method. Granted with conditions for loading machines, roofbolters and section ventilation fans.
magnetic contactor instead of using a circuit breaker considered acceptable alternate method. Granted with conditions for the two 995-volt, 150 horsepower pump motors that are mounted on separate rubber tired carriers, located at the hydraulic pumping stations for the two longwall working sections.

**Docket No.:** M-92-89-C.  
**FR Notice:** 57 FR 38328.  
**Petitioner:** Costain Coal, Inc.  
**Reg Affected:** 30 CFR 75.1700.  
**Summary of Findings:** Petitioner's proposal to plug and mine through oil and gas wells considered acceptable alternate method. Granted with conditions.

**Docket No.:** M-92-90-C.  
**FR Notice:** 57 FR 38328.  
**Petitioner:** Consolidation Coal Company.  
**Reg Affected:** 30 CFR 75.1002.  
**Summary of Findings:** Petitioner's proposal to use high-voltage cables in the last open crosscut to supply power to a longwall mining system from an electrical power system considered acceptable alternate method. Granted with conditions.

**Docket No.:** M-92-91-C.  
**FR Notice:** 57 FR 38328.  
**Petitioner:** Double M No. 2 Mine, Inc.  
**Reg Affected:** 30 CFR 75.1710.  
**Summary of Findings:** Petitioner's proposal to operate the continuous miner and two 6-L Gelis Shuttle cars and the TD 30 roof drill without canopies due to rises and dips in mine roof and floor considered acceptable alternate method. Granted with conditions.

**Docket No.:** M-92-99-C.  
**FR Notice:** 30 CFR 43476.  
**Petitioner:** U.S. Steel Mining Company, Inc.  
**Reg Affected:** 30 CFR 75.1002.  
**Summary of Findings:** Petitioner's request for relief from the location of high-voltage cables within 150 feet of pillar workings and to use 4160 volt cables and equipment to power permissible longwall equipment for the high-voltage longwall system considered acceptable alternate method. Granted with conditions.

**Docket No.:** M-92-101-C.  
**FR Notice:** 57 FR 43476.  
**Petitioner:** Peabody Coal Company.  
**Reg Affected:** 30 CFR 75.1700.  
**Summary of Findings:** Petitioner's proposal to plug and mine through oil and gas wells considered acceptable alternate method. Granted with conditions.

**Docket No.:** M-92-105-C.  
**FR Notice:** 57 FR 44777.  
**Petitioner:** Peabody Coal Company.  
**Reg Affected:** 30 CFR 75.1700.  
**Summary of Findings:** Petitioner's proposal to use a hand-held continuous-duty methane and oxygen monitors on permissible three-wheel battery-powered tractors used to load coal considered acceptable alternate method. Granted with conditions.

**Docket No.:** M-92-122-C.  
**FR Notice:** 30 CFR 47123.  
**Petitioner:** Western Fuels-Utah, Inc.  
**Reg Affected:** 30 CFR 75.1700.  
**Summary of Findings:** Petitioner's proposal to use a nonpermissible submersible pump in return air, bleeder air and sealed areas considered acceptable alternate method. Granted with conditions.

**Docket No.:** M-92-125-C.  
**FR Notice:** 57 FR 47124.  
**Petitioner:** Peabody Coal Company.  
**Reg Affected:** 30 CFR 75.1700.  
**Summary of Findings:** Petitioner's proposal to plug and mine through oil and gas wells considered acceptable alternate method. Granted with conditions.

**Docket No.:** M-92-132-C.  
**FR Notice:** 57 FR 53144.  
**Petitioner:** T & H Construction.  
**Reg Affected:** 30 CFR 75.313.  
**Summary of Findings:** Petitioner's proposal to use a hand-held deck mounted continuous and oxygen monitor on permissible three-wheel battery-powered tractors used to load coal considered acceptable alternate method. Granted with conditions.

**Docket No.:** M-92-135-C.  
**FR Notice:** 57 FR 53144.  
**Petitioner:** Foley Coal Company, Inc.  
**Reg Affected:** 30 CFR 75.313.  
**Summary of Findings:** Petitioner's proposal to use hand-held continuous-duty methane and oxygen monitors on permissible three-wheel battery-powered tractors used to load coal considered acceptable alternate method. Granted with conditions.

**Docket No.:** M-92-136-C.  
**FR Notice:** 57 FR 53144.  
**Petitioner:** Mingo Logan Coal Company.  
**Reg Affected:** 30 CFR 75.1700.  
**Summary of Findings:** Petitioner's proposal to use hand-held continuous-duty methane and oxygen monitors on permissible three-wheel battery-powered tractors used to load coal considered acceptable alternate method. Granted with conditions.

**Docket No.:** M-92-148-C.  
**FR Notice:** 57 FR 58376.  
**Petitioner:** Mallie Coal Company.  
**Reg Affected:** 30 CFR 75.313.  
**Summary of Findings:** Petitioner's proposal to use a hand-held continuous-duty methane and oxygen monitor on permissible three-wheel battery-powered tractors used to load coal considered acceptable alternate method. Granted with conditions.

**Docket No.:** M-91-13-M.  
**FR Notice:** 57 FR 40915.  
**Petitioner:** Richem Construction, Inc.  
**Reg Affected:** 30 CFR 56.14107.  
**Summary of Findings:** Petitioner's proposal to enclose the plant with a six foot chain link fence with electrified barbed wire at the top, and electrified entrance gate and an electrified padlock on the gate instead of installing guards on moving equipment considered acceptable alternate method. Granted with conditions.

**Docket No.:** M-92-03-M.  
**FR Notice:** 57 FR 11093.  
**Petitioner:** Hecla Mining Company.  
**Reg Affected:** 30 CFR 57.14152.  
**Summary of Findings:** Petitioner's proposal to operate underground one-car rail haulage trains without trip lights considered acceptable alternate method. Granted with conditions.

[FR Doc. 93-11242 Filed 5-11-93; 8:45 am]  
**BILLING CODE 4310-43-P**

**Pension and Welfare Benefits Administration**

[Applications No. D--8835-D--8842, et al.]

**Proposed Exemptees; The Penn Central Corporation Master Trust (the PCC Trust), et al.**

**AGENCY:** Pension and Welfare Benefits Administration, Labor.

**ACTION:** Notice of proposed exemptions.

**SUMMARY:** This document contains notices of pendency before the Department of Labor (the Department) of proposed exemptions from certain of the prohibited transaction restrictions of the Employee Retirement Income Security Act of 1974 (ERISA). The Department publishes this document to facilitate public comment on the proposed exemptions.

The proposed exemptions are contained in the notices of pendency before the Department. These notices may be obtained by writing to the Pension and Welfare Benefits Administration, U.S. Department of Labor, 200 Constitution Avenue, N.W., Washington, D.C. 20210.
Act of 1974 (the Act) and/or the Internal Revenue Code of 1986 (the Code).

Written Comments and Hearing Requests

All interested persons are invited to submit written comments or request for a hearing on the pending exemptions, unless otherwise stated in the Notice of Proposed Exemption, within 45 days from the date of publication of this Federal Register Notice. Comments and request for a hearing should state: (1) The name, address, and telephone number of the person making the comment or request, and (2) the nature of the person’s interest in the exemption and the manner in which the person would be adversely affected by the exemption. A request for a hearing must also state the issues to be addressed and include a general description of the evidence to be presented at the hearing. A request for a hearing must also state the issues to be addressed and include a general description of the evidence to be presented at the hearing.

ADRESSES: All written comments and request for a hearing (at least three copies) should be sent to the Pension and Welfare Benefits Administration, Office of Exemption Determinations, room N–2570, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210. Attention: Application No. stated in each Notice of Proposed Exemption. The applications for exemption and the comments received will be available for public inspection in the Public Documents Room of Pension and Welfare Benefits Administration, U.S. Department of Labor, room N–5507, 200 Constitution Avenue NW., Washington, DC 20210.

Notice to Interested Persons

Notice of the proposed exemptions will be provided to all interested persons in the manner agreed upon by the applicant and the Department within 15 days of the date of publication in the Federal Register. Such notice shall include a copy of the notice of proposed exemption as published in the Federal Register and shall inform interested persons of their right to comment and to request a hearing (where appropriate).

SUPPLEMENTARY INFORMATION: The proposed exemptions were requested in applications filed pursuant to section 408(a) of the Act and/or section 4975(c)(2) of the Code, and in accordance with procedures set forth in 29 CFR part 2570, subpart B (35 FR 32836, 32847, August 10, 1970). If the exemption is granted, the restrictions of sections 408(a), 406(b)(1) and (b)(2) and 407(a) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1)(A) through (E) of the Code, shall not apply to: (1) The continued holding of shares of common stock (the PCC Stock) of The Penn Central Corporation (PCC) by the PCC Trust on behalf of plans (the PCC Plans) sponsored by PCC and its affiliates; (2) the acquisition, holding and exercise by the PCC Plans of an irrevocable put option (the PCC Put Option) which permits the PCC Plans to sell the PCC Stock to PCC (a) at a price per share equal to the then current fair market value of the PCC Stock or, if greater, $23.79 and, (b) for shares of PCC Stock acquired after October 1, 1991, at a price per share equal to the then current fair market value of the PCC Stock; (3) the continued holding of shares of common stock (the GCC Stock) of General Cable Corporation (GCC) by the GCC Trust on behalf of plans (the GCC Plans) sponsored by GCC and its affiliates; (4) the acquisition, holding and exercise by the GCC Plans of an irrevocable put option (the GCC Put Option) which permits the GCC Plans to sell the GCC Stock to GCC (a) at a price per share equal to the then current fair market value of the GCC Stock or, if greater, $6.34 and, (b) for shares of GCC Stock acquired after July 1, 1992, at a price per share equal to its then current fair market value, or, if greater, the acquisition price of such shares; and (5) the possible future acquisition by the PCC Plans of additional PCC Stock, and by the GCC Plans of additional GCC Stock, provided the following conditions are satisfied: (a) At the time of acquisition by the PCC Plans, the PCC Stock and any other qualifying employer securities (QES) as defined in section 407(e) of the Act will represent no more than 10% of the assets of any of the PCC Plans; (b) at the time of acquisition by the GCC Plans, the GCC Stock and any other QES as defined in section 407(e) of the Act will represent no more than 10% of the assets of any of the GCC Plans; (c) the independent fiduciary of the PCC Plans and the GCC Plans (together, the Plans) will monitor the holding of the PCC and GCC Stock by the respective Plans and take whatever action is necessary to protect the Plans’ rights, including, but not limited to, the exercising of the Put Options if the independent fiduciary, in its sole discretion, determines that such exercise is appropriate; (d) no further acquisitions of PCC Stock will be made by the PCC Plans, and no further acquisitions of GCC Stock will be made by the GCC Plans, unless such acquisitions are first approved by the Plans’ independent fiduciary, who must make a determination that such acquisitions are appropriate and in the best interests of the respective Plans; (e) the Plans will pay no more than current fair market value with respect to all further acquisitions of PCC and GCC Stock; and (f) a bond, letter of credit, or escrow agreement, as described herein, is maintained for (1) the PCC Plans as long as the PCC Plans continue to hold any shares of PCC Stock, and (2) the GCC Plans as long as the GCC Plans continue to hold any shares of GCC Stock.

Effective Date: If the proposed exemption is granted, the exemption will be effective December 17, 1991.

Summary of Facts and Representations

1. PCC, a corporation headquartered in Cincinnati, Ohio, is the parent company of an affiliated group of corporations. PCC Stock is publicly traded on the New York Stock Exchange. On October 1, 1991, 46,260,692 shares of PCC Stock were outstanding.

2. The PCC Trust, the trustee of which is The Chase Manhattan Bank, N.A., holds the assets of the PCC Plans. The PCC Plans are defined benefit plans described as follows: (a) Penn Central Corporation Retirement Income Guarantee Plan, which has approximately 1,892 participants and...
assets of $28,001,296; (b) Buckeye Pipeline Company Retirement Income Guaranty Plan, which has approximately 531 participants and assets of $6,031,306; (c) G&H Telephone Company Retirement Plan, which has approximately 507 participants and assets of $3,808,270; (d) Indiana Steel and Wire Company Pension Plan, which has approximately 333 participants and assets of $6,181,575; (e) Master Pension Plan for Hourly Rated Employees of Penn Central Industries Group, Inc., which has approximately 3,988 participants and assets of $20,269,457; (g) Retirement Income Plan of Marathon LeTourneau Company, which has approximately 2,087 participants and assets of $26,170,651; and (h) Vitro Technical Industries, Inc. Retirement Plan, which has approximately 2,087 participants and assets of $20,269,457; (g) Retirement Income Plan of Marathon LeTourneau Company, which has approximately 2,087 participants and assets of $26,170,651; and (h) Vitro Corporation Retirement Floor Plan, which has approximately 3,896 participants and assets of $94,684,660.

3. As of October 19, 1991, the PCC Plans owned an aggregate of 350,000 shares of PCC Stock. The PCC Plans also hold certain debentures (the Debentures) of PCC having an estimated fair market value of $5,268,796 as of September 27, 1991. The applicants represent that the Debentures are QES within the meaning of section 407(d)(5) of the Act and may be held by the PCC Plans. The combined value of the 350,000 shares of PCC Stock and the Debentures currently held by the PCC Plans currently totals approximately 6% of the PCC Plans' assets. All of the PCC Stock held by the PCC Plans was acquired after December 31, 1987.

4. The applicants represent that the PCC Stock currently meets, and will continue to meet, the requirements of section 407(f)(1)(A) of the Act. The PCC Stock held by the PCC Plans currently represents approximately 0.76% of the issued and outstanding shares of PCC Stock. However, the applicants represent that on October 1, 1991, American Financial Corporation (AFC) became the owner of more than 50% of the PCC Stock. AFC currently owns approximately 50.06% of the issued and outstanding shares of the PCC Stock. Therefore, since October 1, 1991, the PCC Stock has not satisfied section 407(f)(1)(B) of the Act which requires that at least 50% of the PCC Stock which is issued and outstanding be held by persons who are independent of the issuer. The applicants have requested the relief proposed herein to permit the PCC Plans' continued holding of the PCC Stock, as well as possible future acquisitions of additional PCC Stock.

5. The PCC Plans' continued holding of the PCC Stock, the PCC Plans have obtained the PCC Put Option from PCC. The PCC Put Option will be exercisable by the PCC Plans' independent fiduciary (see rep. 8, below). The PCC Put Option will permit the PCC Plans to require PCC to purchase from them all or any portion of the 350,000 shares of the PCC Stock currently held by the PCC Plans. The sales price of such PCC Stock sold pursuant to the PCC Put Option will be the closing price (or composite price if higher) of PCC Stock on the date of the sale, or, if greater, $23.79 per share (see rep. 7, below). With respect to possible future acquisitions of PCC Stock, the PCC Put Option will also apply. Additional shares of PCC Stock may be acquired by the PCC Plans only at the direction of the Plans' independent fiduciary, and, because the PCC Put Option would also apply to any such shares, only if PCC also approves the acquisition. In the case of shares of PCC Stock acquired by any of the PCC Plans after October 1, 1991, the PCC Put Option price will be the higher per share on the date of acquisition. In the case of shares of PCC Stock acquired by the Plan. If the PCC Stock is not acquired by the PCC Plan by purchase (e.g., by stock split or stock dividend), the PCC Put Option will be based on the closing price (or composite price if higher) per share on the date of acquisition.

6. On July 1, 1992, PCC reorganized its wire and cable operations that made up a major part of its manufacturing businesses. PCC spun off its wire and cable operations into GCC, a new public company. The Board of Directors of PCC determined to undertaking the spinoff for business reasons unrelated to employee benefits. In connection with this spinoff, the GCC Plans also acquired additional PCC Stock. The GCC Plans have obtained the GCC Put Option from GCC that is identical to the PCC Put Option for the PCC Plans (see rep. 5, above). The only differences are that the GCC Put Option will relate to GCC Stock, and the sales price to GCC under the GCC Put Option will be the closing price of GCC Stock on the date of the sale, or, if greater, $6.34 per share. The GCC Put Option price will also apply. Additional shares of GCC Stock may be acquired by the GCC Plans at the direction of the Plans' independent fiduciary, and, because the GCC Put Option would also apply to any such shares, only if GCC also approves the acquisition. In the case of shares of GCC Stock acquired by any of the GCC Plans after October 1, 1991, the GCC Put Option price will be the higher per share on the date of sale, or, if greater, $6.34 per share.

7. In connection with the GCC Plans' continued holding of the GCC Stock, the GCC Plans have obtained the GCC Put Option from GCC that is identical to the PCC Put Option for the PCC Plans (see rep. 5, above). The only differences are that the GCC Put Option will relate to GCC Stock, and the sales price to GCC under the GCC Put Option will be the closing price of GCC Stock on the date of the sale, or, if greater, $6.34 per share. The GCC Put Option price will also apply. Additional shares of GCC Stock may be acquired by the GCC Plans at the direction of the Plans' independent fiduciary, and, because the GCC Put Option would also apply to any such shares, only if GCC also approves the acquisition. In the case of shares of GCC Stock acquired by any of the GCC Plans after October 1, 1991, the GCC Put Option price will be the higher per share on the date of sale, or, if greater, $6.34 per share.
any of their affiliates. The Bank does represent that it currently has limited banking relationships with PCC, GCC, AFC and/or their affiliates. However, the Bank represents that the fees and other revenues generated for the Bank from such relationships for any year is less than 1% of the total gross revenues of the Bank from all sources.

9. The Bank represents that it has made an initial determination that it is appropriate for the Plans to continue to hold the PCC Stock and the GCC Stock as an investment. The Bank represents that it will monitor the Plans' continued holding of the PCC Stock and the GCC Stock and will determine whether it remains appropriate for the Plans to retain the Stock. The Bank represents that it will take into account a variety of factors in determining whether the holding, acquisition of additional shares or sale of the Stock by the Plans is appropriate, including, but not necessarily limited to: (a) Financial information concerning PCC and GCC and their prospects for the future; (b) the anticipated appreciation and other returns on the Stock; (c) the anticipated returns on other alternative investments of a comparable nature; (d) the rating of PCC and GCC securities by any applicable rating agencies; and (e) the current investments of the Plans in assets other than the Stock. The Bank represents that it will take whatever action is appropriate and in the best interest of the Plans with respect to the Stock including the exercising of the PCC and GCC Put Options, which will permit the Bank to require PCC to purchase all or any portion of the PCC Stock held by the Plans and GCC to purchase all or any shares of the GCC Stock held by the GCC Plans. 10. As an additional safeguard for the Plans, PCC and GCC represent that they will take one of three measures designed to ensure the honoring of their obligations under the Put Options. PCC and GCC each represent that they will either: (a) Purchase a letter of credit from an independent bank guaranteeing performance in an amount equal to 25% of the Put Option price of the Stock held by the Plans; (b) purchase a bond from an independent insurance company guaranteeing performance in an amount equal to 25% of the minimum Put Option price; or (c) establish an escrow account with an independent bank which will hold assets having a value equal to at least 25% of the Put Option price. Any such escrow account will be invested in cash or government securities. The escrow account will be increased if on any quarterly date the fair market value of the assets in the account falls below 25% of the minimum Put Option price.

PCC and GCC represent that they have initially secured their obligations under the Put Options by means of the letter of credit with an independent bank. PCC and GCC wish to retain the right to change the security agreement to one of the other two options described above, and PCC and GCC represent that there will never be a gap in the coverage if either or both should decide to change options. The applicants further represent that whichever arrangement is used must provide that if shares of either PCC Stock or GCC Stock are sold by the Bank on behalf of the Plans for less than the per share guaranteed amount under the Put Option, the Plans will be reimbursed from the security arrangement for the difference (if PCC or GCC does not reimburse such difference).

11. In summary, the applicants represent that the subject transactions satisfy the statutory criteria contained in section 408(a) of the Act because: (1) The PCC Stock and GCC Stock, when aggregated with QES, will represent less than 10% of the assets of each of the Plans; (2) the PCC Plans have obtained the PCC Put Option, which will permit the PCC Plans to sell any or all shares of the Stock to PCC upon the independent fiduciary's decision, (a) at a price per share equal to the greater of its then current fair market value or its value on October 1, 1991 (adjusted to reflect the spinoff of GCC), and (b) for shares of PCC Stock acquired after October 1, 1991, at the greater of its then current fair market value or its acquisition price; (3) the GCC Plans have obtained the GCC Put Option, which will permit the GCC Plans to sell any or all shares of the GCC Stock to GCC upon the independent fiduciary's decision, (a) at a price per share equal to the greater of its then current fair market value or the price of its allocable portion of the October 1, 1991 value of the PCC Stock and (b) for shares of GCC acquired after July 1, 1992, at the greater of its then current fair market value or its acquisition price; (4) the Plans' independent fiduciary, the Bank, will monitor the Plans' continued holding of the PCC Stock and GCC Stock and will determine, among other things, whether to exercise the Put Options or to acquire any additional shares of the Stock; and (5) PCC and GCC will either purchase a letter of credit from an independent bank, purchase a bond from an independent insurance company or establish an escrow account with an independent bank having a value of at least 25% of the minimum Put Option prices for the purpose of ensuring their ability to honor their obligations under the Put Options.

FOR FURTHER INFORMATION CONTACT: Gary H. Lefkowitz of the Department, telephone (202) 219-8881. (This is not a toll-free number.)

Kimball International, Inc., Retirement Plan (the Plan) Located in Jasper, Indiana

[Application No. D-9258]

Proposed Exemption

The Department is considering granting an exemption under the authority of section 408(a) of the Act and section 4975(c)(2) of the Code and in accordance with the procedures set forth in 29 CFR part 2570, subpart B (55 FR 32836, 32847, August 10, 1990). If the exemption is granted the restrictions of sections 406(a), 406(b)(1) and (b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1)(A) through (E) of the Code, shall not apply to the proposed sale by the Plan of five parcels of real property (the Properties) to Kimball International, Inc. (the Employer), a party in interest with respect to the Plan, and the subsequent conveyance of one of the parcels to Springs Valley Bank and Trust Company of Jasper, Indiana (the Bank); provided that the following conditions are satisfied:

(A) All terms and conditions of the transaction are at least as favorable to the Plan as the Plan could obtain in an arm's-length transaction with an unrelated party;

(B) The Plan receives a purchase price for the Properties which is no less than the sum of the fair market values of each of the Properties as of the date of the sale, plus a premium of no less than five percent of such sum;

(C) The Plan's interests for all purposes in the transaction are represented by Arthur L. Dillard, Esq., an independent fiduciary acting on behalf of the Plan with respect to the Properties; and

(D) The Plan does not incur any costs or expenses related to the transaction, other than any taxes imposed by law on a seller.

Summary of Facts and Representations

1. The Plan is a defined contribution individual account profit-sharing plan with 7,235 participants and total assets of $217,239,325 as of June 30, 1992. The Plan is a renamed, combined plan resulting from the July 1, 1988 merger of two predecessor plans, the Kimball International, Inc. Direct Retirement Plan and the Kimball International, Inc. Indirect Retirement Plan. The Plan is
sponsored by the Employer, a publicly-
traded Indiana corporation engaged in
the manufacture and marketing of
pianos, organs, furniture, contract
cahines, and processed wood products,
with its principal offices in Jasper,
Indiana. The assets of the Plan are held
in trust by the Bank, which is located in
Jasper, Indiana. Responsibility for the
investment of Plan assets rests with the
Kimball Plan Advisory Committee (the
Committee), comprised of
representatives of the Employer and
representatives of the Bank.

2. Among the assets of the Plan are
five parcels of real property (the
Properties), acquired by the Plan at
various times from 1957 to 1974. Four
of the Properties (the Employer
Properties) are occupied and utilized by
the Employer in its production
operations. The Employer Properties are
leased by the Employer from the Plan
under lease arrangements (the Employer
Leases) which are subject to an
individual administrative exemption
issued by the Department (PTE 84–82,
49 FR 26838, June 29, 1984). The Plan’s
interests under the Employer Leases and
PTE 84–82 are represented exclusively
by an independent fiduciary, Arthur L.
Dillard, Esq. (the Fiduciary), who serves
pursuant to the terms of an agreement
which requires the Fiduciary’s prior
approval of any transaction with respect
to the Employer Properties. The
Employer Properties are described as
follows:

(a) The Electronics Facility is a
production facility, warehouse and
office located on approximately 6.81
acres of land at the northwest corner of
15th and Cherry Streets and Kellerville
Road in Jasper, Indiana. The sole
building on this Property has
approximately 161,798 square feet of
space, constructed in 1968 through 1974,
and abuts newer assembly, shipping
and receiving facilities on
adjoining land of the Employer. The fair
market value of the Electronics Facility
was determined to be $3,392,186 as of
June 10, 1992 by Gerald D. Farlow,
a professional real estate appraiser with
the Farlow-Clements Agency (FCA) in
Paoli, Indiana. Another professional real
estate appraiser, David A. Donan with
Appraisal Consultants, Inc. (ACI) in
Jasper, Indiana, determined that the
Electronics Plant had a fair market value
of $3,220,000 as of June 30, 1992.

(b) The Artec Plant, previously
referred to as the Stylemasters Plant, is
a production plant and office situated
on approximately 1.48 acres of land at
the southwest corner of 15th and Cherry
Streets in Jasper, Indiana. The sole
building on this Property contains
approximately 71,686 square feet of
space, constructed in 1961 and 1962,
and abuts newer manufacturing
facilities on adjoining land of the
Employer. According to an appraisal by
FCA, the Artec Plant had a fair market
value of $1,217,089 as of June 10, 1992.
According to an appraisal by ACI, the
Artec Plant had a fair market value of
$1,160,000 as of June 30, 1992.

(c) The Piano Parcel consists of a
production plant, warehouse and office
located on approximately 22.38 acres of
land on State Road 56 in West Baden
Springs, Indiana. The buildings were
constructed from 1963 through 1974,
and the warehouse abuts a newer
warehouse on adjoining land of the
Employer. The Piano Parcel had a fair
market value of $1,984,770 as of June
10, 1992, according to an appraisal by
FCA. According to an appraisal by ACI,
the Piano Parcel had a fair market value
of $2,075,000 as of June 30, 1992.

(d) The Warehouse Parcel consists of
an approximately 48,980 square foot
warehouse situated on 1.97 acres of land
located on East 16th Street in Jasper,
Indiana. The warehouse on this parcel
was constructed in 1974 and
1975, and it directly abuts a manufacturing facility
on adjoining land of the Employer. FCA
determined that the Warehouse Parcel
had a fair market value of $734,627 as of
June 10, 1992, and ACI determined a
fair market value of $675,000 as of June

A fifth parcel of the Properties is a
parking lot on Maple Street, between
Maple and State Road 56, in French
Lick, Indiana (the Maple Street Parcel).
This parcel is a black-topped parking lot
of approximately .53 acres, leased from
the Plan by the City of French Lick
pursuant to a verbal agreement. The
Maple Street Parcel abuts land owned
and occupied by the Bank as its
principal place of business. FCA
determined that the Maple Street Parcel
had a fair market value of $21,655.27 as of
June 10, 1992, and ACI determined that it had a fair market value of $21,000 as of June 30, 1992.

3. In discharging its oversight
responsibility with respect to Plan
assets, the Committee periodically
reviews the investment performance of
each of the Plan’s investments,
including the Properties. As a result of
a recent review, the Committee has
determined that it would be in the best
interests of the Plan’s participants and
beneficiaries to divest the Plan of all its
investments in real property and,
accordingly, to provide for the Plan’s
sale of the Properties. The Committee
represents that its determination to
divest the Plan of the Properties is based
on the following factors:

(a) The outlook for future capital
appreciation for the Properties is
significantly diminished due to a
general decline in the demand for such
industrial property in the locale of the
Properties.

(b) In a sale of the Properties, the Plan
should be able to recover a return on its
total investments in the Properties and
to prevent further investment losses
attributable to recent declines from the
Properties’ highest historic appraised
values.

(c) The Plan’s potential liability from
holding title to real estate is increasing
due to environmental legislation.

(d) Continued use of the Employer
Properties by the Employer will
continue to conform those Properties to
specific uses, rendering them
increasingly less adaptable to other
uses.

(e) Overall risk related to the
Properties is increasing relative to the
return on the Properties.

4. Having determined to divest the
Plan of the Properties, the Committee
represents that it further determined that it would be in the best interests of the
Plan to seek a sale of all of the
Properties to a single buyer in a single
transaction. The Committee represents that it determined that a single sale of all the Properties to an unrelated buyer
could not be accomplished, due to the
nature and location of the Properties,
well as prevailing market conditions,
and that the Employer constituted the
only prospective purchaser of the
Properties in one transaction. The
Committee also represents that it
determined that the Employer
constituted the only prospective buyer
willing to pay a purchase price which
included the Properties’ appraised fair
market value plus a premium. The
Committee represents that it determined that the Employer would purchase the
Properties from the Plan for the
appraised fair market value, plus a
premium representing the special value
of the Employer Properties to the
Employer, as opposed to an unrelated
party, as purchaser. For these reasons,
the Committee represents no efforts
have been made to sell the Properties to
unrelated parties.

The Committee represents that after it
determined to proceed with a sale of the
Properties to the Employer, it was
advised that the Bank was interested in
acquiring the Maple Street Parcel for use
as its parking lot. As a result, the
Committee and the Employer propose
that the Employer purchase all of the
Properties from the Plan, and then sell
the Maple Street Parcel to the Bank. An
exemption is requested for the Employer
and the Bank to enter into such
transactions under the terms and conditions described herein.

5. The Employer will purchase the Properties from the Plan, for a cash purchase price determined in accordance with a sale contract described herein below, and the Bank will thereafter acquire the Maple Street Parcel from the Employer for cash in the same amount which the Employer paid for the Plan for the Maple Street Parcel. The Employer and the Committee propose the purchase of all of the Properties, including the Maple Street Parcel, and the resale of the Maple Street Parcel to the Bank, rather than a direct sale of that Property to the Bank, as a matter of administrative expediency and convenience to the Plan, in an effort to minimize any delay in the Plan’s divestiture of the Properties. By structuring the sales of the Properties as one transaction, the Plan will be able to sell all the Properties simultaneously without requiring more than one closing transaction. However, because the Employer’s resale of the Maple Street Parcel to the Bank may constitute an indirect sale of a Plan asset to a party in interest with respect to the Plan, exemptive relief is requested for the Bank, in addition to the Employer, for the proposed transactions.

6. All terms of the Employer’s proposed purchase of the Properties from the Plan are embodied in a written agreement (the “Contract”) under which neither the Plan nor its fiduciaries make any warranties or representations as to the condition or value of the Properties. The Contract requires the Employer to pay the Plan a cash purchase price and to pay all costs and expenses related to the transaction, other than any transfer taxes imposed by law on the seller. The purchase price for the Properties is defined in the Contract as the greater of the following:

(a) $7,613,398, which is the sum of $7,250,665, representing the June 1992 valuation of the Properties, as determined by averaging the FCA and ACI valuations of each Property conducted in June 1992 and adding such averaged valuations, plus five percent premium of $362,533; or
(b) The sum of (i) the fair market value of the Properties as of the date of closing (Current Value), as determined by averaging new appraisals of the Properties to be conducted by FCA and ACI, plus (ii) a premium payment in the amount of five percent of the Current Value.

The Committee states that the Contract’s purchase price determination will ensure that the Plan recoups its total investment in the Properties, which the Committee represents to be $3,665,866. The Committee also represents that the Contract’s purchase price determination will also ensure that the Plan receives a purchase price of no less than the fair market values attained by the Properties in June 1992, under market conditions currently causing accelerated declines in values. The Committee proposes a five percent premium in the purchase price as compensation to the Plan for the special value which the Properties hold for the Employer and the Bank as buyers, as opposed to unrelated buyers without interests in properties adjoining the Properties.

7. The terms of the Fiduciary’s appointment to represent the interests of the Plan under the Employer Leases require the Fiduciary’s prior approval of any transaction with respect to the Employer Properties. The Fiduciary represents that he has conducted a review of all aspects of the proposed transaction, and that he has concluded that the Plan’s proposed sale of the Properties to the Employer under the terms of the Contract will be in the best interests of the participants and beneficiaries of the Plan. The Fiduciary states that his determination is based on reviews of the Properties, the appraisals by FCA and ACI, the history of the Properties’ values, the terms of the Contract, his own general knowledge of the real estate market in which the Properties are situated, and the long-term rate of return which the Plan could reasonably anticipate from the Properties as compared to alternative investments. The Fiduciary, who monitors and administers the Employer Leases, certifies that the Employer has been and remains in compliance with all terms and conditions of the Employer Leases for all periods since the Fiduciary commenced his duties as such on October 6, 1982. With respect to the proposed purchase price under the Contract, the Fiduciary states that he has determined that a premium of five percent of the Properties’ appraised fair market value is more than sufficient to represent the special value of the Properties to the Employer and the Bank.

8. In summary, the applicant represents that the criteria of section 408(a) of the Act are satisfied in the proposed transactions for the following reasons: (1) The proposed transactions enable the Plan to commence on favorable terms with disposal of its direct investments in real property, an investment objective which has been determined by the Committee; (2) The Plan will pay no costs or expenses related to the transaction, other than any taxes imposed by law on the seller; (3) The Plan will receive a cash purchase price of no less than the aggregate fair market values of the Properties as of the closing of the sale, and no less than the Properties’ fair market values of June 1992; (4) The purchase price will include a five percent premium to compensate the Plan for any special values of the Properties to the Employer and the Bank as buyers; and (5) The Plan’s independent fiduciary has determined that the sale is appropriate and in the best interests of the Plan.

Old Guard Mutual Insurance Company
Profit Sharing and Retirement Savings
Plan (the Plan) Located in Lancaster,
Pennsylvania

(Application No. D-9297)

Proposed Exemption

The Department is considering granting an exemption under the authority of section 408(a) of the Act and section 4975(c)(2) of the Code and in accordance with the procedures set forth in 29 CFR part 2570, subpart B (55 FR 32836, 32847, August 10, 1990). If the exemption is granted, the restrictions of section 406(a), 406(b)(1) and (b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1)(A) through (E) of the Code, shall not apply to the proposed cash sale of certain limited partnership interests (collectively, the Partnership Interests) by the Plan to Old Guard Mutual Insurance Company (the Employer), the Plan sponsor and a party in interest with respect to the Plan, provided the following conditions are satisfied:

(1) The sale will be a one-time cash transaction;
(2) No commissions or fees will be paid by the Plan as a result of the sale; and
(3) The sale price will be the higher of: (a) the original amounts paid by the Plan at the time of acquisition, less cash distributions through the date of the sale to the Plan (the Balance); or (b) current fair market value of the Partnership Interests on the date of the sale.

Summary of Facts and Representations

1. The Plan is a profit sharing plan with a section 401(k) feature, and has approximately 137 participants and beneficiaries. As of September 30, 1992, the Plan had approximately $3,952,443 in assets, of which $835,460 was attributable to the section 401(k) portion. The Employer is a
Pennsylvania corporation engaged in the business of writing property and casualty insurance in the states of Pennsylvania, Maryland and Delaware. The Plan's trustees are Donald L. Welsh, who was the Employer's Vice President of Information Services until his retirement in September of 1992; Robert L. Wechler, who is also the Employer's Senior Vice President for Claims; and William S. Huber, who is also the chairman of the Board of Directors of the Employer (collectively, the Trustees).

2. The profit sharing portion of the Plan holds the Partnership Interests. The Partnership Interests represent investments in four limited partnerships (collectively, the Partnerships). It is represented that there is no relationship between the Employer and the Partnerships and that none of the Employer's officers individually invested in the Partnerships, and that none of the Employer's officers lease or otherwise use the property or any other assets of the Partnerships.

3. Specifically, on July 18, 1983, the Plan purchased for $199,665, 200 units (CCIP Interests) of the 111,480 units of limited partnership interests offered by Consolidated Capital Institutional Properties (CCIP). It is represented that this offering was specifically structured to avoid in-kind transfers of the Plan's assets, the applicant represents that the Plan's participants and in the size of the sale. The Employer and the Trustees have decided to adopt a Kemper Prototype section 401(k) profit sharing plan, which will allow participants to exercise investment discretion over all of the Plan's assets. In this regard, the Employer and the Trustees decided to utilize the Kemper Group of Mutual Funds (the Kemper Group), such that the Plan participants will be able to exercise full investment discretion of their account balances among five Kemper mutual funds. The Kemper Group will provide all third party administration and record keeping required to administer the Plan. Because Kemper mutual funds are unable to accept in-kind transfers of the Plan's assets, the applicant represents that in order to implement the restructuring of the Plan as described above, the Plan's assets have to be liquidated into cash.

6. Due to lack of an established market for the Partnership Interests, the Employer proposes to purchase the Partnership interests from the Plan for the greater of: (1) the original amounts paid by the Plan at the time of acquisition, less cash distributions through the date of sale to the Plan (the Balance); or (2) current fair market value of the Partnership Interests on the date of the sale. The sales price will be determined by comparing the Balance on each Partnership Interest to the fair market value of that Partnership Interest. Because Balcor Interests and vice versa, the Employer will pay the higher of the two values for each Partnership.

7. It is represented that each of the Partnerships have paid cash distributions to the Plan. For CCIP Interests, the original cost to the Plan was $199,665, with distributions to date of $128,113.31, for a Balance of $71,551.69. For Balcor Interests, the original cost was $100,000, distributions to date $58,066.42, and a Balance of $41,933.58. For HV Interests, the original cost was $94,000, the distributions to date $4,460, for a Balance of $89,540. For PW Interests, the original cost was $100,000, the distributions to date $42,204.20, for a Balance of $57,795.80.

8. In determining fair market value for each of the Partnership Interests, the applicant obtained opinions from general partners of the Partnerships and in some cases from independent brokers. With respect to CCIP, on October 1, 1992, LP Acceptance Corporation, an affiliate of the general partner of CCIP, offered to unitholders a cash liquidity option to sell their units at a cash price of $225 per unit. The tender offer of November 12, 1992, states that since inception, CCIP returned to unitholders $750 per Unit in cash distributions. Therefore, if a unitholder bought a unit at CCIP's inception and accepts the cash liquidity option, the unitholder would receive a total return per unit of approximately $975 compared to the original cost of $1000 per unit. Accordingly, the fair market value of 400 CCIP Interests is $45,000 ($225 x 200), as compared to the Balance of $71,551.69.

With respect to Balcor Interests, the applicant sought an opinion of the Chicago Partnership Board (CPB), a securities firm which acts as a clearing house for market information regarding partnership sales in the secondary market, and which facilitates trades of such partnerships by attempting to match buyers and sellers. James Frith, Jr., president of CPB, indicated that based on CPB's database analysis, which considers interest from potential buyers, specific partnership financial information and transaction price history (where available), the market price as of February 10, 1993, per Balcor Unit was $139.89. Based on this, the fair market value of 202 Balcor Interests is $28,258 (139.89 x 202), as compared to the Balance of $41,933.58. With respect to HV Interests, Frank A. Gerhardt, general partner of High V, stated in a letter of May 31, 1992, that an HV Interest has a value of $47,000, and as such the Plan's total investment has a market value of $94,000 ($47,000 x 2), as compared to the Balance of $85,540.

With respect to PW Interests, Louis Borriello, Account Vice President with Paine Webber indicated that the last sale of PW units took place on January 14,
9. It is represented that the proposed sale is administratively feasible, in the interest and protective of the Plan's participants and beneficiaries. The sale would be a one-time cash transaction and the Plan would incur no fees or commissions with respect to the sale. The proposed sale would enable the Plan to liquidate its assets and would facilitate restructuring of the Plan. The proposed transaction is protective of the Plan because the Employer will purchase the Partnership Interests from the Plan for the greater of: (1) the balance; or (2) current fair market value of the Partnership Interests on the date of the sale. Furthermore, the applicant represents that any amounts received by the Plan as a result of the proposed transaction, which are in excess of the fair market value of the Partnership Interests will be treated as a contribution to the Plan, but that this contribution will not exceed limitations of section 415 of the Internal Revenue Code.

10. In summary, the applicant represents that the transaction satisfies the statutory criteria of section 408(a) of the Act and section 4975(c)(2) of the Code because:

(1) The sale will be a one-time cash transaction;
(2) No commissions or fees will be paid by the Plan as a result of the sale;
(3) The sale will enable the Plan to liquidate its assets and will facilitate restructuring of the Plan; and
(4) The sale price for will be the higher of: (a) the balance; or (b) current fair market value of the Partnership Interests on the date of the sale.

Tax Consequences of Transaction

The Department of Treasury has determined that if a transaction between a qualified employee benefit plan and its sponsoring employer (or an affiliate thereof) results in the plan either paying less or receiving more than fair market value, such excess may be considered to be a contribution by the sponsoring employer to the plan, and therefore must be examined under the applicable provisions of the Internal Revenue Code, including sections 401(a)(4), 404 and 415.

For Further Information Contact: Ekaterina A. Uzlyan of the Department, telephone (202) 219-8883. (This is not a toll-free number.)

General Information

The attention of interested persons is directed to the following:

(1) The fact that a transaction is the subject of an exemption under section 408(a) of the Act and/or section 4975(c)(2) of the Code does not relieve a fiduciary or other party in interest of disqualified person from certain other provisions of the Act and/or the Code, including any prohibited transaction provisions to which the exemption does not apply and the general fiduciary responsibility provisions of section 404 of the Act, which among other things require a fiduciary to discharge his duties respecting the plan solely in the interest of the participants and beneficiaries of the plan and in a prudent fashion in accordance with section 404(a)(1)(b) of the act; nor does it affect the requirement of section 401(a) of the Code that the plan must operate for the exclusive benefit of the employees of the employer maintaining the plan and their beneficiaries;
(2) Before an exemption may be granted under section 408(a) of the Act and/or section 4975(c)(2) of the Code, the Department must find that the exemption is administratively feasible, in the interest of the plan and of its participants and beneficiaries and protective of the rights of participants and beneficiaries of the plan;
(3) The proposed exemptions, if granted, will be supplemental to, and not in derogation of, any other provisions of the Act and/or the Code, including statutory or administrative exemptions and transitional rules. Furthermore, the fact that a transaction is subject to an administrative or statutory exemption is not dispositive of whether the transaction is in fact a prohibited transaction; and
(4) The proposed exemptions, if granted, will be subject to the express condition that the material facts and representations contained in each application are true and complete, and that each application accurately describes all material terms of the transaction which is the subject of the exemption.

Signed at Washington, DC, this 5th day of May 1993.

Ivan Strasfeld,
Director of Exemption Determinations, Pension and Welfare Benefits Administration, U.S. Department of Labor.

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However, should circumstances change during the notice period, the Commission may issue the license amendment before the expiration of the 30-day notice period, provided that its determination is that the amendment involves no significant hazards consideration. The final determination will consider all public and State comments received before action is taken. Should the Commission take this action, it will publish in the Federal Register a notice of issuance and provide for opportunity for a hearing after issuance. The Commission expects that the need to take this action will occur very infrequently.

Written comments may be submitted by mail to the Rules Review and Directives Branch, Division of Freedom of Information and Publications, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and should cite the publication date and page number of this Federal Register notice. Written comments may also be delivered to Room P-223, Phillips Building, 7920 Norfolk Avenue, Bethesda, Maryland from 7:30 a.m. to 4:15 p.m. Federal workdays. Copies of written comments received may be examined at the NRC Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC 20555. The filing of requests for a hearing and petitions for leave to intervene is discussed below.

By June 11, 1993, the licensee may file a request for a hearing with respect to issuance of the amendment to the subject facility operating license and any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written request for a hearing and a petition for leave to intervene. Requests for a hearing and a petition for leave to intervene shall be filed in accordance with the Commission’s “Rules of Practice for Domestic Licensing Proceedings” in 10 CFR Part 2. Interested persons should consult a current copy of 10 CFR 2.714 which is available at the Commission’s Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC 20555 and at the local public document room for the particular facility involved. If a request for a hearing or petition for leave to intervene is filed by the above date, the Commission or an Atomic Safety and Licensing Board, designated by the Commission or by the Chairman of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition; and the Secretary or the designated Atomic Safety and Licensing Board will issue a notice of a hearing or an appropriate order.

As required by 10 CFR 2.714, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following factors: (1) the nature of the petitioner’s right under the Act to be made a party to the proceeding; (2) the nature and extent of the petitioner’s property, financial, or other interest in the proceeding; and (3) the possible effect of any order which may be entered in the proceeding on the petitioner’s interest. The petition should also identify the specific aspect(s) of the subject matter of the proceeding as to which petitioner wishes to intervene. Any person who has filed a petition for leave to intervene or who has been admitted as a party may amend the petition without requesting leave of the Board up to 15 days prior to the first prehearing conference scheduled in the proceeding, but such an amended petition must satisfy the specificity requirements described above.

Not later than 15 days prior to the first prehearing conference scheduled in the proceeding, a petitioner shall file a supplement to the petition to intervene which must include a list of the contentions which are sought to be litigated in the matter. Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted in the hearing. The petitioner shall provide a brief explanation of the bases of the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner intends to rely in proving the contention at the hearing. The petitioner must also provide references to those specific sources and documents of which the petitioner is aware and on which the petitioner intends to rely to establish those facts or expert opinion. Petitioner must provide sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact. Contentions shall be limited to matters within the scope of the amendment under consideration. The contention must be one which, if proven, would entitle the petitioner to relief. A petitioner who fails to file such a supplement which satisfies these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing, including the opportunity to present evidence and cross-examine witnesses.

If a hearing is requested, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to decide when the hearing is held. If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendment. If the final determination is that the amendment request involves a significant hazards consideration, any hearing held would take place before the issuance of any amendment.

A request for a hearing or a petition for leave to intervene must be filed with the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Services Branch, or may be delivered to the Commission’s Public Document Room, the Gelman Building, 2120 L Street, NW., Washington DC 20555, by the above date. Where petitions are filed during the last 10 days of the notice period, it is requested that the petitioner promptly so inform the Commission by a toll-free telephone call to Western Union at 1-(800) 246-5100 (in Missouri 1-(800) 342-6700). The Western Union should be given Datagram Identification Number N1023 and the following message addressed to (Project Director):
petitioner’s name and telephone number, date petition was mailed, plant name, and publication date and page number of this Federal Register notice.

A copy of the petition should also be sent to the Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and to the attorney for the licensee.

Nontimely filings of petitions for leave to intervene, amended petitions, supplemental petitions and/or requests for a hearing will not be entertained absent a determination by the Commission, the presiding officer or the Atomic Safety and Licensing Board that the petition and/or request should be granted based upon a balancing of factors specified in 10 CFR 2.714(a)(1)(i)-(v) and 2.144(d).
For further details with respect to this action, see the application for amendment which is available for public inspection at the Commission’s Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC 20555, and at the local public document room for the particular facility involved.

Baltimore Gas and Electric Company, Docket Nos. 50-317 and 50-318, Calvert Cliffs Nuclear Power Plant, Unit Nos. 1 and 2, Calvert County, Maryland

Date of amendments request: April 1, 1993

Description of amendments request:

The proposed amendments would revise Technical Specification (TS) 3/4.8.2, “Onsite Power Distribution Systems AC Power Distribution - Operating,” in relation to the actions to be taken if any of the 120 volt AC vital busses are not operable. The existing TS 3.8.2.1 action statement requires that an inoperable vital bus be restored to operable status within 8 hours or in at least hot standby within the next 6 hours and cold shutdown within the following 30 hours. The proposed action statement change would add an additional option. An inoperable vital bus would be powered from its associated inverter, which is the normal source of power, within 48 hours or be in at least hot standby within the next 6 hours and cold shutdown within the following 30 hours.

Basis for proposed no significant hazards consideration determination:

As required by 10 CFR 50.91(n), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Would not involve a significant increase in the probability or consequences of an accident previously evaluated.

The 120 Volt Vital Alternating Current (AC) system is designed to supply continuous power to plant vital instrumentation and control systems. The only event evaluated in the Updated Final Safety Analysis Report (UFSAR) potentially affected by the 120 Volt Alternating Current (VAC) vital bus being energized by the inverter backup bus is the loss of off-site power (LOOP). Allowing the vital bus to be energized by the inverter backup bus does not affect the probability of having a LOOP, since this lineup is not an initiator to the event. No precursors to any of the accidents in the UFSAR are affected when the plant is in this lineup. Therefore, having a 120 VAC vital bus energized by the inverter backup bus for 48 hours does not involve a significant increase in the probability of an accident previously evaluated.

The consequences of having a LOOP while a 120 VAC vital bus is energized by the inverter backup bus are the same for the existing 8-hour Action Statement and the proposed 48-hour Action Statement. In either case, if there is a LOOP while a vital bus is on the inverter backup bus, the vital bus will experience an interruption of power until the diesel restores power to the inverter backup bus. This causes the Reactor Protective System (RPS) and Engineered Safety Features Actuation System (ESFAS) sensors on the channel powered by this vital bus to trip and increase the possibility of an inadvertent actuation.

This interruption of power may also cause an actuation channel to be de-energized resulting in an emergency diesel generator (EDG) not receiving an undervoltage signal. The result of having a de-energized actuation channel is not a change nor are there significantly different types of operations being introduced. Therefore, this change will not involve a significant increase in the probability of consequences of an accident previously evaluated.

2. Would not create the possibility of a new or different type of accident from any accident previously evaluated.

The proposed change to add an Action Statement to the AC Electrical Distribution System Technical Specification to allow a 120 VAC vital bus to be energized by the inverter backup bus for 48 hours does not represent a change in the configuration of the plant. Specifically, no new hardware is being added to the plant as part of the proposed change nor are there significantly different types of operations being introduced. Allowing a vital bus to be powered by the inverter backup bus for 48 hours does not create the possibility of a new or different type of accident. Therefore, this change would not create the possibility of a new or different type of accident from any accident previously evaluated.

3. Would not involve a significant reduction in the margin of safety.

The proposed change to add an Action Statement to the AC Electrical Distribution System Technical Specification to allow a 120 VAC vital bus to be energized by the inverter backup bus for 48 hours does not represent a significant reduction in the margin of safety. By using the inverter backup bus to supply power to a 120 VAC vital bus, the RPS and ESFAS channels, which would be in the tripped position if the vital bus was de-energized, is able to perform its function for all analyzed design basis accidents except for those involving a concurrent LOOP.

During a LOOP, the vital bus powered by the backup bus will experience a loss of power. Allowing a vital bus to be on the backup bus for 48 hours does not involve a significant reduction in the margin of safety. The result of having a de-energized actuation channel is equivalent to having an inoperable EDG: one train of ESFAS equipment would not be operable. Current Technical Specifications allow an EDG to be inoperable for 72 hours. The proposed action allows a vital bus to be on the backup bus for 48 hours and is therefore more restrictive than the AOT for an inoperable EDG.

Currently, the Technical Specifications have an AOT of eight hours for a de-energized vital bus. Using the inverter backup bus to energize a 120 VAC vital bus when an inverter is out-of-service improves the reliability of the safety protection system when compared with operating with a de-energized vital bus. Therefore, the proposed change would not involve a significant reduction in the margin of safety.

The NRC staff has reviewed the licensee’s analysis and, based on this review, it appears that the three standards of 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendments request involves no significant hazards consideration.

Local Public Document Room location: Calvert County Library, Prince Frederick, Maryland 20678.

Attorney for licensee: Jay E. Silbert, Esquire, Shaw, Pittman, Potts and Trowbridge, 2300 N Street, NW., Washington, DC 20037.

NRC Project Director: Robert A. Capra

Baltimore Gas and Electric Company, Docket Nos. 50-317 and 50-318, Calvert Cliffs Nuclear Power Plant, Unit Nos. 1 and 2, Calvert County, Maryland

Date of amendments request: April 1, 1993

Description of amendments request:

The proposed amendments request administrative, editorial, and format changes to Facility Operating License No. DPR-53 and Facility Operating License No. DPR-69 for the Calvert Cliffs Nuclear Power Plant, Unit Nos. 1 and 2, respectively. The request is to delete, or incorporate as appropriate, all handwritten or “pasted-up” changes and the removal of all previous license conditions that have been completed to the satisfaction of the Commission. The proposed changes and reformatting will result in the operating licenses containing only those license conditions that are currently applicable.
The proposed deletions to facility Operating License No. DPR-53 are:

Paragraph 2.C.(3) relating to fire protection with the exception of the sentence which states: “The licensee is required to implement and maintain the administrative controls identified in Section 6 of the NRC's Fire Protection Safety Evaluation on the facility dated September 14, 1979.”

Paragraph 2.D relating to consideration of an optimum cooling tower system.

The following items relating to construction and preoperational testing which have been completed are also requested to be deleted:

Preoperational Testing Items A.1.a Reactor Protection System, A.1.b Control Element Drive Module Cooling System, A.1.c Reactor Component Handling, and A.1.d Main Steam Isolation Valves. Construction Items A.2.a administrative controls to prevent overpressurization, A.2.b replacement and spacers to the expansion joints in the salt water system, and A.2.c hydrogen supply line to the volume control tank.

Items to be completed prior to postcore loading hot functional testing. Items B.1.a Liquid Waste System Evaporators tests, B.1.b Radiation Monitoring and Process Radiation Systems tests, B.1.c Variable Overpower Trip System tests, and B.2.a Installation and design documentation of safety related pipe hangers, restraints, and supports.

Items to be completed prior to proceeding beyond low power physics testing. Items C.1.a Solid Waste System tests, C.1.b Hydrogen Purge System tests, C.2.a Evaluation of the adequacy of the diesel generator air start system modifications, C.2.b completion of incore instrumentation, C.2.c Completion of reactor internals vibration monitoring capability, and C.2.d Modification of the primary Control Element Assembly Indication system.

The proposed deletions to Facility Operating License No. DPR-69 are:

Paragraph 2.C.2.a exempting the license from compliance with technical specification requirements applying to charcoal testing with the first refueling outage or replacement of the existing charcoal prior to the first outage.

Paragraph 2.C.3 pertaining to incomplete construction items tests and other items. These items included determining over stressing of safety related systems due to inoperable snubbers, conduct an inspection or test program relating to inoperable snubbers during operation, and completion of portions of the snubber inspection program.

Paragraph 2.C.4 pertaining to specified additional reactivity and power distribution surveillances.

Paragraph 2.C.6 relating to fire protection requirements with the exception of the sentence which states: “The licensee is required to implement and maintain the administrative controls identified in Section 6 of the NRC's Fire Protection Safety Evaluation on the facility dated September 14, 1979.”

Paragraph 2.E relating to a reference to paragraph 2.D.2 which is no longer valid.

Paragraph 2.G relating to legal action making any license granted between July 21, 1976, and such time as a mandate is issued on the proceedings making the license subject to the outcome. The proceedings have been completed with no conditions applicable to Calvert Cliffs.

Basis for proposed no significant hazards consideration determination:

As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration. The NRC staff has reviewed the licensee's analysis against the standards of 10 CFR 50.92(c). The NRC staff's review is presented below.

1. Would not involve a significant increase in the probability or consequences of an accident previously evaluated;

The licensee is requesting license amendments which will result in amending the Unit 1 and Unit 2 Facility Operating Licenses in a clean, consistent format. All past handwritten and "pasted-up" changes will be deleted or incorporated as appropriate, and all license conditions that have been completed to the satisfaction of the NRC will be removed.

The proposed changes are editorial and administrative and do not constitute a substantive change to the operating licenses. Therefore, the changes do not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Would not create the possibility of a new or different type of accident from any accident previously evaluated; or

The proposed changes do not modify the plant's configuration or operation as they are editorial and administrative. As a result, no new accident initiators are introduced. Therefore, the changes do not create the possibility of a new or different type of accident from any accident previously evaluated.

3. Would not involve a significant reduction in a margin of safety.

As the proposed changes are editorial and administrative and do not constitute a substantive change to the operating licenses, the margin of safety is not affected.

Based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Calvert County Library, Prince Frederick, Maryland 20678.

Attorney for licensee: Jay E. Silbert, Esquire, Shaw, Pittman, Potts and Trowbridge, 2300 N Street, NW., Washington, DC 20037.

NRC Project Director: Robert A. Capra

Consumers Power Company, Docket No. 50-155, Big Rock Point Plant, Charlevoix County, Michigan

Date of amendment request: March 4, 1993, as revised March 14, 1993

Description of amendment request:

The proposed change will revise the Technical Specifications (TS) to conform to the wording of the revised 10 CFR Part 20 and to reflect a separation of Chemistry and Radiation Protection responsibilities.

Basis for proposed no significant hazards consideration determination:

As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Will the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

The proposed change does not affect the probability or consequences of an accident. The proposed change is to the ADMINISTRATIVE and RADIOLOGICAL EFFLUENT RELEASE sections of the facility Technical Specifications, and are administrative in nature:

- Change "Chemistry and Radiation Protection Supervisor" to "Radiation Protection Supervisor".

- The change from "mRh" to mrem is solely a change in terminology since the revised 10 CFR 20 does not recognize or define the roentgen as a unit of radiation.

- The Liquid Effluents Concentration section and the associated bases have been revised to conform with the revised 10 CFR Part 20. Maximum Permissible Concentration (MPC) terminology has been replaced with "Effluent Concentration".

- The actual instantaneous does rate limits of the Gaseous Effluents Dose Rate section have not changed. However, the bases section has. Under the former 10 CFR 20, these dose rates correspond roughly to the maximum permissible concentration and dose(s) received by the maximum exposed member of the public if allowed to continue for an entire year. These limits are used more as
instantaneous limits (dose rates above which are not allowed to continue for more than one hour at a time) so as to provide assurance not to exceed 10 CFR 50, Appendix I limits. 2. Will the proposed change(s) create the possibility of a new or different kind of accident any previously evaluated?  This proposed change is required by the implementation of the new 10 CFR Part 20 requirements (except for the title change) and are administrative in nature. Neither the material condition of the facility nor the accident analyses are affected by this proposed change. Therefore, the proposed change does not create the possibility of a different type of accident than previously evaluated.

3. Will the proposed change involve a significant reduction in the margin of safety? Each limit that was affected increased the margin of safety by making the limit more conservative; or remained the same.

- The change of distance to "30 centimeters" (12 inches) is more conservative, providing a higher degree of protection for occupationally exposed workers.  
- Most of the effluent concentrations have changed to reflect new scientific information and a change in the public dose limit from 300 rem to 50 rem.
- The limit for dissolved and entrained noble gases was changed from 2 x 10^{-4} to 1.4 x 10^{-4} microcuries/ml. The changes described above reflect lower effluent concentrations and therefore result in a greater degree of protection to the general public.

- Effluent alarm setpoints were reviewed to determine any necessary changes and were found to be set appropriately. No change will be necessary.

- The instantaneous release rate limits for airborne release will not be changed because they are imposed on licensees as a control to ensure that licensees meet Appendix I requirements. Alarm setpoints for these rate limits may change slightly due to changes in scientific data and will be reviewed and changed as appropriate prior to implementation.

Therefore, the proposed change does not involve a reduction in the margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

**Local Public Document Room location:** North Central Michigan College, 1515 Howard Street, Petoskey, Michigan 49770

**Attorney for licensee:** Judd L. Bacon, Esquire, Consumers Power Company, 212 West Michigan Avenue, Jackson, Michigan 49201

**NRC Project Director:** L. B. Marsh

**Consumers Power Company, Docket No. 50-255, Palisades Plant, Van Buren County, Michigan**

**Date of amendment request:** March 29, 1993

**Description of amendment request:**

The proposed amendment would change the Palisades Technical Specification Table 4.2.2 as follows:

1. Change the surveillance interval for Item 2, "Partial Movement of All Rods (Minimum of 6 Inches)" from once "Every Two Weeks" to once "Every 92 Days."

2. Delete the footnote to that table, which provides for reduced testing of CRD-20 and CRD-31 during the remainder of Cycle 10.

3. Correct the FSAR references in that table to reflect the arrangement of the Palisades Updated FSAR.

**Basis for proposed no significant hazards consideration determination:**

As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. **Involve a significant increase in the probability or consequences of an accident previously evaluated.**

The proposed change to the Technical Specifications reduces the frequency of control rod exercising surveillance testing from bi-weekly to quarterly. The presumed intent of this surveillance is to provide assurance that the control rods are not mechanically bound so as to prevent their inserting into the core upon a reactor trip. The exercising of control rods is only capable of determining the ability of the CRDM (Control Rod Drive Mechanism) motor to move the rods a small distance. While this rod motion does provide assurance that the control rod is not firmly mechanically bound at a fully withdrawn position, such binding has never occurred. When the reactor is operating at power, this small range of travel is where the CRDM clearances are the greatest so the test has little chance of detecting mechanical interference if it were to occur. The surveillance cannot, and was not intended to, detect failures in the electrical clutch which releases the control rod. Operating history has shown that other required testing, which is performed following any maintenance requiring disassembly of the CRDM pressure housing, has been able to detect nearly all mechanical problems which affect the control rod trip and insertion capability. Palisades operating history shows that the subject surveillance has never detected such a mechanical problem.

Since the subject surveillance, control rod exercising, has little probability of detecting the faults which it is intended to detect, and since other required testing can, and has, reliably detected such failures prior to entering the operating modes where rod exercising is required, reducing the frequency of control rod exercising will have no significant effect on the probability of reactor operation with any control rod which will not insert upon a reactor trip signal.

Therefore, operation of the facility in accordance with the proposed Technical Specifications would not result in a significant increase in the consequences of an accident previously evaluated.

2. **Create the possibility of a new or different kind of accident from any previously evaluated.**

The proposed change to Technical Specifications alters only the frequency of a surveillance test. It does not alter the manner of testing or the manner in which any plant systems are operated. Therefore, operation of the facility in accordance with the proposed Technical Specifications would not create the possibility of a new or different kind of accident from any previously evaluated.

3. **Involve a significant reduction in a margin of safety.**

The proposed change to the Technical Specifications does not significantly affect the probability of a control rod failing to insert (the only CRDM safety function assumed in the safety analyses), as discussed under question 1, above. The change is in agreement with the control rod exercising frequency required by the Standard Technical Specifications - Combustion Engineering Plants, NUREG 1432, Revision 0, and with the recommendations of "Improvements to Technical Specifications Surveillance Requirements" of NUREG 1366.

Therefore, operation of the facility in accordance with the proposed change to the Technical Specifications would not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

**Local Public Document Room location:** Van Wylen Library, Hope College, Holland, Michigan 49423

**Attorney for licensee:** Judd L. Bacon, Esquire, Consumers Power Company, 212 West Michigan Avenue, Jackson, Michigan 49201

**NRC Project Director:** L. B. Marsh

**Detroit Edison Company, Docket No. 50-341, Fermi-2, Monroe County, Michigan**

**Date of amendment request:** March 23, 1992

**Description of amendment request:**

The proposed amendment would modify License Condition 2.C.(10) to eliminate the Emergency Diesel Generator (EDG) main engine bearing special inspection requirements.

**Basis for proposed no significant hazards consideration determination:**

As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

The proposed change to eliminate the Special Emergency Diesel Generator (EDG) bearing inspection program contained in License Condition 2.C.(10) does not:
(1) Involve a significant increase in the probability or consequences of an accident previously evaluated. The inspection program proposed for elimination has not detected any degradation in any EDG engine bearings. The Fermi 2 EDG’s have been shown to be reliable and will be maintained through effective performance monitoring and preventative maintenance. Therefore, the change does not adversely affect EDG reliability. The change increases the EDG availability by eliminating EDG out-of-service time which is required to perform these inspections. Therefore, the change does not involve a significant increase in the probability or consequences of a previously evaluated accident.

(2) Create the possibility of a new or different kind of accident from any accident previously evaluated. This proposal does not affect the manner of EDG operation or, the design of the plant and does not involve a special test. No new or different accidents are created.

(3) Involve a significant reduction in a margin of safety. Since EDG reliability is maintained and EDG availability is improved, safety margins are not reduced.

The NRC staff has reviewed the licensee’s analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room
location: Monroe County Library System, 3700 South Custer Road, Monroe, Michigan 48161

Attorney for licensee: John Flynn, Esq., Detroit Edison Company, 2000 Second Avenue, Detroit, Michigan 48226

NRC Project Director: L. B. Marsh

Detroit Edison Company, Docket No. 50-341, Fermi-2, Monroe County, Michigan

Date of amendment request: March 23, 1993

Description of amendment request: The proposed amendment would eliminate the qualification on some 18-month surveillance requirements that the surveillance is to be performed “during shutdown.” The proposal follows the guidance of Generic Letter 91-04, which gives guidance for Technical Specification (TS) changes to accommodate a 24-month fuel cycle. The licensee is not planning to extend the fuel cycle at this time.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

The proposed change eliminates the qualification that certain 18-month surveillances be performed during shutdown. The change does not:

(1) Involve a significant increase in the probability or consequences of an accident previously evaluated. The change removes a requirement that certain surveillances be performed during shutdown. The surveillances will still be required to be performed under the provisions of the TS Limiting Condition for Operation (LCO) and Action Requirements. These provisions assure that adequate equipment is available to mitigate accidents. The proposed change does not eliminate, but rather reinforces, the guidance that surveillance activities must be scheduled with regard to their impact on plant safety. Therefore, the change does not involve a significant increase in the probability or consequences of an accident.

(2) Create the possibility of a new or different kind of accident from any accident previously evaluated. The proposed change does not affect the plant design. Equipment removed from service and any plant surveillance activities are still restricted by the TS LCO’s and Action Requirements and all Surveillances must still be scheduled with regard to their impact on plant safety.

(3) Involve a significant reduction in a margin of safety. By giving flexibility to schedule surveillances during operation when consistent with safe plant operation the margin of safety is not significantly affected.

Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards.

Local Public Document Room
location: Monroe County Library System, 3700 South Custer Road, Monroe, Michigan 48161

Attorney for licensee: John Flynn, Esq., Detroit Edison Company, 2000 Second Avenue, Detroit, Michigan 48226

NRC Project Director: L. B. Marsh

Entergy Operations, Inc., et al., Docket No. 50-416, Grand Gulf Nuclear Station, Unit 1, Claiborne County, Mississippi

Date of amendment request: April 21, 1993

Description of amendment request: The proposed amendment revises the requirement for control rod testing to increase the “notch testing” surveillance interval for partially withdrawn control rods from once every 7 days to once every 31 days.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. The proposed change does not significantly increase the probability or consequences of an accident previously evaluated. The current and proposed surveillance requirements for the control rod drives...
include verifying each withdrawn control rod is capable of moving at least one notch once per seven days when operating above the lower power setpoint of the Rod Pattern Control System (RPCS). This surveillance (4.1.3.1.2.a) provides a means of identifying control rods that are immovable as a result of excessive friction or mechanical interference and provides a means of identifying problems with the rod position indicating system (Surveillance Requirement 4.1.3.5.b).

No safety-related equipment or function will be altered as a result of this change. The proposed amendment only increases the surveillance interval for partially withdrawn control rods from once per seven days to once per 31 days. Based on the demonstrated reliability of the control rod drive (CRD) system at Grand Gulf Nuclear Station (GGNS) and similar facilities, the reliability of the CRD surveillance function to reliably control reactivity changes during abnormal operational transients is not compromised. This change has no influence or impact on the probability of any accident or malfunction evaluated in the GGNS Updated Final Safety Analysis Report (USFAR). No accident or malfunctions evaluated are affected; therefore, the consequences of these have not significantly increased.

Based on the above, the proposed change does not significantly increase the probability or consequences of any accident previously evaluated.

2. The proposed change would not create the possibility of a new or different kind of accident from any previously analyzed. Extending the surveillance interval from 7 days to 31 days. As stated above, no safety-related equipment or safety functions are altered as a result of this change.

Therefore, change does not create the possibility of a new or different kind of accident from any accident previously analyzed.

3. The proposed change does not involve a significant reduction in a margin of safety. The proposed change does not alter the requirement that all control rods be OPERABLE in OPERATIONAL CONDITIONS 1 and 2. The proposed change does not change those required actions if a control rod is inoperable. The revised surveillance in conjunction with other control rod surveillances continues to maintain the reliability and availability of the scram function as well as the required shutdown margin. Technical Specifications will continue to require the majority of the control rods to be tested once per seven days. The margin of safety provided by the current TS is not affected by increasing the surveillance interval to 31 days.

Therefore, the proposed change does not result in a significant reduction in a margin of safety.

Based on the above evaluation, operation in accordance with the proposed amendment involves no significant hazards considerations.

The NRC staff has reviewed the licensee’s analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Judge George W. Armstrong Library, Post Office Box 1406, S. Commerce at Washington, Natchez, Mississippi 39120

Attorney for licensee: Nicholas S. Reynolds, Esquire, Winston and Strawin, 1400 L Street, N.W., 12th Floor, Washington, DC 20005-3502

NRC Project Director: John L. Pellet (Acting)

Entergy Operations, Inc., et al., Docket No. 50-416, Grand Gulf Nuclear Station, Unit 1, Claiborne County, Mississippi

Date of amendment request: April 21, 1993

Description of amendment request: This amendment would delete the requirement for flux monitoring as outlined in Regulatory Guide 1.97, “Instrumentation For Light-Water-Cooled Nuclear Power Plants to Access Plant and Environments Conditions During and Following an Accident,” for the Grand Gulf Nuclear Station (GGNS) since analysis shows that these requirements are being met by alternative methods.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

a. No significant increase in the probability or consequences of an accident previously evaluated results from this change.

b. The removal of this License Condition will not affect the physical configuration or operation of the plant, so the probability of an accident previously evaluated is not increased.

The NEDO-31558 report analyzed event scenarios to determine the consequences of neutron flux monitoring unavailability and concludes that the failure of this instrumentation will not prevent the operator from determining reactor power levels. Alternate parameter status will be available from which reactor power may be inferred. Sufficient information will be available upon which to base operational decisions and to conclude that reactivity control has been accomplished, thereby not increasing the consequences of an accident. Additionally, criteria contained in NEDO-31558 regarding the neutron flux monitoring instrumentation provide sufficient confidence that the instrumentation will be available to confirm reactor shutdown for a wide range of events, including Anticipated Transients Without Scram. Based upon the BWR (boiling water reactor) Owners’ Group submittals, the NRC has determined that Category 1 neutron flux monitoring instrumentation is not needed for existing BWRs to cope with Loss of Coolant Accidents, Anticipated Transients Without Scram, or other accidents that do not result in severe core damage conditions.

Based on the above, removal of License Condition (c)(4) of Attachment 1 to the GGNS Operating License will not significantly increase the probability or consequences of a previously analyzed accident.

b. The change would not create the possibility of a new or different kind of accident from any previously analyzed.

This change proposes removal of License Condition (c)(4) of Attachment 1 to the GGNS Operating License. No physical changes to the plant would result if this particular License Condition is removed, nor would any changes in plant operation occur.

The conclusion of the NEDO-31558 was that the failure of the neutron flux monitoring instrumentation will not prevent the operator from determining reactor power levels. Sufficient information is available upon which to base operational decisions and to conclude that reactivity control has been accomplished. The NEDO-31558 also provided an alternate criteria for neutron flux instrumentation to meet, which is acceptable in lieu of the Category 1 criteria of Regulatory Guide 1.97. Based upon the BWR Owners’ Group submittals, the NRC has determined that Category 1 neutron flux monitoring instrumentation is not needed for existing BWRs to cope with Loss of Coolant Accidents, Anticipated Transients Without Scram, or other accidents that do not result in severe core damage conditions.

Based on the information provided above, the removal of License Condition (c)(4) of Attachment 1 to the GGNS Operating License will not create the possibility of a new or different kind of accident from any previously analyzed.

c. This change would not involve a significant reduction in the margin of safety. No changes to plant operation, testing, or physical configuration of the plant will be necessary with the removal of this License Condition.

As stated in the NEDO-31558, failure of the existing neutron flux monitoring instrumentation will not prevent the operator from determining reactor power levels. Sufficient information will be available upon which to base operational decisions and to conclude that reactivity control has been accomplished.

Thus, the margin of safety will not be reduced by deleting License Condition (c)(4) of Attachment 1 to the GGNS Operating License.

The NRC staff has reviewed the licensee’s analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.
Description of amendment request: The proposed amendment would increase the membership and quorum requirements of the Plant Operation Review Committee (PORC), to reflect current plant management positions, and would add three analytical methods to the list of those approved by the NRC for determining core operating limits. Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.92(c), the licensee has provided its analysis of the issue of no significant hazards consideration. The NRC staff has reviewed the licensee’s analysis against the standards of 10 CFR 50.92(c). The NRC staff’s review is presented below.

1. The proposed amendment does not involve a significant increase in the probability or consequences of an accident previously evaluated.

Because the proposed changes do not involve any alterations to the plant, changes to setpoints, or operating conditions or parameters, the response of the plant to previously evaluated accidents is not affected. Therefore, the proposed Technical Specifications changes will not increase the probability or consequences of an accident previously evaluated.

2. The proposed amendment does not create the possibility of a new or different kind of accident from any accident previously evaluated.

The proposed amendment constitutes administrative changes that do not affect the design, operation, maintenance or testing of the plant. Thus, no new modes of failure are created. Therefore, these changes do not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. The proposed amendment does not involve a significant reduction in a margin of safety.

The proposed amendment to PORC membership and quorum requirements modifies neither the qualifications required by, nor the competence of, any PORC member. Adding the Manager of Planning and Scheduling, and the Manager of Plant Engineering to PORC membership expands the capability of management to more completely cover appropriate aspects of station operation. Increasing the number of PORC members required for a quorum will ensure that a quorum will continue to be majority of PORC members. The capability of PORC to meet its responsibilities is not diminished.

The proposed addition of three analytical methods to the list approved by the NRC (Technical Specification 5.14.2) for determining Maine Yankee’s core operating limits does not change the requirement that core operating limits meet all conditions of the safety analysis, and thus does not represent a reduction in a margin of safety. The proposed changes are administrative in nature and do not involve a significant reduction in a margin of safety.

Based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room

The proposed changes simply remove the provisions of the Fire Protection Program that are contained in the Technical Specifications and places them in the TRM [Technical Requirements Manual]. No current requirements are being added or deleted aside from removal of the special reports section. Review of the Fire Protection Program and its revisions will be the responsibility of the PORC [Plant Operations Review Committee] and SORC [Site Operations Review Committee], just as it has always been the responsibility of these groups to review changes to fire protection Limiting Condition for Operation and Surveillance Requirements when they were part of the Technical Specifications. In addition, no design basis accidents are affected by this change, nor are safety systems adversely affected by these changes. Therefore, the new change is not an impact on the probability of occurrence or the consequences of any design basis accidents.

2. Create the possibility of a new or different kind of accident from any previously evaluated.

The proposed changes simply remove the provisions of the Fire Protection Program that are contained in the Technical Specifications and places them in the TRM. Plant procedures will continue to provide the specific instructions necessary for the implementation of the requirements, just as when the requirements resided in the Technical Specifications. Fire Protection Program changes will be governed by the provisions of 10CFR50.59 and the current fire protection license condition. As such, the changes do not directly affect any protective boundaries or does it impact the safety limits for the boundary. Thus, there are no adverse impacts on the protective boundaries, safety limits, or margin of safety.

No change is being proposed for the Fire Protection Program requirements themselves. The relevant Technical Specifications are being deleted, and the requirements contained therein are being incorporated into the TRM. Plant procedures will continue to provide the specific instructions necessary for the implementation of the requirements, just as when the requirements resided in the Technical Specifications. Fire Protection Program changes will be governed by the provisions of 10CFR50.59 and the current fire protection license condition. As such, the changes do not directly affect any protective boundaries or does it impact the safety limits for the boundary. Thus, there are no adverse impacts on the protective boundaries, safety limits, or margin of safety.

The NRC staff has reviewed the licensee’s analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.
changes would not:

As required by 10 CFR 50.91(a), the technical specifications.

requirements existing elsewhere in the technical specifications.

The proposed amendment modifies requirements when certain electrical power sources are not operable to prohibit certain operations, and to remove a current requirement to vent the reactor coolant system, based on adequate overpressure protection requirements existing elsewhere in the technical specifications.

Basis for proposed no significant hazards consideration determination.

As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

The proposed changes do not involve a significant hazards consideration because the changes would not:

1. Involve a significant increase in the probability or consequences of an accident previously analyzed. Three of the proposed changes add additional restrictions to the technical specifications while one change removes an unnecessary restriction which is adequately covered by Technical Specification 3.4.9.3. Overpressure Protection. The proposed changes do not affect any of the design basis accidents nor are there any malfunctions associated with these changes.

2. Create the possibility of a new or different kind of accident from any previously analyzed accident. The proposed change to eliminate the requirement to depressurize and vent the reactor coolant system RCS does not create the possibility of a different accident since the function that the vent provided, overpressure protection, is being fulfilled by Technical Specification 3.4.9.3. Thus, as long as this overpressure protection is in place there is no possibility of an accident of a different type than previously evaluated.

3. Involve a significant reduction in the margin of safety. The bases for the requirement to depressurize and vent the RCS upon a loss of AC or DC power or the associated busses while shutdown was to ensure that the reactor vessel cannot be overpressurized. Technical Specification 3.4.9.3 requires one of three systems be operable to provide overpressure protection. This can be two [residual heat removal] RHR suction relief valves, two [power-operated relief valves] PORVs, or a vent area of 5.4 square inches. Since one of these systems must be operable by Technical Specification 3.4.9.3, it is not necessary to have another technical specification require the vent. Only the PORVs require electrical power (battery) to function. By procedure, the PORV must be declared inoperable when its associated battery is inoperable. Thus, Technical Specification 3.4.9.3 adequately ensures that the RCS pressure boundary is protected. As a result, the proposed change does not impact the margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.


NRC Project Director: John F. Stolz
Pennsylvania Power and Light Company, Docket Nos. 50-387 and 50-388 Susquehanna Steam Electric Station, Units 1 and 2, Luzerne County, Pennsylvania

Date of amendment request: April 16, 1993

Description of amendment request: The amendments would revise the Technical Specifications (TS) as requested by NRC Generic Letter (GL)88-01, "NRC Position on IGSCC in BWR Austenitic Stainless Steel Piping." GL 88-01 requested licensees to submit TS changes to include a statement in the section on Inservice Inspection (ISI) that the ISI program for piping covered by the scope of GL 88-01 would be performed in accordance with the staff positions on schedule, methods, personnel, and sample expansion as outlined in the GL. Also, licensees were requested to modify the section on unidentified leakage within containment to limit any increase to 2 gpm within any 24-hour period. The licensee's submittal is their response to GL 88-01.

Basis for proposed no significant hazards consideration determination:

As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

The proposed change does not:

1. Involve a significant increase in the probability or consequences of any accident previously evaluated.

Incorporation of the more restrictive leakage limit is intended to improve the timeliness of detecting any RCS leakage and to allow for any required action to occur earlier. Limiting the applicability of this leakage rate along with increasing the time allowed for determining its source is intended to prevent any unnecessary plant shutdowns and subsequent equipment transients. Additionally, changes to the monitoring of this leakage level are proposed to reduce operator burden and further enhance overall plant operation, thus decreasing the probability of previously evaluated events. The consequences of those events are not changed by this proposal. The administrative correction to delete the outdated footnote has no safety impact.

2. Create the possibility of a new or different kind of accident from any accident previously evaluated.

As stated above these proposed changes are intended to improve the early detection of RCS leakage while enhancing operator availability for determining this source of leakage by the elimination of unnecessary burdens. Limiting of the Applicability to Operational Condition 1 will assure that steady state conditions have been established, while increasing the time to conduct thorough investigations. Therefore these changes will not create the possibility of a new or different kind of event.

3. Involve a significant reduction in a margin of safety.

The motivation for proposing these changes is to improve the detection capabilities of the operator by incorporating stricter limits and eliminating some unnecessary burdens, thus increasing, not decreasing the margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Osterhout Free Library, Reference Department, 71 South Franklin Street, Wilkes-Barre, Pennsylvania 18701
Attorney for licensee: Jay Silberg, Esquire, Shaw, Pittman, Potts and Trowbridge, 2300 N Street NW., Washington, D.C. 20037
NRC Project Director: Charles L. Miller
Tennessee Valley Authority, Docket Nos. 50-327 and 50-328, Sequoyah Nuclear Plant, Units 1 and 2, Hamilton County, Tennessee

Date of amendment request: March 10, 1993 (TS 92-08)

Description of amendment request: The proposed amendment would revise various technical specification requirements to allow a reduction in the boric acid concentration in the boric acid tanks (BAT's) from 12 percent to approximately 3.5 to 4.0 percent by weight. To accomplish this, the
following changes were proposed: (1) Limiting Condition for Operation (LCO) 3.1.1.1 and 3.1.1.2 Action Statements would be revised to increase the flow rate from 10 to 35 gpm (gallons per minute) and to decrease the boron concentration from 20,000 ppm (parts per million) to greater than or equal to 6120 ppm; (2) Surveillance Requirements (SRs) 4.1.2.1 and 4.1.2.2 would be revised to better describe the heat traced flow path, to change the minimum heat trace solution temperature limit from 145°F to an ambient temperature limit of 63°F, and to establish requirements should the area temperature drop below the limit; (3) SR 4.1.2.2 would be changed to raise the required flow rate; (4) LCO 3.1.2.5 would be changed by deleting the heat trace requirement, increasing the minimum boron volume and decreasing the minimum solution temperature required in the boric acid tanks, increasing the minimum containment borated water volume in the refueling water storage tank, and expand the applicability to include mode 4; (5) SRs 4.1.2.5 and 4.1.2.6 would be changed to add a requirement to verify that the boric acid tank solution temperature is greater than 63°F every 7 days by verifying that the area temperature is greater than 63°F, indicating the action that must be taken if the temperature is below 63°F, and changing the format of the SR by separating the requirements for the boric acid storage system from those for the refueling water storage tank (RWST) requirements; (6) LCO 3.1.2.6 would be changed by deleting the heat trace requirement, replacing the minimum contained borated water volume specification with a figure that relates minimum concentration to minimum volume stored for various RWST concentrations, reducing the minimum solution temperature, removing Mode 4 from applicability of the LCO, and changing the required Action statement to require that the plant be placed in the Hot shutdown condition rather than the Cold shutdown condition if stated conditions cannot be satisfied; (7) LCOs 3.9.1 and 3.10.1 would be changed to increase the required boration flow rate and decrease the required boron concentration; and (8) other administrative and applicable Basis changes.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.92(c), the licensee has provided its analysis of the issues of no significant hazards consideration, which is presented below:

TVAs has evaluated the proposed technical specification (TS) change and has determined that it does not represent a significant hazards consideration based on criteria established in 10 CFR 50.92(c). Operation of Sequoyah Nuclear Plant (SQN) in accordance with the proposed amendment will not:

1. Involve a significant increase in the probability or consequences of an accident previously evaluated.

The reduction in the boric acid concentration in the boric acid tanks (BAT) and elimination of requirements for the associated heat trace circuits will not significantly increase the probability or consequence of an accident previously evaluated. Only minor modifications are planned; and while operating processes will change to reflect the new boration method, the capability to safely shut down the area temperature limit of 63°F, the boron addition rate remains essentially the same. In addition, as boron addition from the BATs is not taken credit for in any accident analysis, the probability or consequences of any accident previously evaluated will not be affected.

As part of this change, for consistency Mode 4 was removed and remains TS 3.1.2.6 and placed in TS 3.1.2.5. The analysis performed supports the relocation and demonstrates that there is sufficient borated water volume and concentration to provide the required shutdown margin. Based upon this analysis, this change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Create the possibility of a new or different kind of accident from any previously analyzed.

The original SQN design required heat trace circuits to ensure the boron, which was at 12 percent by weight, would remain in solution and be available for reactor coolant system reactivity control throughout core life. By lowering the boron concentration to approximately 3.5 to 4.0 percent by weight, chemical analysis has shown there is no possibility of boron precipitating out of solution as long as the boric acid solution remains above 58 degrees Fahrenheit (F). The auxiliary building, where this equipment is located normally, remains well above 58 degrees F. Continuous monitoring of the required area temperatures, in conjunction with an alarm in the main control room, will allow for operator actions to ensure the solution temperature remains above the TS-required temperature of greater than or equal to 63 degrees F. By eliminating the need for the heat trace, there is an increase in the availability of the boric acid storage system. In addition, the boron concentration remains well above expected RCS concentration. Therefore, the removal of requirements for heat trace circuits and the reduction of the boron concentration in the BATs do not create the possibility of a new or different kind of accident from any previously analyzed.

As previously stated, Mode 4 has been delayed from TS 3.1.2.6 and added to TS 3.1.2.5 to provide consistency between these two TSs and TSs 3.1.2.1 and 3.1.2.2. The analysis provides the basis that sufficient shutdown margin still remains to meet the TS requirement for Mode 4 when it is added to TS 3.1.2.5. Therefore, this change does not create the possibility of a new or different kind of accident from any previously analyzed.

3. Involve a significant reduction in a margin of safety.

The margin of safety requirements is not affected by the removal of the heat trace circuits and the reduction of the boric acid concentration in the BATs. The required flow paths and borated water sources are still available as before. The required quantity of borated water is still available based upon the new evaluation, and the ability to deliver this borated water remains the same. As stated previously, the reduction of the boric acid concentration in the BATs to well above expected RCS concentration. The margin of safety requirements is not significantly increased.

Moving Mode 4 applicability from TS 3.1.2.6 to TS 3.1.2.5 does not involve a reduction in the margin of safety. This is supported by the analysis, which establishes the minimum boron requirements to ensure that there still remains adequate shutdown margin for cooldown below 350 degrees F (Mode 4).

The NRC has reviewed the licensee's analysis and, based on that review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room
location: Chattanooga-Hamilton County Library, 1101 Broad Street, Chattanooga, Tennessee 37402

Attorney for licensee: General Counsel, Tennessee Valley Authority, 400 West Summit Hill Drive, ET 11H, Knoxville, Tennessee 37902.

NRC Project Director: Frederick J. Hebdon

Tennessee Valley Authority, Docket Nos. 50-327 and 50-328, Sequoyah Nuclear Plant, Units 1 and 2, Hamilton County, Tennessee

Date of amendment request: March 10, 1993 (TS 93-02)

Description of amendment request: The proposed amendment would add a reference to the test requirements of 10 CFR Part 50, Appendix J, "Primary Reactor Containment Leakage Testing for Water-Cooled Power Reactors" to the technical specifications, and remove the
As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issues of no significant hazards consideration, which is presented below:

TVA has evaluated the proposed technical specification (TS) change and has determined that it does not represent a significant hazards consideration based on criteria established in 10 CFR 50.92(c). Operation of Sequoyah Nuclear Plant (SQN) in accordance with the proposed amendment will not:

1. Involve a significant increase in the probability or consequences of an accident previously evaluated.

SQN's primary containment design includes the features required to satisfy the testing requirements of 10 CFR 50, Appendix J. The evaluation for determining containment leakage rate limits and offsite dose limits following an accident is not affected. SQN's current acceptance criteria governing containment leak rate limits (0.75 L/s for periodic Type A testing and 0.60 L/s for Types B and C testing) remain unchanged. TVA's proposed change removes detailed requirements such as containment test requirements, test schedules, and test accuracies from TSs. These detailed requirements are governed by 10 CFR 50, Appendix J, and have not been affected by TVA's proposed change. Individual leakage limits associated with SQN's containment air locks, purge valves, or secondary bypass leakage to the auxiliary building are site specific (not specifically part of the acceptance criteria of 10 CFR 50, Appendix J) and are retained in SQN TSs. All other proposed changes are clarifications and do not affect the intent of the affected specifications. Consequently, TVA's proposed change will not affect the margin of safety.

The NRC has reviewed the licensee's analysis and, based on this review, it appears that the three standards of SQN's primary containment design will not affect the margin of safety.

In conclusion, TVA's proposed TS change will not affect containment test criteria, system conditions, or plant configurations, and will not affect SQN's accident analysis. The proposed change is considered by TVA to be a TS improvement that is consistent with the guidance contained in the recently approved NUREG-1431. Consequently, this change will not increase the probability or consequences of an accident previously evaluated.

2. Create the possibility of a new or different kind of accident from any previously analyzed.

No physical modification is being made to any plant equipment, operating setpoints, limits, or operating procedures as a result of this change. TVA's proposed TS amendment is designed to remove detailed containment test requirements from TSs and maintain these containment test requirements under 10 CFR 50, Appendix J. The proposed change does not alter any accident analysis or any assumptions used to support the accident analysis. Consequently, the containment leak rate assumptions used to determine offsite dose limits for compliance with 10 CFR 100 are not affected. All other proposed changes are clarifications, including the revised wording for the footnote to TS Table 3.6-2. These clarifications do not impact the intent of the affected specifications.

3. Involve a significant reduction in a margin of safety.

The margin of safety provided by SQN's allowable containment leakage rate test limits (0.75 L/s for periodic Type A testing and 0.60 L/s for Types B and C testing) remains unchanged. TVA's proposed change removes detailed requirements such as containment test requirements, test schedules, and test accuracies from TSs. These detailed requirements are governed by 10 CFR 50, Appendix J, and have not been affected by TVA's proposed change. Individual leakage limits associated with SQN's containment air locks, purge valves, or secondary bypass leakage to the auxiliary building are site specific (not specifically part of the acceptance criteria of 10 CFR 50, Appendix J) and are retained in SQN TSs. All other proposed changes are clarifications and do not affect the intent of the affected specifications. Consequently, TVA's proposed change will not affect the margin of safety.

The NRC has reviewed the licensee's analysis and, based on this review, it appears that the three standards of SQN's primary containment design will not affect the margin of safety.
Section 6.2.6, and the exemption to 10 CFR Part 50, General Design Criteria 56, provided in NUREG-1232. A seven-day timeframe for returning an inoperable vacuum relief isolation valve to operable status is provided and is consistent with other TS action requirements that are applicable upon unavailability of SQN's control air system (i.e., reference TS 3/4.7.8, "Auxiliary Building Gas Treatment Systems; TS 3/4.1.8, "Emergency Gas Treatment Systems; and TS 3/4.7.7, "Control Room Emergency Ventilation System"). The seven-day timeframe ensures that redundant isolation capability is restored in a reasonable amount of time such that reliance upon a single vacuum relief valve does not exist for an indefinite period of time. Accordingly, the proposed TS change does not involve an increase in the probability or consequences of an accident previously evaluated.

No physical modification is being made to any plant hardware, plant operating setpoints, limits, or operating procedures as a result of this proposed change. TVA's proposed change provides a TS improvement that clarifies the configuration and function of SQN's vacuum relief valves as designed. The proposed change removes the potential for creating a conflict between Specification 3/4.6.3, "Control Room Vacuum Relief Valves," and Specification 3/4.6.6, "Vacuum Relief Valves." SQN's vacuum relief valves provide qualified containment isolation protection that meets the intent of the TS action requirement for containment penetration isolation. The proposed change does not alter any accident analysis or any assumptions used to support the accident analyses. The containment leakage assumptions used to determine offsite dose limits for compliance with 10 CFR 100 are not affected.

A seven-day timeframe for returning an inoperable vacuum relief isolation valve to operable status is provided and is consistent with other TS action requirements that are applicable upon unavailability of SQN's control air system (i.e., reference TS 3/4.7.8, TS 3/4.1.8, and TS 3/4.7.7). The seven-day timeframe ensures that redundant isolation capability is restored in a reasonable amount of time such that reliance upon a single vacuum relief valve does not exist for an indefinite period of time. Consequently, the proposed change does not create the possibility of a new or different kind of accident from any previously analyzed.

3. Involve a significant reduction in a margin of safety

The margin of safety provided by the design of SQN's containment vacuum relief penetration remains unchanged. TVA's proposed change does not affect the containment isolation function or the allowable containment leakage rate values specified in the TSs. The proposed change ensures that the proper action is taken in the event the automatic closure capability of the butterfly isolation valve is lost for any reason (improper action would be the isolation of a vacuum relief penetration that is required to be operable in accordance with TS 3/4.6.6). Considering SQN's vacuum relief valves as deactivated automatic valves, will ensure that the TS action requirements remain consistent with the design functions. Both vacuum relief and containment isolation requirements will continue to be provided. Accordingly, the proposed change does not involve a reduction in the margin of safety.

The NRC has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room
location: Chattanooga-Hamilton County Library, 1101 Broad Street, Chattanooga, Tennessee 37402

Attorney for licensee: General Counsel, Tennessee Valley Authority, 400 West Summit Hill Drive, ET 11H, Knoxville, Tennessee 37902

NRC Project Director: Frederick J. Hebdon

Toldeo Edison Company, Centerior Service Company, and The Cleveland Electric Illuminating Company, Docket No. 50-346, Davis-Besse Nuclear Power Station, Unit No. 1, Ottawa County, Ohio

Date of amendment request: November 9, 1992

Description of amendment request: The proposed amendment would revise Technical Specification (TS) TS 3/4.5.2, TS Bases 3/4.5.2 and 3/4.5.3, and TS Bases 3/4.6.2.1 to allow the de-energization of the Borated Water Storage Tank outlet isolation valves DH-7A and DH-7B, in the open position, during operational Modes 1, 2, 3, and 4. The effect of these changes will allow the licensee to perform control room evacuation actions in the event of a fire with one less person on each shift. In addition, as a related change, TS Surveillance Requirement 4.5.2.d.2.b is proposed to be revised to reflect the testing of the valves' interlocks only during times of energization.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

Toldeo Edison has reviewed the proposed changes and determined that a significant hazards consideration does not exist because operation of the Davis-Besse Nuclear Power Station, Unit Number 1, in accordance with the proposed changes would:

1. Not involve a significant increase in the probability of an accident previously evaluated because the removal of power to these valves does not affect the large break loss of coolant accident (LOCA) probability.

1b. Not involve a significant increase in the consequences of an accident previously evaluated because the change does not alter the Updated Safety Analysis Report (USAR) LOCA evaluation and ensure that the plant can be safely shutdown for an 10 CFR Part 50, Appendix A, General Design Criteria 19.

2a. Not create the possibility of a new kind of accident from any accident previously evaluated because adequate time is available under the LOCA sequence of events to close the breakers before the operator is required to transfer pump suction to the containment emergency sump. Procedures are in place that the breakers are closed by the operators. The cumulative radiation dose received by the operator while performing these manual actions would be below the guidelines of 10 CFR Part 20 and the 10 CFR Part 50, Appendix A, General Design Criteria 19.

2b. Not create the possibility of a different kind of accident from any accident previously evaluated because adequate time is available to close the breakers before the operator is required to transfer pump suction from the BWST outlet valves and the containment emergency sump valves when needed. The breakers needed to restore the power to these valves are located in radiologically accessible areas post-LOCA.

3. Not involve a significant reduction in a margin of safety because these are not significant changes to the initial conditions contributing to accident severity or consequences. There is sufficient time available to close the breakers before the operator is required to transfer pump suction from the BWST to the Containment Emergency Sump.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room
location: University of Toledo Library, Documents Department, 2801 Bancroft Avenue, Toledo, Ohio 43606

Attorney for licensee: Jay E. Silberg, Esquire, Shaw, Pittman, Potts and Trowbridge, 2300 N Street, N.W., Washington, DC 20037

NRC Project Director: John N. Hannon

Union Electric Company, Docket No. 50-483, Callaway Plant, Unit 1, Callaway County, Missouri

Date of amendment request: November 11, 1992

Description of amendment request: The amendment would revise Technical Specification 3.9.7 and associated Bases to allow the fuel pool transfer gates to
travel over fuel assemblies in the spent fuel pool for refueling activities, fuel handling system maintenance, and transfer gate seal replacement.

**Basis for proposed no significant hazards consideration determination:** As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

The proposed change does not involve a significant hazard consideration because operation of the Callaway Plant with this change would not:

1. Involve a significant increase in the probability or consequences of an accident previously evaluated.

   The Callaway Safety Analysis Report has been reviewed and found to be unaffected by this proposed change. The design of the plant assumed gate movement to support plant refuel and fuel handling system maintenance. Allowing gate movement over the spent fuel pool will not increase the consequences of any accident or malfunction of equipment since the fuel racks have been shown to be able to withstand a transfer gate drop from 15 inches above the racks with no damage to stored fuel.

2. Create the possibility of a new or different kind of accident from any previously evaluated.

   Technical Specifications and administrative controls will assure that the transfer gates will not be dropped on the racks in a manner which can damage fuel. Therefore, there is no new type of accident or malfunction created.

3. Involve a significant reduction in a margin of safety.

   The margin of safety remains unaffected since the Technical Specifications and administrative controls will assure that the gates will not be dropped on the racks in a manner which can damage fuel. The NRC staff has reviewed the licensee’s analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

   **Local Public Document Room location:** Callaway County Public Library, 710 Court Street, Fulton, Missouri 65251.

   **Attorney for licensee:** Gerald Charnoff, Esq., Shaw, Pittman, Potts & Trowbridge, 2300 N Street, N.W., Washington, DC 20037

   **NRC Project Director:** John N. Hannon

   **Virginia Electric and Power Company, Docket No. 50-339, North Anna Power Station, Unit No. 2, Louisa County, Virginia**

   **Date of amendment request:** April 8, 1993

   **Description of amendment request:** The proposed changes would revise the Technical Specifications (TS) for the North Anna Power Station, Unit No. 2 (NA-2). The proposed changes would allow steam generator (SG) tube sleeving in accordance with the Westinghouse laser welding process described in WCAP 13088, Rev. 1, and WCAP 13619, "Specific Application of Laser Welded Sleeves for North Anna Unit 2 Steam Generators," January 1993. The employment of two SGs has increased the consequences of any accident or malfunction created.

   These primary-to-secondary leak rates provide a large leak-before-break margin. Using the bounding conditions of the Westinghouse Series 44 and 51 steam generators, the WCAP-13088, Rev. 1, generic limiting leak rate satisfies the leak-before-break criteria for Alloy 690 sleeved tubes.

   Despite the fact that leak-before-break is considered to be applicable (historically no primary-to-secondary leakage or degradation has been evidenced in Westinghouse sleeves) to the sleeved tube assembly, the hypothetical consequences of failure of the sleeve would be bounded by the current steam generator tube rupture analysis included in the North Anna Power Station UFSAR (Updated Final Safety Analysis Report).

   **Basis for proposed no significant hazards consideration determination:** As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below in condensed form:

   1. Operation of the North Anna Power Station Unit 2 in accordance with the proposed license amendment does not involve a significant increase in the probability or consequences of an accident previously evaluated.

      The tubesheet and/or tube support plate intersection laser welded sleeve configuration has been designed and analyzed in accordance with the requirements of the ASME Code and Regulatory Guide 1.121. Fatigue and stress analyses of the sleeved tube assemblies produced acceptable results. Mechanical testing has shown that the structural strength of the Alloy 690 sleeves under normal, faulted and upset conditions is within acceptable limits. Leak testing has demonstrated that primary-to-secondary leakage is not expected during all plant conditions, including the case where the seal weld is not produced in the lower joint of the tubesheet sleeve.

   A conservative leak-before-break evaluation has been performed for the sleeved tube assembly, using bounding values for operating regimes 44 and 51 steam generators. The evaluation is considered conservative in that no credit for the parent tube is assumed in determining the burst pressure of the sleeved tube assembly. The leak-before-break criteria compares the postulated throughwall crack length which will leak at a specified value at normal operating conditions, thereby permitting adequate leakage detection and safe shutdown of the plant prior to the crack achieving a length equal to the critical crack length which could be postulated to burst at steam line break conditions. The North Anna Unit 2 Technical Specifications limit primary-to-secondary leakage. Additionally, North Anna Power Station maintains an administrative maximum allowable leak rate limit (of 50 gallons per day (GPD) per steam generator).

   **These primary-to-secondary leak limit rates provide a large leak-before-break margin.**

   Using the bounding conditions of the Westinghouse Series 44 and 51 steam generators, the WCAP-13088, Rev. 1, generic limiting leak rate satisfies the leak-before-break criteria for Alloy 690 sleeved tubes.

   **Basis for proposed no significant hazards consideration determination:** As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below in condensed form:

   1. Operation of the North Anna Power Station Unit 2 in accordance with the proposed license amendment does not involve a significant increase in the probability or consequences of an accident previously evaluated.

      The tubesheet and/or tube support plate intersection laser welded sleeve configuration has been designed and analyzed in accordance with the requirements of the ASME Code and Regulatory Guide 1.121. Fatigue and stress analyses of the sleeved tube assemblies produced acceptable results. Mechanical testing has shown that the structural strength of the Alloy 690 sleeves under normal, faulted and upset conditions is within acceptable limits. Leak testing has demonstrated that primary-to-secondary leakage is not expected during all plant conditions, including the case where the seal weld is not produced in the lower joint of the tubesheet sleeve.

   A conservative leak-before-break evaluation has been performed for the sleeved tube assembly, using bounding values for operating regimes 44 and 51 steam generators. The evaluation is considered conservative in that the parent tube is assumed in determining the burst pressure of the sleeved tube assembly. The leak-before-break criteria compares the postulated throughwall crack length which will leak at a specified value at normal operating conditions, thereby permitting adequate leakage detection and safe shutdown of the plant prior to the crack achieving a length equal to the critical crack length which could be postulated to burst at steam line break conditions. The North Anna Unit 2 Technical Specifications limit primary-to-secondary leakage. Additionally, North Anna Power Station maintains an administrative maximum allowable leak rate limit (of 50 gallons per day (GPD) per steam generator).

   **These primary-to-secondary leak limit rates provide a large leak-before-break margin.**

   Using the bounding conditions of the Westinghouse Series 44 and 51 steam generators, the WCAP-13088, Rev. 1, generic limiting leak rate satisfies the leak-before-break criteria for Alloy 690 sleeved tubes.

   **Basis for proposed no significant hazards consideration determination:** As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below in condensed form:

   1. Operation of the North Anna Power Station Unit 2 in accordance with the proposed license amendment does not involve a significant increase in the probability or consequences of an accident previously evaluated.

      The tubesheet and/or tube support plate intersection laser welded sleeve configuration has been designed and analyzed in accordance with the requirements of the ASME Code and Regulatory Guide 1.121. Fatigue and stress analyses of the sleeved tube assemblies produced acceptable results. Mechanical testing has shown that the structural strength of the Alloy 690 sleeves under normal, faulted and upset conditions is within acceptable limits. Leak testing has demonstrated that primary-to-secondary leakage is not expected during all plant conditions, including the case where the seal weld is not produced in the lower joint of the tubesheet sleeve.

   A conservative leak-before-break evaluation has been performed for the sleeved tube assembly, using bounding values for operating regimes 44 and 51 steam generators. The evaluation is considered conservative in that the parent tube is assumed in determining the burst pressure of the sleeved tube assembly. The leak-before-break criteria compares the postulated throughwall crack length which will leak at a specified value at normal operating conditions, thereby permitting adequate leakage detection and safe shutdown of the plant prior to the crack achieving a length equal to the critical crack length which could be postulated to burst at steam line break conditions. The North Anna Unit 2 Technical Specifications limit primary-to-secondary leakage. Additionally, North Anna Power Station maintains an administrative maximum allowable leak rate limit (of 50 gallons per day (GPD) per steam generator).

   **These primary-to-secondary leak limit rates provide a large leak-before-break margin.**

   Using the bounding conditions of the Westinghouse Series 44 and 51 steam generators, the WCAP-13088, Rev. 1, generic limiting leak rate satisfies the leak-before-break criteria for Alloy 690 sleeved tubes.

   **Basis for proposed no significant hazards consideration determination:** As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below in condensed form:

   1. Operation of the North Anna Power Station Unit 2 in accordance with the proposed license amendment does not involve a significant increase in the probability or consequences of an accident previously evaluated.

      The tubesheet and/or tube support plate intersection laser welded sleeve configuration has been designed and analyzed in accordance with the requirements of the ASME Code and Regulatory Guide 1.121. Fatigue and stress analyses of the sleeved tube assemblies produced acceptable results. Mechanical testing has shown that the structural strength of the Alloy 690 sleeves under normal, faulted and upset conditions is within acceptable limits. Leak testing has demonstrated that primary-to-secondary leakage is not expected during all plant conditions, including the case where the seal weld is not produced in the lower joint of the tubesheet sleeve.

   A conservative leak-before-break evaluation has been performed for the sleeved tube assembly, using bounding values for operating regimes 44 and 51 steam generators. The evaluation is considered conservative in that the parent tube is assumed in determining the burst pressure of the sleeved tube assembly. The leak-before-break criteria compares the postulated throughwall crack length which will leak at a specified value at normal operating conditions, thereby permitting adequate leakage detection and safe shutdown of the plant prior to the crack achieving a length equal to the critical crack length which could be postulated to burst at steam line break conditions. The North Anna Unit 2 Technical Specifications limit primary-to-secondary leakage. Additionally, North Anna Power Station maintains an administrative maximum allowable leak rate limit (of 50 gallons per day (GPD) per steam generator).

   **These primary-to-secondary leak limit rates provide a large leak-before-break margin.**

   Using the bounding conditions of the Westinghouse Series 44 and 51 steam generators, the WCAP-13088, Rev. 1, generic limiting leak rate satisfies the leak-before-break criteria for Alloy 690 sleeved tubes.
support the conclusion that installation of laser welded tube sleeves will not increase the probability or consequences of an accident previously evaluated. Depending upon the break location for a postulated steam generator tube rupture event, implementation of tube sleeving could act to reduce the radiological consequences to the public due to reduced flow rate through a sleeved tube compared to a non-sleeved tube based on the restriction afforded by the sleeve wall thickness.

2. The proposed license amendment does not create the possibility of a new or different kind of accident previously evaluated.

Implementation of laser welded sleeving will not introduce significant or adverse changes to the plant design basis. Stress and fatigue analysis of the repair has shown the ASME Code and Regulatory Guide 1.121 allowable values are met. Implementation of laser welded sleeving maintains overall tube bundle structural and leakage integrity at a level consistent to that of the originally supplied tubing during all plant conditions. Leak and mechanical testing of sleeved tubes support the conclusions of the calculations that the sleeve retains both structural and leakage integrity during all conditions. Sleeving of tubes does not provide a mechanism resulting in an accident outside of the area affected by the sleeves. Any hypothetical accident as a result of potential tube or sleeve degradation in the repaired portion of the tube is bounded by the existing tube rupture accident analysis. Since the sleeve design does not affect any other component or location of the tube outside of the immediate area repaired, in addition to the fact that the installation of sleeves and the impact on current plugging level analyses is accounted for, the possibility that laser welded sleeving creates a new or different type of accident is not supported.

3. The proposed license amendment does not involve a significant reduction in a margin of safety.

The laser welded sleeving repair of degraded steam generator tubes as identified in WCAP-13088, Rev. 1 has been demonstrated to restore the integrity of the tube bundle under normal and postulated accident conditions. The safety factors used in the design of sleeves for the repair of degraded tubes are consistent with the safety factors in the ASME Boiler and Pressure Vessel Code used in steam generator design. The plugging limit criteria for the sleeves have been established using the methodology of Regulatory Guide 1.121. The design of the sleeve joints has been verified by testing to preclude leakage during normal and postulated accident conditions. Implementation of laser welded sleeving will reduce the probability for primary-to-secondary leakage during a postulated steam line break while maintaining available primary coolant flow area in the event of a LOCA. By removing from service degraded intersections through repair, the potential for steam line break leakage is reduced. These degraded intersections now are returned to a condition consistent with the Design Basis. While the installation of a sleeve causes a reduction in flow, the reduction is far below the reduction incurred by plugging. Therefore, far greater primary coolant flow area is maintained through sleeving. Use of Regulatory Guide 1.121 criteria assures that the margin of safety with respect to structural integrity is the same for the sleeves as for the original steam generator tubes.

The portion of the installed sleeve assembly which represent the reactor coolant pressure boundary can be monitored for the initiation and progression of sleeve/tube wall degradation, thus satisfying the requirements of Regulatory Guide 1.83. Portions of the tube bridged by the sleeve joints are effectively removed from the pressure boundary, and the sleeve then forms the pressure boundary in these areas. The areas of the sleeved tube assembly which require inspection are defined in the Bases to the North Anna Unit 2 Technical Specifications.

* * * * *

The effect of sleeving on the design transients and accident analyses have been reviewed based on the installation of sleeves up to the level of steam generator tube plugging coincident with the minimum reactor flow rate. Currently the North Anna Technical Specifications limit minimum reactor coolant flow rate at 284.00 gpm total. Virginia Electric and Power Company has [separately] submitted a proposed license amendment to lower the minimum measured flow rate to 275.300 gpm . . . . The installation of sleeves is . . . evaluated as the equivalent of some level of steam generator tube plugging.

* * * * *

Evaluation of the installation of sleeves is based on the determination that LOCA evaluations for the licensed minimum reactor coolant flow bound the effect of a combination of tube plugging and sleeving up to an equivalent of the actual steam generator tube plugging limit. Information provided in WCAP-13088, Rev. 1 describes the method to determine the flow equivalency for all combinations of tubesheet and tube support plates in order that the minimum flow requirements are met.

* * * * *

Based on the preceding analysis, it is concluded that operation of North Anna Power Station Unit 2 following the installation of Alloy 690 laser welded sleeves at the tube support elevations and within the tubesheet region of the steam generators, in accordance with the proposed amendment does not result in the creation of an unreviewed safety question, an increase in the probability of an accident previously evaluated, create the possibility of a new or, different kind of accident from any accident previously evaluated, nor reduce any margins to plant safety.

* * * * *

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: The Alderman Library, Special Collections Department, University of Virginia, Charlottesville, Virginia 22903-2498.

Date of amendment request: April 8, 1993

Description of amendment request: The proposed changes would revise the Technical Specifications (TS) for the North Anna Power Station, Units No. 1 and No. 2 (NA-I&2). The changes would separate the containment recirculation spray subsystems into two containment recirculation spray trains. TS 3.6.2.2 describes the various subsystems that are included in the Containment Recirculation Spray System (CRSS) and the actions required if these subsystems become inoperable. CRSS is used to reduce and maintain containment pressure below atmospheric pressure following a high energy line break and provide for long-term post-accident cooling. The current description of the CRSS in the TS describes the system as consisting of six separate and independent subsystems and a casing cooling tank. If more than one of the six subsystems becomes inoperable, then within one hour the inoperable subsystems are required to be restored or the affected unit must be shut down. This could result in unnecessary plant shutdowns even though the units are still within the design parameters of the accident analysis bases.

The current TS does not accurately reflect the terminology used in the Updated Final Safety Analysis Report (UFSAR) or the CRSS design basis document. The TS changes would separate the CRS subsystems into two containment recirculation spray trains. Each train would consist of one inside recirculation spray subsystem and one outside recirculation spray subsystem and its associated casing cooling pump. This change would more accurately describe the CRSS as it is addressed in the UFSAR and the CRSS design basis document. The TS changes are also consistent with the accident analysis bases.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration which is presented below:
Specifically, operation of North Anna Power Station in accordance with the Technical Specification changes will not:
1. Involve a significant increase in the probability or consequences of an accident previously evaluated in the UFSAR. The changes would divide the four subsystems of the Containment Recirculation Spray System into two independent rains and add new ACTION statements for each Unit that addresses the inoperability of one or more recirculation spray subsystems while the current ACTION statement only addresses the inoperable system. These Technical Specification changes are consistent with the way the UFSAR addresses the Containment Recirculation Spray System. The changes do not involve a modification to plant equipment nor do they affect the manner by which the facility is operated. Therefore, there is no change to the probability or consequences of any accident.

2. Create the possibility of a new or different kind of accident from any accident previously evaluated. The changes do not affect the manner by which the facility is operated or involve a change to equipment or features which affect the operational characteristics of the facility. The proposed changes merely add additional restrictions with regard to the time the facility can be operated with more than one recirculation spray subsystem inoperable. These Technical Specification changes are consistent with the accident analysis bases.

3. Involve a significant reduction in a margin of safety. The proposed changes do not affect the manner by which the facility is operated or involve a change to equipment or features which affect the operational characteristics of the facility. These Technical Specification changes are consistent with the UFSAR, the accident analysis bases and the Containment Recirculation Spray System [design basis document].

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of safety are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room
Location: The Alderman Library, Special Collections Department, University of Virginia, Charlottesville, Virginia 22903-2498.

Attorney for licensee: Michael W. Maupin, Esq., Hunton and Williams, Riverfront Plaza, East Tower, 951 E. Byrd Street, Richmond, Virginia 23219.

NRC Project Director: Herbert N. Berkow

Virginia Electric and Power Company, Docket Nos. 50-280 and 50-281, Surry Power Station, Unit Nos. 1 and 2, Surry County, Virginia

Date of amendment request: March 19, 1993

Description of amendment request:

The proposed changes will revise Technical Specifications (TS) 3.12.A, Control Bank Insertion Limits; 3.12.B, Power Distribution Limits; 3.12.C, Inoperable Control Rods; 3.12.D, Core Quadrant Power Balance; 3.12.E, Rod Position Indicator Channels; and Table 4.1-2A, Minimum Frequency for Equipment Tests, for Surry Power Station Units 1 and 2. These proposed changes address operation with a rod urgent failure condition (control rod assemblies immovable due to a failure external to the individual control rod assembly drive mechanisms, i.e., programming circuitry, but remaining trippable), including limited operation with one control or shutdown bank inserted slightly below its insertion limit.

Additional changes involving explicit definition of actions and time limits for certain Limiting Conditions for Operation where none are currently defined are also added. Certain administrative changes are proposed which provide consistency and readability, through capitalization of defined terms, standardization of operating mode nomenclature, and deletion of obsolete figures. Changing of the control rod assembly partial movement surveillance test frequency from biweekly to monthly is also proposed.

Basis for proposed no significant hazards consideration determination:

As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. The proposed changes will not involve a significant increase in either the probability of occurrence or potential consequences of an accident previously evaluated in the Updated Final Safety Analysis Report. Allowing up to 200 hours for diagnosis and repair associated with electronic or electrical malfunctions of the Control Rod Drive System is acceptable, since the primary safety function of the control rod assemblies (tractor trip) will remain unaffected during the repair period. During the extended troubleshooting and maintenance period, the requirements for control rod assembly alignment, insertion limits (except for a small allowed deviation for one bank) and shutdown margin will be maintained. The small deviation from the control rod insertion limits allowed for one bank during the repair period will have only a minor effect on normal core power distributions.

2. The proposed changes involve no new failure modes or mechanisms associated with plant operation for an extended period to perform maintenance on the Control Rod Drive System. Limited periods of operation with immovable but trippable control rod assemblies does not involve any modification in the operational limits or physical design of the involved systems. There are no new failure modes or mechanisms associated with plant operation for an extended period to perform maintenance on the Control Rod Drive System. Limited periods of operation with immovable but trippable control rod assemblies does not involve any modification in the operational limits or physical design of the involved systems. Limited periods of operation with immovable but trippable control rod assemblies does not involve any modification in the operational limits or physical design of the involved systems. Limited periods of operation with immovable but trippable control rod assemblies does not involve any modification in the operational limits or physical design of the involved systems. Limited periods of operation with immovable but trippable control rod assemblies does not involve any modification in the operational limits or physical design of the involved systems. The proposed changes involve no physical alterations to the plant or new modes of operation. Thus, a new failure mode or accident is not made possible by these changes.

3. The results of the current accident analyses are not impacted by this change. Therefore, the margin of safety is not impacted.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room
Location: Swem Library, College of William and Mary, Williamsburg, Virginia 23185.
The proposed amendment would provide seven days of DG operation post-LOCA are maintained. Thus the proposed amendment maintains existing margins of safety.

Based on the NRC staff review of the licensee's analysis, it appears that the three standards of 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Richland Public Library, 955 Northgate Street, Richland, Washington 99352


NRC Project Director: Theodore R. Quay


Date of amendment request: April 1, 1993

Description of amendment request:

The proposed amendment would require increased minimum levels of diesel generator (DG) fuel storage capacity. These changes are based on testing and revised calculations that demonstrated the existing levels of DG fuel storage capacities were inadequate to meet the post-loss of coolant accident (LOCA) fuel consumption requirements for seven days of operation.

Basis for proposed no significant hazards consideration determination:

As required by 10 CFR 50.91(a), the licensee has provided an analysis of the issue of no significant hazards consideration. The NRC staff has reviewed the licensee's analysis against the standards of 10 CFR 50.92(c). The staff presents its evaluation of the licensee's analysis below:

1. Does the amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

The amount of DG fuel stored on site is not considered in the initiating sequences for any accidents previously evaluated. The design assumptions require DG operation for seven days post-LOCA. The amendment assures that the design assumptions are attained based on actual test results and revised calculations to incorporate the test information and other TS limitations. Maintaining the original design assumptions ensures that the consequences from the accident analyses are also maintained. The proposed change, therefore, does not affect the probability or consequences of any accidents previously evaluated.

2. Does the amendment create the possibility of a new or different kind of accident from any accident previously evaluated?

The proposed TS changes the minimum amount of DG fuel required to be stored prior to LOCA. This change does not represent a change in modes of operation of the plant or the plant itself, require physical modification to the plant, or introduce new or different failure modes of existing systems, structures, and components. The proposed amendment does not, therefore, create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the amendment involve a significant reduction in a margin of safety?

The proposed TS assures that the original design basis requirements for DG fuel to provide seven days of DG operation post-LOCA are maintained. Thus the proposed amendment maintains existing margins of safety.

Based on the NRC staff review of the licensee's analysis, it appears that the three standards of 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Richland Public Library, 955 Northgate Street, Richland, Washington 99352


NRC Project Director: Theodore R. Quay


Date of amendment request: April 1, 1993

Description of amendment request:

The proposed amendment would add in-service inspection requirements to the Technical Specifications (TS) in accordance with Generic Letter 88-01, “NRC Position on Intergranular Stress Corrosion Cracking (IGSCC) in BWR Austenitic Stainless Steel Piping.” In addition, the proposed amendment would correct an unrelated administrative error in the TS related to a reference to a table listing high/low pressure interface valve leakage pressure monitors.

Basis for proposed no significant hazards consideration determination:

As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

The changes to the IS1 program do not involve a significant increase in the probability or consequences of an accident previously evaluated because inspections are not assumed as the initiator of any analyzed event. The increased surveillance requirements for inspections may facilitate early detection of a failure associated with IGSCC and serve to mitigate the consequences of such a failure, thereby enhancing safety.

2. Does the amendment create the possibility of a new or different kind of accident from any accident previously evaluated?

The changes do not create the possibility of a new or different kind of accident from any accident previously evaluated because the proposed changes do not introduce any new mode of plant operation or require any physical modification to the plant.

3. Does the amendment involve a significant reduction in a margin of safety?

There is no reduction in a margin to safety due to these changes because the additional inspections have been established to assure the earliest possible detection of problems with or the need of repair or replacement of piping that may be susceptible to failure due to IGSCC.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Richland Public Library, 955 Northgate Street, Richland, Washington 99352


NRC Project Director: Theodore R. Quay

Previously Published Notices of Consideration of Issuance of Amendments to Facility Operating Licenses, Proposed No Significant Hazards Consideration Determination, and Opportunity for a Hearing

The following notices were previously published as separate individual notices. The notice content was the same as above. They were published as individual notices either because time did not allow the Commission to wait for this biweekly notice or because the action involved exigent circumstances. They are repeated here because the biweekly notice lists all amendments issued or proposed to be issued involving no significant hazards consideration.

For details, see the individual notice in the Federal Register on the day and page cited. This notice does not extend the notice period of the original notice.

Duquesne Light Company, et al., Docket No. 50-412, Beaver Valley Power Station, Unit No. 2, Shippingport, Pennsylvania

Date of amendment request: April 14, 1993

Description of amendment request:

The proposed amendment would modify Table 4.3-1 of the Technical Specifications (TS) to add a footnote which states: “Complete verification of OPERABILITY of the manual reactor trip switch circuitry shall be performed prior to startup from the first shutdown.
to MODE 3 occurring after April 6, 1993."

Date of publication of individual notice in Federal Register: April 27, 1993 (58 FR 25676)
Expiration date of individual notice: May 27, 1993

Florida Power and Light Company, Docket Nos. 50-250 and 50-251, Turkey Point Plant Units 3 and 4, Dade County, Florida

Date of amendment request: April 13, 1993
Description of amendment request: The proposed amendment would revise the Technical Specifications (TS) 3.3.3.2 relating to the Moveable Incore Detector System to reduce the minimum number of operable detector thimbles from 38 to 25 and to increase the minimum number of detector thimbles per quadrant from two to three whenever the number of operable thimbles is less than 38. To compensate for this reduction in the number of detector thimbles, TS 3.4/2.2, Heat Flux Hot Channel Factor - Fq (z) and TS 3.4/2.3, Nuclear Enthalpy Rise Hot Channel Factor - F(delta)H, and their associated bases would also be revised to increase their measurement uncertainty factors. The proposed amendment would be applicable to Turkey Point Unit 3 only for the remaining period of its Cycle 13.

Date of publication of individual notice in Federal Register: April 27, 1993 (58 FR 25678)
Expiration date of individual notice: May 27, 1993
Local Public Document Room location: Florida International University, University Park, Miami, Florida 33199

Tennessee Valley Authority, Docket Nos. 50-253, 50-260 and 50-296, Browns Ferry Nuclear Plant, Units 1, 2, and 3, Limestone County, Alabama

Date of amendment request: March 18, 1993 (TS 331)
Brief description of amendments: The proposed changes consist of administrative changes to the Technical Specifications for the Browns Ferry Nuclear Plant (BFN), Units 1, 2, and 3. The changes include deletion of requirements applicable only to BFN Unit 2 Cycle 6 operation, various administrative error corrections, correct discrepancies between the Technical Specification Bases and the BFN Final Safety Analysis Report, and clarification of certain requirements to ensure consistency in application.

Date of publication of individual notice in the Federal Register: April 1, 1993 (58 FR 17258)
Expiration date of individual notice: May 3, 1993
Local Public Document Room location: Athens Public Library, South Street, Athens, Alabama 35611
Notice of Issuance of Amendments to Facility Operating Licenses
During the period since publication of the last biweekly notice, the Commission has issued the following amendments. The Commission has determined for each of these amendments that the application complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR Chapter I, which are set forth in the license amendment.

Notice of Consideration of Issuance of Amendment to Facility Operating License, Proposed No Significant Hazards Consideration Determination, and Opportunity for A Hearing in connection with these actions was published in the Federal Register as indicated.

Unless otherwise indicated, the Commission has determined that these amendments satisfy the criteria for categorical exclusion in accordance with 10 CFR 51.22. Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared for these amendments. If the Commission has prepared an environmental assessment under the special circumstances provision in 10 CFR 51.12(b) and has made a determination based on that assessment, it is so indicated.

For further details with respect to the action see (1) the applications for amendment, (2) the amendment, and (3) the Commission's related letter, Safety Evaluation and/or Environmental Assessment as indicated. All of these items are available for public inspection at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC 20555, and at the local public document rooms for the particular facilities involved.

Arizona Public Service Company, et al., Docket Nos. STN 50-528, STN 50-529, and STN 50-530, Palo Verde Nuclear Generating Station, Units 1, 2, and 3, Maricopa County, Arizona


Brief description of amendments: These amendments revise the largest load to be rejected in the 18-month test for each of the emergency diesel generators; change the loading sequence for the 110 percent load test within the 24-hour full-load test; and add a requirement to conduct a full-load rejection test once every 18 months.

Date of issuance: April 30, 1993
Effective date: April 30, 1993
Amendment Nos.: 70, 56, and 43 Facility Operating License Nos. NPF-41, NPF-51, and NPF-75: The amendments revised the Technical Specifications.

Date of initial notice in Federal Register: November 13, 1991 (56 FR 57689) and March 25, 1993 (58 FR 16217).

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated April 30, 1993. No significant hazards consideration comments received: No.

Local Public Document Room location: Phoenix Public Library, 12 East McDowell Road, Phoenix, Arizona 85004

Carolina Power & Light Company, Docket No. 50-261, H. B. Robinson Steam Electric Plant, Unit No. 2, Darlington County, South Carolina

Date of application for amendment: November 27, 1991.
Brief description of amendment: The amendment revises the TS to allow one safety injection accumulator to be inoperable due to improper pressure, borated water volume, or boron concentration for the same amount of time currently allowed for inoperability due to isolation.

Date of issuance: April 19, 1993
Effective date: April 19, 1993
Amendment No. 146
Facility Operating License No. DPR-23. Amendment revises the Technical Specifications.

Date of initial notice in Federal Register: September 30, 1992 (57 FR 45078)

The Commission’s related evaluation of the amendment is contained in a Safety Evaluation dated April 19, 1993. No significant hazards consideration comments received: No.

Local Public Document Room location: Hartsville Memorial Library, Home and Fifth Avenues, Hartsville, South Carolina 29525

Duke Power Company, Docket Nos. 50-369 and 50-370, McGuire Nuclear Station, Units 1 and 2, Mecklenburg County, North Carolina

Date of application for amendments: October 23, 1990, as supplemented July
Brief description of amendments: The amendments revise Technical Specification 3/4.7.5., “Standby Nuclear Service Water Pond,” to require an average water temperature of less than or equal to 82 degrees F at an elevation of 722 feet.

**Date of issuance:** April 5, 1993
**Effective date:** April 5, 1993
**Amendment Nos.:** 136 and 118
**Facility Operating License Nos.:** NPF-9 and NPF-17: Amendments revised the Technical Specifications.

The amendments revise the Technical Specifications (TSs) for containment penetration overcurrent protective devices. The changes include adding four devices to TS Table 3.8-1, adding a new surveillance requirement section numbered 4.8.2.5.a.2 for the 480V air frame breakers, renumbering existing Surveillance Requirement 4.8.2.5.a.2 as 4.8.2.5.a.3, and rewording Surveillance Requirement 4.8.2.5.b to clarify its intent.

**Date of issuance:** April 16, 1993
**Effective date:** 30 days from the date of issuance
**Amendment No.:** 146
**Facility Operating License No.:** NPF-6
**Amendment revised the Technical Specifications.**

**Date of initial notice in Federal Register:** August 21, 1991 (56 FR 41583).

The Commission’s related evaluation of the amendment is contained in a Safety Evaluation dated April 16, 1993. No significant hazards consideration comments received: No.

**Local Public Document Room location:** Tomlinson Library, Arkansas Tech University, Russellville, Arkansas 72801

**Entergy Operations, Inc., Docket Nos. 50-313 and 50-368, Arkansas Nuclear One, Unit Nos. 1 and 2, Pope County, Arkansas**

**Date of amendment request:** November 10, 1992
**Brief description of amendments:** The amendments revised the description of the Plant Safety Committee (PSC) composition, revised the PSC responsibilities, and established a technical review and control process for the review of most procedures.

**Date of issuance:** April 21, 1993
**Effective date:** 30 days from the date of issuance
**Amendment Nos.:** 165 and 147
**Facility Operating License Nos.:** DPR-51 and NPF-6. Amendments revised the Technical Specifications.

The Commission’s related evaluation of the amendments is contained in a Safety Evaluation dated April 21, 1993. No significant hazards consideration comments received: No.

**Local Public Document Room location:** Tomlinson Library, Arkansas Tech University, Russellville, Arkansas 72801

**Entergy Operations, Inc., Docket No. 50-368, Arkansas Nuclear One, Unit No. 2, Pope County, Arkansas**

**Date of application for amendment:** June 27, 1991, as supplemented by letter dated April 29, 1992
**Brief description of amendment:** The amendment revised the Technical Specifications (TSs) for containment penetration overcurrent protective devices. The changes include adding four devices to TS Table 3.8-1, adding a new surveillance requirement section numbered 4.8.2.5.a.2 for the 480V air frame breakers, renumbering existing Surveillance Requirement 4.8.2.5.a.2 as 4.8.2.5.a.3, and rewording Surveillance Requirement 4.8.2.5.b to clarify its intent.

**Date of issuance:** April 16, 1993
**Effective date:** 30 days from the date of issuance
**Amendment No.:** 146
**Facility Operating License No.:** NPF-6
**Amendment revised the Technical Specifications.**

The amendments incorporate allowable out-of-service times for surveillance and repair with extended functional test intervals for Emergency Core Cooling, Isolation Actuation Instrumentation, Reactor Protection System, control rod blocks, Reactor Core Isolation Cooling, and selected instrumentation.

**Date of issuance:** April 30, 1993
**Effective date:** No later than 60 days from the date of issuance
**Amendment Nos.:** 185 and 125
**Facility Operating License Nos.:** DPR-57 and NPF-5. Amendments revised the Technical Specifications.

The December 21, 1992, and February 17, 1993, letters provided additional information in support of the amendments. The December 21, 1992, letter did not change the NRC staff’s proposed no significant hazards consideration determination.

The Commission’s related evaluation of the amendments is contained in a Safety Evaluation dated April 30, 1993. No significant hazards consideration comments received: No.

**Local Public Document Room location:** Appling County Public Library, 301 City Hall Drive, Baxley, Georgia 31513

**Nebraska Public Power District, Docket No. 50-298, Cooper Nuclear Station, Nemaha County, Nebraska**

**Date of amendment request:** September 9, 1992
**Brief description of amendment:** The proposed changes modify the Cooper Nuclear Station Technical Specifications by making a number of administrative changes to clarify and improve consistency, and correct a variety of minor errors.

**Date of issuance:** April 23, 1993
**Effective date:** April 23, 1993
**Amendment No.:** 162
**Facility Operating License No.:** DPR-46. Amended revised the Technical Specifications.

**Date of initial notice in Federal Register:** December 23, 1992 (57 FR 61114)

The Commission’s related evaluation of the amendment is contained in a Safety Evaluation dated April 23, 1993. No significant hazards consideration comments received: No.

**Local Public Document Room location:** Auburn Public Library, 118 15th Street, Auburn, Nebraska 68305.

**North Atlantic Energy Service Corporation, Docket No. 50-443, Seabrook Station, Unit No. 1, Rockingham County, New Hampshire**

**Date of amendment request:** November 3, 1992, as supplemented by letter dated February 26, 1993.

**Description of amendment request:** The amendment modifies Technical Specification (TS) 6.2.2 relating to senior reactor operator license (SRO) requirements for the Operations Manager. Specifically, the amendment removes the requirement that the Operations Manager maintain an SRO license, however, the Operations Manager must either hold or have held an SRO license for the Seabrook Station prior to appointment to the position.

**Date of issuance:** April 26, 1993
**Effective date:** April 26, 1993
**Amendment No.:** 20
Facility Operating License No. NPF-86. Amendment revised the Technical Specifications.

Date of initial notice in Federal Register: December 23, 1992 (57 FR 61119).
The licensee's letter dated February 26, 1993, provides additional supporting information; the information does not change the initial proposed no significant hazards consideration determination.

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated April 26, 1993.
No significant hazards consideration comments received: No
Local Public Document Room location: Exeter Public Library, 47 Front Street, Exeter, New Hampshire 03833.

Philadelphia Electric Company, Docket Nos. 50-352 and 50-353, Limerick Generating Station, Units 1 and 2, Montgomery County, Pennsylvania

Date of application for amendments: April 3, 1992, as supplemented January 12, 21 and 22, 1993.

Brief description of amendment: The amendments revise the Technical Specifications (TS) Surveillance Requirements of the Stand-by Liquid Containment Vent Isolation System to accommodate the changing operating environment at the Limerick Generating Station.

Effective date: April 20, 1993
Facility Operating License Nos. NPF-39 and NPF-85. The amendments revised the Technical Specifications.

Date of initial notice in Federal Register: February 17, 1993 (58 FR 8777).
The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated April 20, 1993.
No significant hazards consideration comments received: No
Local Public Document Room location: Pottstown Public Library, 500 High Street, Pottstown, Pennsylvania 19464.

Power Authority Of The State of New York, Docket No. 50-286, Indian Point Nuclear Generating Unit No. 3, Westchester County, New York

Date of application for amendment: October 9, 1992
Brief description of amendment: The amendment revised the Technical Specifications (TSs) to incorporate the following changes:

1. The containment fan cooler unit filtration system testing frequency (specified in TS Section 4.5.A.4) was changed to accommodate operation on a 24-month cycle.
2. The central control room filtration system testing frequency (specified in TS Section 4.5.A.5) was changed to accommodate operation on a 24-month cycle.
3. The containment vent isolation valve mechanical stop verification frequency (specified in TS Section 4.13.A) was changed to accommodate operation on a 24-month cycle.

These changes followed the guidance provided in Generic Letter 91-04, "Changes in Technical Specification Surveillance Intervals to Accommodate a 24-Month Fuel Cycle."

Date of issuance: April 16, 1993
Effective date: April 16, 1993
Amendment No.: 130
Facility Operating License No. DPR-64: Amendment revised the Technical Specifications.

Date of initial notice in Federal Register: February 17, 1993 (58 FR 8779).
The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated April 26, 1993.
No significant hazards consideration comments received: No

Public Service Electric & Gas Company, Docket No. 50-311, Salem Nuclear Generating Station, Unit No. 2, Salem County, New Jersey

Date of application for amendment: April 24, 1992, and supplemented by letter dated February 2, 1993
Brief description of amendment: The amendment reduces the required minimum safety injection flow rates, increases the maximum allowed emergency core cooling system (ECCS) pump runout flow rates, modifies the acceptable criteria for ECCS pump performance, and updates the Bases section.

Date of issuance: April 21, 1993
Effective date: April 21, 1993
Amendment No.: 118
Facility Operating License No. DPR-75: This amendment revised the Technical Specifications.

Date of initial notice in Federal Register: September 2, 1992 (57 FR 40219).
The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated April 21, 1993.
No significant hazards consideration comments received: No
Local Public Document Room location: Salem Free Public Library, 112
Amendment Nos.: 211 - Unit 2; 168 - Unit 3
Facility Operating License Nos. DPR-52 and DPR-68: Amendments revise the TS.

Date of initial notice in Federal Register: October 28, 1992 (57 FR 48826)
The Commission’s related evaluation of the amendment is contained in a Safety Evaluation dated April 22, 1993.

No significant hazards consideration comments received: None
Local Public Document Room location: Athens Public Library, South Street, Athens, Alabama 35611

Tennessee Valley Authority, Docket Nos. 50-327 and 50-328, Sequoyah Nuclear Plant, Units 1 and 2, Hamilton County, Tennessee

Date of application for amendments: March 27, 1992; supplemented May 11, May 28, September 8, and October 8, 1992; February 18 and April 1, 1993 (TS 92-01).

Brief description of amendments: The amendments incorporate the technical specification changes that are necessary for expansion of the spent fuel pool storage capacity to 2091 fuel assemblies and additional of a fuel rack storage module to be located in the cask loading area of the cask pit to accommodate no more than 225 additional fuel assemblies. The new racks increase the total spent fuel storage capacity to 2316 fuel bundles and extend the projected storage capacity into the year 2005 or 2006.

Date of issuance: April 28, 1993
Effective date: April 28, 1993
Amendment Nos.: Unit 1 - 167: Unit 2 - 157
Facility Operating License Nos. DPR-77 and DPR-79: Amendments revise the technical specifications.

Date of initial notice in Federal Register: June 24, 1992 (57 FR 28217)
The Commission’s related evaluation of the amendments is contained in a Safety Evaluation dated April 28, 1993.

No significant hazards consideration comments received: None
Local Public Document Room location: Chattanooga-Hamilton County Library, 1101 Broad Street, Chattanooga, Tennessee 37402


Date of application for amendment: February 26, 1993

Brief description of amendment: The amendment revised Technical Specification 6.3.1 for temporary relief to permit a specific individual to assume the active duties of Manager, Perry Operations Section, within the Perry Nuclear Power Plant Department, without currently holding a Senior Reactor Operator (SRO) license for the Perry Nuclear Power Plant, Unit 1. The temporary relief has been approved for a limited period of time during which the SRO license qualification requirement will be met. The individual will be included in the next scheduled Senior Reactor Operator/Reactor Operator Training and examination program currently scheduled to begin in June 1994 and will sit for the next SRO license examination scheduled for August 1995.

Date of issuance: April 16, 1993
Effective date: April 16, 1993
Amendment No. 47
Facility Operating License No. NPF-58. This amendment revised the Technical Specifications.

Date of initial notice in Federal Register: March 31, 1993 (58 FR 13511)
The Commission’s related evaluation of the amendment is contained in a Safety Evaluation dated April 16, 1993.

No significant hazards consideration comments received: No
Local Public Document Room location: Perry Public Library, 3753 Main Street, Perry, Ohio 44081

Union Electric Company, Docket No. 50-483, Callaway Plant, Unit 1, Callaway County, Missouri

Date of application for amendment: March 5, 1993

Brief description of amendment: The amendment revised Technical Specification Surveillance Requirement 4.7.8.d to allow a one-time schedule extension of the snubber transient event inspection.

Date of issuance: April 27, 1993
Effective date: April 27, 1993
Amendment No.: 79
Facility Operating License No. NPF-30: Amendment revised the Technical Specifications.

Date of initial notice in Federal Register: March 25, 1993 (58 FR 16247)
The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated April 27, 1993.

No significant hazards consideration comments received: No
Local Public Document Room location: Callaway County Public Library, 710 Court Street, Fulton, Missouri 65251.

Date of application for amendments: October 26, 1992

Brief description of amendments: These amendments, which are in partial response to your application, will increase the limit for the intermediate range high flux reactor trip setpoint and establish an allowed outage time for the source range instruments when the reactor power is below a specified level.

Date of issuance: April 21, 1993

Effective date: April 21, 1993

Amendment Nos. 176, 175

Facility Operating License Nos. DPR-32 and DPR-37: Amendments revised the Technical Specifications.

Date of initial notice in Federal Register: December 23, 1992 (57 FR 61122).

The Commission’s related evaluation of the amendment is contained in a Safety Evaluation dated April 21, 1993.

No significant hazards consideration comments received: No

Local Public Document Room location: Swem Library, College of William and Mary, Williamsburg, Virginia 23185


Date of application for amendments: December 11, 1993

Brief description of amendments: These amendments eliminate the reactor coolant system loop stop valves interlocks operability requirement.

Date of issuance: April 22, 1993

Effective date: April 22, 1993

Amendment Nos. 177, 176

Facility Operating License Nos. DPR-32 and DPR-37: Amendments revised the Technical Specifications.

Date of initial notice in Federal Register: January 21, 1993 (58 FR 5436).

The Commission’s related evaluation of the amendment is contained in a Safety Evaluation dated April 22, 1993.

No significant hazards consideration comments received: No

Local Public Document Room location: Swem Library, College of William and Mary, Williamsburg, Virginia 23185

Wisconsin Public Service Corporation, Docket No. 50-305, Kewaunee Nuclear Power Plant, Kewaunee County, Wisconsin


Brief description of amendment: The amendment revised Technical Specification (TS) Section 6.13, “High Radiation Area,” so that the specification more closely resembles the Westinghouse Standard Technical Specifications (NUREG-0452). In addition, TS 6.4, “Training,” and TS 6.5, “Review and Audit,” were revised to account for recent organization changes at Kewaunee. Finally, TS 6. “Administrative Controls,” was revised due to administrative and format changes.

Date of issuance: April 21, 1993

Effective date: April 21, 1993

Amendment No. 19

Facility Operating License No. DPR-43. Amendment revised the Technical Specifications.

Date of initial notice in Federal Register: October 28, 1992 (57 FR 48832).

The Commission’s related evaluation of the amendment is contained in a Safety Evaluation dated April 21, 1993.

No significant hazards consideration comments received: No.

Local Public Document Room location: University of Wisconsin Library Learning Center, 2420 Nicolet Drive, Green Bay, Wisconsin 54301.

Notice of Issuance of Amendments to Facility Operating Licenses and Final Determination of No Significant Hazards Consideration and Opportunity for a Hearing (Exigent, Public Announcement or Emergency Circumstances)

During the period since publication of the last biweekly notice, the Commission has issued the following amendments. The Commission has determined for each of these amendments that the application for the amendment complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission’s rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission’s rules and regulations in 10 CFR Chapter 1, which are set forth in the license amendment.

Because of exigent or emergency circumstances associated with the date the amendment was needed, there was not time for the Commission to publish, for public comment before issuance, its usual 30-day Notice of Consideration of Issuance of Amendment, Proposed No Significant Hazards Consideration Determination, and Opportunity for a Hearing.

For exigent circumstances, the Commission has either issued a Federal Register notice providing opportunity for public comment or has used local media to provide notice to the public in the area surrounding a licensee’s facility of the licensees’ application and of the Commission’s proposed determination of no significant hazards consideration. The Commission has provided a reasonable opportunity for the public to comment, using its best efforts to make available to the public means of communication for the public to respond quickly, and in the case of telephone comments, the comments have been recorded or transcribed as appropriate and the licensee has been informed of the public comments.

In circumstances where failure to act in a timely way would have resulted, for example, in derating or shutdown of a nuclear power plant or in prevention of either resumption of operation or of increase in power output up to the plant’s licensed power level, the Commission may have had an opportunity to provide for public comment on its no significant hazards consideration determination. In such case, the license amendment has been issued without opportunity for comment. If there has been some time for public comment but less than 30 days, the Commission may provide an opportunity for public comment. If comments have been requested, it is so stated. In either event, the State has been consulted by telephone whenever possible.

Under its regulations, the Commission may issue and make an amendment immediately effective, notwithstanding the pendency before it of a request for a hearing. In advance of the hearing, any comments have been requested, it is so stated. In either event, the State has been consulted by telephone whenever possible.
under the special circumstances
provision in 10 CFR 51.12(b) and has
made a determination based on that
assessment, it is so indicated.

For further details with respect to the
action see (1) the application for
amendment, (2) the amendment to
Facility Operating License, and (3) the
Commission's related letter, Safety
Evaluation and/or Environmental
Assessment, as indicated. All of these
items are available for public inspection
at the Commission's Public Document
Room, the Gelman Building, 2120 L
Street, NW., Washington, DC 20555, and
at the local public document room for
the particular facility involved.

The Commission is also offering an
opportunity for a hearing with respect to
the issuance of the amendment. By June
11, 1993, the licensee may file a request
for a hearing with respect to issuance of
the amendment to the subject facility
operating license and any person whose
interest may be affected by this
proceeding may file a request to
participate as a party in the proceeding
must file a written request for a hearing
and a petition for leave to intervene.

Requests for a hearing and a petition for
leave to intervene shall be filed in
accordance with the Commission's
“Rules of Practice for Domestic
 Licensing Proceedings” in 10 CFR Part
2. Interested persons should consult a
current copy of 10 CFR 2.714 which is
available at the Commission's Public
Document Room, the Gelman Building,
2120 L Street, NW., Washington, DC
20555 and at the local public document
room for the particular facility involved.

If a request for a hearing or petition for
leave to intervene is filed by the above
date, the Commission or an Atomic
Safety and Licensing Board, designated
by the Commission or by the Chairman of
the Atomic Safety and Licensing
Board Panel, will rule on the request
and/or petition. The Secretary or the
designated Atomic Safety and Licensing
Board will issue a notice of a hearing or
an appropriate order.

As required by 10 CFR 2.714, a
petition for leave to intervene shall set
forth with particularity the interest of
the petitioner in the proceeding, and
how that interest may be affected by
the results of the proceeding. The
petition should specifically explain the
reasons why intervention should be permitted
with particular reference to the
following factors: (1) the nature of
the petitioner's right under the Act to
be made a party to the proceeding; (2)
the nature and extent of the petitioner's
property, financial, or other interest
in the proceeding; and (3) the possible
effect of any order which may be
entered in the proceeding on the
petitioner's interest. The petition
should also identify the specific aspect(s)
of the subject matter of the proceeding as to
which petitioner wishes to intervene.

An interested person who files a
petition for leave to intervene or who has
been admitted as a party may amend
the petition without requesting leave of
the Board up to 15 days prior to the first
prehearing conference scheduled in
the proceeding, but such an amended
petition must satisfy the specificity
requirements described above.

Not later than 15 days prior to the first
prehearing conference scheduled in the
proceeding, a petitioner shall file a
supplement to the petition to intervene
which must include a list of the
contentions which are sought to be
litigated in the matter. Each contention
must consist of a specific statement of
the issue of law or fact to be raised or
controversied. In addition, the petitioner
shall provide a brief explanation of the
bases of the contention and a concise
statement of the alleged facts or expert
opinion which support the contention
and on which the petitioner intends to
rely in proving the contention at the
hearing. The petitioner must also
provide references to those specific
sources and documents of which the
petitioner is aware and on which the
petitioner intends to rely to establish
those facts or expert opinion. Petitioner
must provide sufficient information to
show that a genuine dispute exists with
the applicant on a material issue of law
or fact. Contentions shall be limited to
matters within the scope of the
amendment under consideration.

The contention must be one which, if
proven, would entitle the petitioner to
relief. A petitioner who fails to file such
a supplement which satisfies these
requirements with respect to at least one
contention will not be permitted to
participate as a party.

Those permitted to intervene become
parties to the proceeding, subject to any
limitations in the order granting leave to
intervene, and have the opportunity to
participate fully in the conduct of the
hearing, including the opportunity to
present evidence and cross-examine
witnesses. Since the Commission has
made a final determination that the
amendment involves no significant
hazards consideration, if a hearing is
requested, it will not stay the
effectiveness of the amendment. Any
hearing held would take place while the
amendment is in effect.

A request for a hearing or a petition
for leave to intervene must be filed with
the Secretary of the Commission, U.S.
Nuclear Regulatory Commission,
Washington, DC 20555, Attention:
Docketing and Services Branch, or may
be delivered to the Commission's Public
Document Room, the Gelman Building,
2120 L Street, NW., Washington, DC
20555, by the above date. Where
petitions are filed during the last 10
days of the notice period, it is requested
that the petitioner promptly so inform
the Commission by a toll-free telephone
call to Western Union at 1-(800) 248-
5100 (in Missouri 1-(800) 342-6700).
The Western Union operator should be
given Datagram Identification Number
N1023 and the following message
addressed to (Project Director):
petitioner's name and telephone
number, date petition was mailed, plant
name, and publication date and page
number of this Federal Register notice.
A copy of the petition should also be
sent to the Office of the General
Counsel, U.S. Nuclear Regulatory
Commission, Washington, DC 20555,
and to the attorney for the licensee.

Nontimely filings of petitions for
leave to intervene, amended petitions,
supplemental petitions and/or requests
for a hearing will not be entertained
absent a determination by the
Commission, the presiding officer or the
Atomic Safety and Licensing Board that
the petition and/or request should be
granted based upon a balancing of the
factors specified in 10 CFR
2.714(a)(1)(i)-(v) and 2.714(d).
Dated at Rockville, Maryland, this 6th
day of May 1993.

For the Nuclear Regulatory Commission
Jack W. Roe,
Director, Division of Reactor Projects - III/
IV/V, Office of Nuclear Reactor Regulation
[Doc. 93-11081 Filed 5-11-93; 8:45 am]
BILLING CODE 7550-01-F

SECURITIES AND EXCHANGE
COMMISSION

[Release No. 34-32269; International Series
Release No. 544; File No. SR-AMEX-93-
14]

Self-Regulatory Organizations; Filing
of Proposed Rule Change by the
American Stock Exchange Relating to
a Proposal to List for Trading Index
Warrants on the Amex Hong Kong
Index


Pursuant to section 19(b)(1) of the
Securities Exchange Act of 1934
hereby given that on April 13, 1993, the
American Stock Exchange, Inc.
(“AMEX” or “Exchange”) filed with the
Securities and Exchange Commission
(“Commission”) the proposed rule
change as described in items I, II, and
III below, which items have been
prepared by the Amex. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Amex has submitted a proposal to list for trading pursuant to Section 106 of the Amex Company Guide, warrants based on the Amex Hong Kong Index ("HKSE Index" or "Index"), a new index developed by the Exchange. The Index is comprised of thirty common stocks which trade on The Stock Exchange of Hong Kong ("HKSE"). The text of the proposed rule change is available at the Office of the Secretary, the Amex, and at the Commission.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Amex included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Amex has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statements.

(A) Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change


The Exchange is now proposing to list warrants based on the Index, a new market capitalization weighted index which has been designed and created by the Amex. The Index is comprised of thirty equity securities traded on the HKSE. The Index level was set at a value of 182.85 at the close of the HKSE market on March 8, 1991. The market value of the component stocks was HK$604,610,834,000 (equivalent to approximately US$77,390,187,000) on that date and the divisor used to calculate the Index was 3,310,215,352.

A listing of the component stocks comprising the Index together with their respective industry groups is attached to the Amex proposed rule filing as Exhibit A. Exhibit A also shows as of March 23, 1993, that the three largest stocks accounted for approximately 35.69% of the market capitalization of the Index, with the largest being HML Holdings Plc (15.44%), followed by the Hong Kong Telecommunications, Ltd. (10.44%) and Hang Seng Bank (9.41%).

For valuation purposes, one Hong Kong Index unit is assigned a fixed value of one U.S. dollar. At the close of the market on March 19, 1993, the Index level was 309.01.

The securities comprising the Index have been selected on the basis of their market weight, trading liquidity, and representation of the business industries reflected on the HKSE. A chart showing price movements of the Index from March 8, 1991 to March 19, 1993 is attached to the Amex proposed rule filing as Exhibit B.

The Amex has established qualification criteria for inclusion of equity securities in the Index, based on the following standards:

1. Each component security shall be issued by a Hong Kong issuer and traded on the HKSE.

2. The minimum market value in Hong Kong dollars for each component security during the twenty business days preceding inclusion in the index as measured by the total number of shares outstanding times the latest price per share must be at least three billion Hong Kong dollars (approximately US$380,000,000).

3. The per share price for each component security during the preceding twenty business days before inclusion in the index may not be lower than 2.50 Hong Kong dollars (approximately US$0.32).

4. All securities selected for inclusion in the Index must have traded an average of more than ten million shares per month over the previous six months. The Exchange will monitor the trading of all component securities and, if it determines that any component security fails to meet this liquidity threshold, consideration will be given to substituting another security with greater liquidity, consistent with maintaining a balanced industry representation.

Observing that the above stated component security minimum price criteria is lower in comparison to the minimum price criteria generally utilized for component securities on existing U.S. exchange traded domestic index options products, the Amex notes that prices of individual stocks traded on the HKSE tend to be much lower than for stocks of similar capitalization traded in the U.S. markets.

At the close of the market on Tuesday, March 23, 1993, the average closing price of the component stocks of the Index was HK$19.39 (US$2.51), with the highest priced stock closing at HK$66.00 (US$8.54) and lowest priced stock closing at HK$3.20 (US$0.41). Of the thirty stocks to be included in the Index, seven closed at prices lower than HK$7.50, or approximately US$1.00.

Since the HKSE does not operate in an overlapping time zone with trading on the Amex, the Amex will calculate the Index once each day based on previously reported closing prices on the HKSE. The Amex will administer the Index, making such adjustments to the divisor as may be necessary in light of stock splits, stock replacements, or other corporate actions which would otherwise cause a break in continuity in the Index value. The Index value will be published through the Exchange's market data system and made available to established vendors.

As of March 23, 1993, the total capitalization of the Hong Kong Index component stocks was US$134.7 billion.

Warrent issues on the Index will conform to the listing guidelines under Section 106 of the Amex Company Guide, which provides that:

1. The issuer shall have assets in excess of US$100,000,000 and otherwise substantially exceed the size and
2. The Hong Kong dollar exchange rate on March 23, 1993 was 0.125.
The term of the warrants shall be for a period ranging from one to five years from date of issuance; and

(3) The minimum public distribution of such issues shall be 1,000,000 warrants, together with a minimum of 400 public holders, and a minimum aggregate market value of US$4,000,000. Hong Kong Index warrants will be direct obligations of their issuer subject to cash settlement in U.S. dollars, and either exercisable throughout their life (i.e., American-style) or exercisable only on their expiration date (i.e., European-style). Upon exercise, or at the warrant expiration date (if not exercisable prior to such date), the holder of a warrant structured as a “put” would receive payment in U.S. dollars to the extent that the Hong Kong Index has declined below a prestated cash settlement value. Conversely, holders of a warrant structured as a “call” would, upon exercise or at expiration, receive payment in U.S. dollars to the extent that the Hong Kong Index has increased above the pre-stated cash settlement value. If “out-of-the-money” at the time of expiration, the warrants would expire worthless.

The Amex has adopted suitability standards applicable to recommendations to customers of index warrants and transactions in customer accounts. Specifically, the Amex will require that Amex member firms can only sell Hong Kong Index warrants to investors whose accounts have been approved for options trading pursuant to Amex Rule 921. Additionally, the Amex requires, pursuant to Amex Rule 421, Commentary .02, that a Senior Registered Options Principal or a Registered Options Principal approve and initial a discretionary order in index warrants on the day such order is entered. Moreover, the Amex, prior to the commencement of trading, will distribute a circular to its membership calling attention to specific risks associated with Hong Kong Index warrants.

In its approval order for index warrants (Release No. 34-26152, October 3, 1988), the Commission noted that, in connection with trading of index warrants based on a foreign index, there should be adequate surveillance sharing agreements with respect to the component stocks of the underlying index. In this regard, the Amex has in place a surveillance sharing agreement with the HKSE, which the Amex believes is sufficient to enable it to fulfill its regulatory responsibilities regarding the surveillance of trading in securities related to the Index. In this respect, the agreement, among other things, provides for the sharing of time and sales information, clearing data, and the identity of persons who bought or sold securities.

The Exchange believes that the proposed rule change is consistent with section 6(b) of the Act, in general, and furthers the objectives of section 6(b)(5) in particular, that it is designed to prevent fraudulent and manipulative acts and practices and to promote just and equitable principles of trade, and is not designed to permit unfair discrimination between customers, issuers, brokers and dealers.

(B) Self-Regulatory Organization’s Statement on Burden on Competition

The Amex does not believe that the proposed rule change will impose any inappropriate burden on competition.

(C) Self-Regulatory Organization’s Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the Federal Register or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its resources for so finding or (ii) to which the self-regulatory organization consents, the Commission will:

(A) By order approve such proposed rule change, or

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission’s Public Reference Section, 450 Fifth Street, NW., Washington, DC. Copies of such filing will also be available for inspection and copying at the principal office of the Amex. All submissions should refer to File No. SR-Amex-93-14 and should be submitted by June 2, 1993.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.²

Jonathan G. Katz, Secretary.

[FR Doc. 93–11221 Filed 5–11–93; 8:45 am]

BILLING CODE 8011–01–M


Self-Regulatory Organizations; Filing of Proposed Rule Change by the American Stock Exchange, Inc.; Relating to the Listing and Trading of Options on the Morgan Stanley Cyclical and Consumer Indexes

May 6, 1993.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"), 15 U.S.C. 78s(b)(1), notice is hereby given that on March 8, 1993, the American Stock Exchange, Inc. ("Amex" or "Exchange") filed with the Securities and Exchange Commission ("Commission" or "SEC") the proposed rule change as described in Items I, II, and III below, which items have been prepared by the Amex. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization’s Statement of the Terms of Substance of the Proposed Rule Change

The Amex proposes to trade standardized index options on the Morgan Stanley Cyclical Index and the Morgan Stanley Consumer Index ("Indexes") developed by Morgan Stanley & Co., Inc. ("Morgan Stanley"). The text of the proposed rule change is available at the Office of the Secretary, Amex, and at the Commission.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Amex included statements concerning the purpose of and basis for the proposed rule change and discussed any

comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Amex has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statements.

A. Self-Regulatory Organization’s Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

(1) Purpose

The Exchange is proposing to trade standardized index options on the Morgan Stanley Consumer Index ("Consumer Index") and the Morgan Stanley Cyclical Index ("Cyclical Index"). Developed by Morgan Stanley, both Indexes represent diversified portfolios of thirty U.S. blue chip common stocks and are designed to track the broad U.S. market in different ways as described below.

The Cyclical Index. The Cyclical Index is designed to measure the performance of stocks in industries that are highly sensitive to movements in the economic business cycle. As the U.S. economy strengthens out of recession, consumer and business demand for goods and services enjoyed by cyclical companies tend to grow substantially. Conversely, during expansions, cyclical stocks tend to grow substantially. Consequently, during expansions, cyclical stocks tend to outperform the overall market.

Conversely, as the economy weakens into recession, consumer and business demand slackens for the goods and services produced by cyclical companies, and consequently cyclical stocks tend to underperform the overall economy during such times. Twenty-five separate industries are represented in the Cyclical Index and include such major industries as: autos, metals, papers, machinery, chemicals, and transportation.

The Consumer Index. In contrast to the Cyclical Index, the Consumer Index is designed to track the performance of consumer-oriented, stable, "defensive" industries. The Consumer Index is composed of companies whose products and services enjoy relatively stable consumer and business demand over the economic business cycles. Stocks in the Consumer Index are drawn from twenty different industry groups and include such major industries as: beverages, foods, health care, tobaccos, and personal computer products.

Index Calculation. The Amex will calculate the index values of both the Cyclical and Consumer Indexes. In performing this function, the Amex will disseminate over Network B to market-data vendors the values of the Indexes based on the most recently reported prices of the component stocks in the Indexes at 15 second intervals during regular Amex trading hours. The Indexes are calculated using an "equal-dollar weighting" methodology designed to ensure that each of the component securities are represented in approximately equal dollar amounts in each index at the time of annual rebalancing.1

The following is a description of how the "equal-dollar weighting" calculation method works. As of the market close on December 31, 1991, portfolios of Cyclical and Consumer Index stocks were established representing investments of $333,333 in the stocks (to the nearest whole share) of each of the companies in each index. The value of each Index equals the current market value (i.e., based on U.S. primary market prices) of the assigned number of shares of each of the stocks in the Index portfolios divided by the Index divisor. Both the Cyclical and Consumer Index divisors were initially calculated to yield benchmark values of 200.00 on December 31, 1991. Each year thereafter, following the close of trading on the third Friday of December, each Index portfolio will be adjusted by changing the number of shares of each component stock so that each company is again represented in "equal" dollar amounts. If necessary, a divisor adjustment will be made to ensure continuity of the Indexes’ values. The newly adjusted portfolios then become the basis for each Index’s value on the first trading day following the yearly adjustment.

The number of shares of component stocks in each Index’s portfolio will remain fixed between annual reviews except in the event of certain types of corporate actions such as the payment of an extraordinary cash dividend, stock distribution, stock split, rights offering, distribution, reorganization, recapitalization, or similar event with respect to the component stocks, or a merger, consolidation, dissolution or liquidation of an issuer of a component stock, in which case the number of shares of that security in the portfolio may be adjusted, to the nearest whole share, to maintain the component’s relative weight in the Index at the level immediately prior to the corporate action.

In the event of a stock replacement in either of the Indexes, the average dollar value of the remaining portfolio components will be recalculated and that amount invested in the stock of a new component, to the nearest whole share. In both of the above cases, the divisors will be adjusted, if necessary, to ensure Index continuity.

Index Maintenance. As the proprietor of the Indexes, Morgan Stanley will determine if and when stock replacements are necessary in either or both Indexes, and will advise the Exchange on the handling of unusual corporate actions which may arise from time to time. Routine corporate actions (e.g., stock splits, routine spinoffs, etc.) which require straightforward index divisor adjustments will be handled by Exchange staff without consultation with Morgan Stanley. All stock replacements and unusual divisor adjustments caused by non-routine spinoffs, extraordinary dividends, etc., will be made by Exchange staff in consultation with Morgan Stanley. All stock replacements and the intended index handling of non-routine corporate actions will be announced at least ten business days in advance of such effective change, whenever practicable. As with all options currently trading on the Amex, the Exchange will make this information available to the public through dissemination of an information circular.

Eligibility Standards for Index Components. Morgan Stanley intends to adhere to Amex Rule 901C, which specifies criteria for inclusion of stocks in an index on which options will be traded on the Exchange. In choosing among stocks that meet the minimum criteria set forth in Rule 901C, Morgan Stanley will focus only on stocks that are traded on either the New York Stock Exchange, Inc. ("NYSE"), Amex (subject to the limitations of Rule 901C) or the National Market System ("NMS") tier of the National Association of Securities Dealers Automated Quotation ("NASDAQ") system. In addition, Morgan Stanley intends to consider only those stocks that: (1) Have a minimum market value (in U.S. dollars) of at least $75 million, and (2) have an average monthly trading volume in U.S. markets over the previous six month period of not less than 500,000 shares. Although the stocks currently selected for inclusion in each of the Indexes meet or surpass the above additional criteria, Morgan Stanley intends the above criteria to be used as guidelines only and reserves the right to include stocks in the Index that may not meet these...
Options on the Indexes—Expiration and Settlement. The proposed options on the Cyclical and Consumer Indexes are European-style (i.e., exercises are permitted at expiration only) and cash settled. The Exchange's standard option trading hours from 9:30 a.m. to 4:15
p.m. (New York time) will apply. These options will expire on the Saturday ("Expiration Saturday") following the third Friday ("Expiration Friday") of the expiration month. The last trading day in an expiring series will normally be the second to last business day preceding Expiration Saturday (normally a Thursday), with trading to cease at the close of business on such day.

The Index value for purposes of settling the Cyclical Index option or Consumer Index option will be calculated based upon the opening prices of the component securities pursuant to the normal opening procedures of the primary exchange where the securities are traded on Expiration Friday. In the case of securities traded through the NASDAQ system, the first reported sale price will be used. As trading begins in each of the Index's component securities, its opening sale price is captured for use in the calculation. Once all of the component stocks have opened, the Index settlement value is then determined. If any of the component stocks do not open for trading on the last trading day before expiration, then the prior day's last sale price is used in the calculation.

Amex Rules Applicable to Stock Index Options. Amex Rules 900C through 980C will apply to the trading of option contracts based on both the Cyclical and Consumer Indexes. These Rules cover issues such as surveillance, exercise prices, and position limits. Surveillance procedures currently used to monitor trading in each of the Exchange's other index options will also be used to monitor trading in options on these Indexes which are deemed to be broad market stock index groups under Rule 900C(b)(1). Under Rule 903C, the Exchange intends to list up to three near-term monthly and two additional calendar months in three month intervals in the December cycle. Further, the Exchange would like to introduce 2½ point strike price intervals for certain near-the-money series (within 10 points above or below the current index value). For both Indexes, position limits which are governed by Rule 904C(b) will be set at no more than 25,000 contracts on the same side of the market with no more than 15,000 of such contracts in series with the nearest expiration month.

Lastly, pursuant to Amex Rule 903C(a)(iii), the Exchange may list option series on the Indexes having up to thirty-six months to expiration. However, in lieu of long-term options on the full value of the Indexes, the Exchange may choose to list long-term, reduced value put and call options (known as LEAPS) on the Indexes. Cyclical and Consumer Index LEAPS would trade independent of and in addition to regular options on the Indexes and would be subject to the same rules which govern the trading of all Exchange index options, including sales practices rules, margin requirements, and floor trading procedures. Position limits for LEAPS would be equivalent to the position limits for regular options on the Indexes and would be aggregated with such options.

(2) Basis

The Exchange believes that the proposed rule change is consistent with section 6(b) of the Act, in general, and section 6(b)(5), in particular, that it is designed to prevent fraudulent and manipulative acts and practices and to promote just and equitable principles of trade.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Amex believes that the proposed rule change will not impose a burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the Federal Register or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents the Commission will:

(a) By order approve such proposed rule change, or

(b) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Section, 450 Fifth Street, NW., Washington, DC 20549. Copies of such filing will also be available for inspection and copying at the principal office of the Amex. All submissions should refer to the file number in the caption above and should be submitted by June 2, 1993.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.2

Jonathan G. Katz,
Secretary.

[FR Doc. 93-11214 Filed 6-3-93; 8:45 am]
BILLING CODE 3010-01-M

[Release No. 34-32252; File No. 600-23]

Self-Regulatory Organizations; Government Securities Clearing Corporation; Notice of Filing of an Amended Application for Full Clearing Agency Registration and a Request for Extension of Temporary Registration as a Clearing Agency

April 30, 1993.

Notice is hereby given that on February 5, 1993, pursuant to Sections 17A and 19(a) of the Securities Exchange Act of 1934 ("Act"),1 the Government Securities Clearing Corporation ("GSCC") requested that the Securities and Exchange Commission ("Commission") grant GSCC full registration as a clearing agency, or, in the alternative, extend GSCC's temporary registration as a clearing agency until such time as the Commission is able to grant GSCC

permanent registration. On March 1, 1993, GSCC filed with the Commission an amended form CA–1. On May 24, 1988, the Commission granted the application of GSCC for registration as a clearing agency, pursuant to sections 17A and 19(a) of the Act, and Rule 17Ab2–1 thereunder, for a period of three years. On May 24, 1991, the Commission extended GSCC’s registration until May 31, 1993. GSCC provides clearance and settlement services for members in processing transactions in government securities. GSCC offers its members services for next-day settling trades, the bilateral netting of trades, the novation of netted trades, and daily marking-to-market. In connection with GSCC’s clearance and settlement services GSCC provides a centralized loss allocation procedure and maintains margin to offset netting and settlement risks.

At the time of GSCC’s initial registration, the Commission granted GSCC exemptions from compliance with the participation standards in sections 17A(b)(3)(B) and 17A(b)(4)(B) and the fair representation requirements in section 17A(b)(3)(C) of the Act. GSCC has requested that the Commission remove GSCC’s exemption from the participation standards in sections 17A(b)(3)(B) and 17A(b)(4)(B) of the Act. The Commission is reviewing GSCC’s request to remove that exemption.

Interested persons are invited to submit written data, views, and arguments concerning the foregoing application within twenty one days of the date of publication of this notice in the Federal Register. Such written data, views and arguments will be considered by the Commission in granting registration or instituting proceedings to determine whether registration should be denied in accordance with section 19(a)(1) of the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Reference should be made to File No. 600–23. Copies of the application for registration and all written comments will be available for inspection at the Commission’s Public Reference Section, 450 Fifth Street, NW., Washington, DC 20549.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Jonathan G. Katz, Secretary.

[FR Doc. 93–11224 Filed 5–11–93; 8:45 am]

BILLING CODE 8010–01–M


Self-Regulatory Organizations; Delta Government Options Corp.; Filing of Proposed Rule Change Relating to Procedures for the Definition of Exercise Price

May 4, 1993.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),1 notice is hereby given that on April 6, 1993, Delta Government Options Corp. ("DGOC") filed with the Securities and Exchange Commission ("Commission") the proposed rule change (File No. SR–DGOC–93–01) as described in Items I, II, and III below, which items have been prepared primarily by DGOC, a self-regulatory organization ("SRO"). On April 12, 1993, DGOC filed an amendment to the proposed rule change.2 The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. SRO’s Statement of the Terms of Substance of the Proposed Rule Change

The proposed rule change will amend DGOC’s definition of Exercise Price to provide that each Exercise Price shall be stated in whole numbers and sixteens or in the gradations or in such other manner that will conform with the then current practice for the expression of prices of Treasury Bills, Notes, or Bonds among primary dealers of U.S. Government Securities.

II. SRO’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, DGOC included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. DGOC has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. SRO’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

The purpose of the proposed rule change is to respond to Participants’ requests for finer gradations in Exercise Prices especially with respect to options that expire shortly and/or that have underlying securities with short term to maturity. The proposal will authorize DGOC to clear options with Exercise Prices stated in gradations of sixteens of a dollar in place of the current exercise price gradations of sixteens of a dollar. DGOC states that more precise Exercise Prices will afford its Participants greater flexibility and will enable its Participants to engage in more trading especially during periods of low volatility where small incremental changes in options pricing become a more significant component of the decision to buy or sell an option.

In particular, the proposed amendment to the definition of Exercise Price will afford DGOC Participants additional flexibility in choosing Exercise Prices that will match more precisely their overall U.S. Treasury securities portfolios. The proposal will enable Participants to submit for processing at DGOC trades in over-the-

1 Letter from Charles A. Moran, President, GSCC, to Brandon Becker, Deputy Director, Division of Market Regulation, Commission, dated March 15, 1991.

2 Letter from David J. Malloy, President, DGOC, to Jerry W. Carpenter, Branch Chief, Division of Market Regulation, Commission (April 6, 1993).
counter options on U.S. Treasury securities that currently cannot be submitted because the stated Exercise Prices are not available through DGOC. Therefore, DGOC states that the proposed rule change will allow for the automated clearance and settlement of securities transactions within the DGOC system that otherwise would have to be cleared through a decentralized, inefficient, and labor-intensive process outside the DGOC system.

DGOC also is amending the definition of Exercise Price to give itself the ability to process options with exercise prices not only stated in sixty-fourths but also in other gradations or in such other manner that will conform with the then current practice for the expression of prices of Treasury Bills, Notes, or Bonds among primary dealers of U.S. Government Securities. This will enable DGOC to provide uninterrupted clearing and settlement services for its Participants, under the DGOC system. This will enable DGOC to provide uninterrupted clearing and settlement services for its Participants should there be a change in the manner in which prices of Treasury Securities are expressed in the U.S. Government Securities market.

DGOC believes that the proposed rule change is consistent with the Act, particularly section 17A of the Act, and the rules and regulations thereunder applicable to DGOC because it will promote the prompt and accurate clearance and settlement of securities transactions.

B. SRO's Statement on Burden on Competition

DGOC believes that the proposed rule change will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. SRO's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

DGOC has not solicited or received any comments with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within thirty-five days of the date of publication of this notice in the Federal Register or within such longer period as the Commission may designate up to ninety days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the SRO consents, the Commission will:

(A) By order approve such proposed rule change or (B) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Section, 450 Fifth Street, NW., Washington, DC 20549. Copies of such filing will also be available for inspection and copying at the principal office of DGOC. All submissions should refer to File No. SR-DGOC-93-01 and should be submitted by June 2, 1993.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.

Jonathan G. Katz, Secretary.

[FR Doc. 93-11220 Filed 5-11-93; 8:45 am]
BILLING CODE 8010-01-M

[Release No. 34-32256; File No. SR-SR-MSE-93-07]

Self-Regulatory Organizations; Filing and Immediate Effectiveness of Proposed Rule Change by the Midwest Stock Exchange, Inc. Relating to Amendments to Its Membership Dues and Fees.


Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"), 15 U.S.C. 78s(b)(1), notice is hereby given that on March 29, 1993, the Midwest Stock Exchange, Inc. ("MSE" or "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II and III below, which items have been prepared by the self-regulatory organization. On April 16, 1993, the MSE submitted to the Commission Amendment No. 1 to the proposed rule change. 1 The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The MSE proposes to amend Section (c), Transaction Fee Schedule, of the Exchange's Membership Dues and Fees by differentiating between round lot agency market orders and round lot agency limit orders electronically submitted to the Exchange floor, and, amending the monthly share volume 2 discounts and making them applicable to net billable shares 3 rather than gross shares; discontinuing the current round lot volume discount and annualized volume discount; and, changing the monthly share volume discount for floor brokerage operations. The changes to the Transaction Fee Schedule are set forth in Exhibit A to File No. SR-MSE-93-07.

MAX system 4 credits will apply to all MAX system orders executed on the MSE regardless of the source of the contra side of the transaction. As such, and by way of example, if a firm sends a MAX order to the MSE floor and that order is executed against any other order, including an order sent to an MSE specialist over the Intermarket Trading System ("ITS"), the executed MAX order will receive the appropriate MAX credit. That order will also be charged the appropriate MSE transaction fee by virtue of the fact that the order was executed on the MSE. An order sent out over the ITS from the MSE is an ITS order and, therefore, no MAX system credits can apply.

1 See letter from Daniel J. Liberti, Associate Counsel, MSE, to Diana Luka-Hopson, Branch Chief, Commission, dated April 15, 1993. Amendment No. 1 clarified the application of the amendments made to the MSE's transaction fee schedule.
2 Monthly share volume is the gross number of shares traded.
3 Net billable share volume is the gross number of shares traded reduced by the number of shares not subject to the MSE fee.
4 The MSE's MAX System (Midwest Automated Execution System) provides an automated order routing and execution mechanism for market and limit orders.
5 TL = ITS and the MAX system are separate facilities. While order sending firms can be linked to the MAX system, they do not have a linkage to the ITS and, therefore, cannot utilize ITS except through a floor member intermediary. As such, orders received on the MSE from member firms, even if received through the MAX system, and subsequently out over the ITS will not receive any MAX credit. The MAX credit is applicable to orders sent over the MAX system, accepted by the MSE specialist, and executed on the MSE. Firms that utilize the order routing capabilities of the MAX system do not qualify for the MAX system credit.

However, the order will be charged appropriate Exchange transaction fees. The MSE is also amending the applicable schedule of discounts to be applied against a firm’s net transaction fees. The discounts will be applied according to the level of a firm’s monthly billable share volume. Billable volume is that volume of shares executed on the MSE for which transaction fees are charged. Because the MSE currently waives transaction fees for Tape B eligible issues, none of a firm’s Amex order flow will be considered when computing monthly volume for this discount. Additionally, the MSE charges a maximum fee of $100 per trade. As such, a firm submitting orders in excess of 22,000 shares will not be charged anything for the incremental share portion of the order. Therefore, the incremental shares over 22,000 are not billable and will not be considered when computing the monthly volume for this discount.

Finally, the MSE is amending the discount available to floor broker operations which will be applied to a floor brokerage firm’s net transaction fees after the application of other monthly discount credits. However, unlike the monthly volume discount available to a firm based on billable share volume, the floor broker discount will consider all shares for which the floor broker acts as intermediary.

**MEMBERSHIP DUES AND FEES—MIDWEST STOCK EXCHANGE, INC.**

(c) Transaction fee schedule:

<table>
<thead>
<tr>
<th>Round lots/mixed lots.</th>
<th>45 cents per 100 shares [for New York Stock Exchange listed issues]. $100.00 maximum per trade.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odd lots</td>
<td>35 cents per trade [for New York Stock Exchange listed issues]. $400.00 maximum monthly fee.</td>
</tr>
</tbody>
</table>

The above fees include all applicable trade recording fees, as set out in the Midwest Clearing Corporation (MCC) “Services and Schedule of Charges” bulletin, relating to floor executed trades.

The above fees shall not apply to transactions in Tape B eligible issues for firms sending orders in Tape B eligible issues to the Exchange Floor through December 31, 1993; however, all applicable trade recording fees relating to Tape B trades will be assessed as set out in the MCC “Services and Schedule of Charges” bulletin.

(1) Credits and Discounts

For billable round lot orders entered through the MAX System, the order entering member firm will receive a network utilization credit of $1.5 per 100 shares, [with a minimum credit of $30 and] to a maximum credit of $270. The credit may be applied against the firm’s total monthly Exchange bill. [In addition, order entering member firms will receive a monthly trade volume credit for trades executed on the floor according to the following schedule.]

<table>
<thead>
<tr>
<th>[Total monthly round lots]</th>
<th>[Credit]</th>
</tr>
</thead>
<tbody>
<tr>
<td>250–750</td>
<td>.05</td>
</tr>
<tr>
<td>751–1,000</td>
<td>.15</td>
</tr>
<tr>
<td>1,001–5,000</td>
<td>.25</td>
</tr>
<tr>
<td>5,001–10,000</td>
<td>.35</td>
</tr>
<tr>
<td>10,001 and above</td>
<td>.45</td>
</tr>
</tbody>
</table>

(A year-to-date share discount will be applied a firm’s net transaction fees. After having reached a qualifying accumulated share level, the firm will receive a discount for the remainder of the calendar year in accordance with the following schedule:

<table>
<thead>
<tr>
<th>Year-to-date shares (in millions)</th>
<th>Discount (percent)</th>
</tr>
</thead>
<tbody>
<tr>
<td>100–200</td>
<td>5</td>
</tr>
<tr>
<td>200–300</td>
<td>10</td>
</tr>
<tr>
<td>300 and above</td>
<td>15</td>
</tr>
</tbody>
</table>

In addition, a monthly share [value] volume discount will be applied against net transaction fees according to the following schedule:

<table>
<thead>
<tr>
<th>Monthly billable share volume</th>
<th>Discount (percent)</th>
</tr>
</thead>
<tbody>
<tr>
<td>[9,000,000–6,000,000]</td>
<td>5</td>
</tr>
<tr>
<td>6,000,001–9,000,000</td>
<td>10</td>
</tr>
<tr>
<td>9,000,001–12,000,000</td>
<td>15</td>
</tr>
<tr>
<td>12,000,001–15,000,000</td>
<td>20</td>
</tr>
<tr>
<td>15,000,001–20,000,000</td>
<td>25</td>
</tr>
<tr>
<td>20,000,001–25,000,000</td>
<td>35</td>
</tr>
<tr>
<td>25,000,001–and above</td>
<td>45</td>
</tr>
<tr>
<td>10,000,001–15,000,000</td>
<td>10</td>
</tr>
<tr>
<td>15,000,001–20,000,000</td>
<td>15</td>
</tr>
<tr>
<td>20,000,001–25,000,000</td>
<td>20</td>
</tr>
<tr>
<td>25,000,001–30,000,000</td>
<td>30</td>
</tr>
<tr>
<td>30,000,001–35,000,000</td>
<td>40</td>
</tr>
<tr>
<td>35,000,001+</td>
<td>50</td>
</tr>
</tbody>
</table>

[The above] A monthly share volume schedule shall also apply to floor broker operations after monthly and annual discount credits have been calculated. The applicable discount shall be based on aggregate share volume executed by
the floor brokerage operation on a monthly basis.

<table>
<thead>
<tr>
<th>Monthly aggregate share volume</th>
<th>Discount (percent)</th>
</tr>
</thead>
<tbody>
<tr>
<td>10,000,001–15,000,000</td>
<td>10</td>
</tr>
<tr>
<td>15,000,001–20,000,000</td>
<td>25</td>
</tr>
<tr>
<td>25,000,001–30,000,000</td>
<td>40</td>
</tr>
<tr>
<td>30,000,001–35,000,000</td>
<td>55</td>
</tr>
<tr>
<td>35,000,001+</td>
<td>70</td>
</tr>
</tbody>
</table>

2. Statutory Basis

The proposed rule change is consistent with Section 6(b)(4) of the Act in that it provides for the equitable allocation of reasonable fees and other charges among members using its facilities.

B. Self-Regulatory Organization’s Statement on Burden on Competition

The Exchange believes that the proposed rule change will not impose any burden on competition.

C. Self-Regulatory Organization’s Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change establishes or changes a due, fee, or other charge imposed by the Exchange and therefore has become effective pursuant to section 19(b)(3)(A) of the Act and subparagraph (e) of Rule 19b-4 thereunder. At any time within 60 days of the filing of such proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying at the Commission’s Public Reference Section, 450 Fifth Street NW., Washington, DC 20549. Copies of such filing will also be available for inspection and copying at the principal office of the MSE. All submissions should refer to File No. SR–MSE–93–07 and should be submitted by June 2, 1993.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Jonathan G. Katz, Secretary.

[FR Doc. 93–11219 Filed 5–11–93; 8:45 am]

BILLING CODE 8010–01–M


Self-Regulatory Organization; National Association of Securities Dealers, Inc. (“NASD”); Notice of Filing and Order Granting Accelerated Temporary Approval of Proposed Rule Change Relating to the Quotation Linkage Between the NASD and the London Stock Exchange


Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”), notice is hereby given that on April 27, 1993, the National Association of Securities Dealers, Inc. (“NASD” or “Association”) filed with Securities and Exchange Commission (“Commission” or “SEC”) the proposed rule change as described in Items I, and II below, which Items have been prepared by the NASD. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization’s Statement of the Terms of Substance of the Proposed Rule Change

On October 2, 1987, the Commission issued an order approving operation of a market information linkage between the NASD and the London Stock Exchange (“LSE”) (formerly, the International Stock Exchange of the United Kingdom and the Republic of Ireland) for a pilot term of two years. This experimental linkage is designed to provide an interchange of quotation information (“linkage information”) on about 740 securities (“linkage securities”); of that total, each marketplace has designated approximately half as its “pilot group” of linkage securities. NASD and LSE members that function as market makers in one or more of a subset of linkage securities that are quoted in both the Nasdaq and LSE dealer systems (“common issues”) are authorized to access linkage information without paying a separate charge to receive it. Operation of the linkage in this fashion comports with the terms of the Commission’s October 1987 Order. Most recently, the Commission authorized an extension of this pilot linkage through May 5, 1993, by approving File No. SR–NASD–92–44.

Pursuant to section 19(b)(1) of the Act and Rule 19b–4 thereunder, the NASD submits this proposed rule change to obtain Commission approval of the NASD/LSE pilot linkage through November 5, 1993.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the NASD included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The test of these statements may be examined at the places specified in Item IV below. The NASD has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statements.

A. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

The purpose of this rule filing is to obtain an interim extension of the Commission’s temporary approval of the NASD/LSE linkages through November 5, 1993. Absent an extension, authorization for the linkage will expire as of May 5, 1993.

During the proposed extension, the NASD and LSE will continue to discuss possible options regarding the linkage’s future structure and operational capabilities in relation to the needs of the international investment community. These discussions may lead to a substantive enhancement of the linkage, the pursuit of another joint initiative, or a decision to act independently in developing international systems that are
responsive to the business needs of the sponsors' constituencies. Any decision to enhance the linkage or to develop jointly an alternative system will entail another Rule 19b-4 filing that will afford the Commission (and other interested parties) an opportunity to focus on the relevant policy and regulatory issues. Meanwhile, continuation of the pilot linkage, as proposed, would be supportive of the NASD’s and LSE’s efforts to define systems capable of accommodating cross-border trading more efficiently.

The NASD submits that the statutory bases for the NASD/LSE pilot linkage and the requested extension thereof, are contained in sections 11A(a)(1) (B) and (C), 15A(b)(6), and 17a(a)(1) of the Act. Subsections (B) and (C) of section 11A(a)(1) set forth the Congressional goals of achieving more efficient and effective market operations, the availability of information with respect to quotations for securities and the execution of investor orders in the best market through the application of new data processing and communications techniques. Section 15A(b)(6) requires, inter alia, that the rules of the NASD be designed to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing and other interested parties will have ample opportunity to comment on any subsequent Rule 19b-4 filing involving permanent approval or substantive enhancement of the linkage. Finally, during the requested extension, the sponsoring markets will not use linkage information for purposes of operating of an intermarket, automated execution system.

C. Self-Regulatory Organization’s Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The NASD requests that the Commission find good cause for approving this proposed rule change prior to the 30th day following publication of notice of filing in the Federal Register, and, in any event, by May 5, 1993, the expiration of the linkage’s present authorization. The NASD believes that the requested extension of the pilot period is fully consistent with the statutory provisions and policy goals referenced in Section II of this Rule 19b-4 filing. Moreover, the additional time will enable the sponsoring markets to consider various options and determine the future course of this experimental project. Those deliberations will focus on evaluating feasible enhancements to the linkage as well as alternative projects intended to advance the internationalization of securities markets through more efficient computerized systems. Under these circumstances, it would be counterproductive to allow the NASD/LSE linkage to cease operation. Accordingly, the NASD believes that good cause exists to accelerate the effectiveness of this rule change to a date no later than May 5, 1993.

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to the NASD and, in particular, the requirements of sections 11A(a)(1)(B) and (C), 15A(b)(6), and 17a(a)(1) and the rules and regulations thereunder.

The Commission finds good cause for approving the proposed rule change prior to the 30th day after the date of publication of notice of filing thereof. The Commission believes that accelerated approval will avoid an unnecessary interruption of the pilot linkage while allowing the NASD and LSE to consider feasible options for enhancing the linkage or defining other automation initiatives to facilitate the efficient handling of international order flow. Accordingly, the Commission believes the NASD/LSE linkage should not be terminated while these efforts are ongoing.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submissions should file copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission’s Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the NASD. All submissions should refer to the file
number in the caption above and should be submitted by June 2, 1993.

It is therefore ordered, Pursuant to section 19(b)(2) of the Act, that the proposed rule change be, and hereby is, temporarily approved thereby extending the NASD/LSE linkage until November 5, 1993.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.6

Jonathan G. Katz,
Secretary.

[FR Doc. 93–11223 Filed 5–11–93; 8:45 am]
BILLING CODE 0010–01–M

[Rel No. IC–19458; 811–783]
American Investors Growth Fund, Inc.; Application

May 6, 1993.

AGENCY: Securities and Exchange Commission ("SEC").

ACTION: Notice of application for deregistration under the Investment Company Act of 1940 (the "Act").

APPLICANT: American Investors Growth Fund, Inc.

RELEVANT ACT SECTION: Section 8(f).

SUMMARY OF APPLICATION: Applicant seeks an order declaring that it has ceased to be an investment company.

FILING DATE: The application was filed on February 5, 1993 and amended on April 28, 1993.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the SEC orders a hearing.

Interested persons may request a hearing by writing to the SEC's Secretary and serving applicant with a copy of the request, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on June 1, 1993, and should be accompanied by proof of service on applicant, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the SEC's Secretary.

ADDRESSES: Secretary, SEC, 450 Fifth Street, NW., Washington, DC 20549. Applicant, 797 West Putnam Avenue, Greenwich, Connecticut 06836.

FOR FURTHER INFORMATION CONTACT: Marc Duffy, Staff Attorney, (202) 272–2511, or C. David Messman, Branch Chief, (202) 272–3018 (Division of Investment Management, Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained for a fee from the SEC's Public Reference Branch.

Applicant’s Representations

1. Applicant is a diversified open-end management company incorporated under the laws of Maryland. On April 22, 1987, applicant filed Articles of Incorporation with New York, but reincorporated in Maryland on October 5, 1989. In 1988, applicant filed a Notification of Registration under section 8(a) of the Act and a registration statement under section 8(b) of the Act. Also in 1988, applicant filed a registration statement under the Securities Act of 1933, to register 1,000,000 shares of common stock, which was later amended to allow for an infinite number of shares. Applicant’s registration statement was declared effective and an initial public offering was commenced on June 10, 1988.

2. On November 5, 1992, applicant’s board of directors approved an Agreement and Plan of Reorganization (the "Reorganization") between applicant and Ivy Growth Fund and recommended that the Reorganization be approved by applicant’s shareholders. On December 20, 1992, applicant mailed proxy materials relating to the Reorganization to its shareholders. On January 28, 1993, applicant held a special shareholder meeting, at which more than the required majority of applicant’s outstanding shares voted to approve the Reorganization.

3. On January 29, 1993, applicant had 7,099,913.65 shares outstanding with a net asset value per share of $5.36 and an aggregate net asset value of $47,869,833.71. On February 1, 1993 (the "Closing Date"), applicant transferred all of its assets and known liabilities to Ivy Growth Fund in exchange for shares of beneficial interest of Ivy Growth Fund. The number of shares of Ivy Growth Fund so received was determined by dividing the value of the net assets of applicant by the net asset value per share of Ivy Growth Fund. Immediately after such transfer of assets, applicant distributed pro rata to its shareholders the Ivy Growth Fund shares it received.

4. The Reorganization was effected as a purchase of applicant’s net assets in exchange for shares of Ivy Growth Fund, rather than a merger, in order to protect Ivy Growth Fund’s shareholders from any undisclosed liabilities of applicant.

5. As part of the Reorganization, applicant agreed to transfer its interest in its directors’ professional liability insurance policy to Ivy Growth Fund, which in turn, agreed to indemnify applicant’s directors to the same extent as applicant could indemnify them under applicable law. The continued existence of this insurance policy is intended to protect applicant’s directors against post-Reorganization claims that relate to causes of action occurring prior to the Reorganization. Because the insurance carrier was unwilling to recognize an assignment of the policy, applicant agreed to retain, at the insistence of Ivy Growth Fund, its corporate existence for the remaining policy period (18 months from the Closing Date) for the sole purpose of making any required claim under the policy on behalf of Ivy Growth Fund.

6. At the time of filing of the application, applicant had approximately 8,720 shareholders. Although applicant’s shareholders retain their shares, applicant has not retained any assets and has no debts or liabilities. Applicant believes that its shareholders are not exposed to any potential liability by retaining shareholders for eighteen months after the Closing Date. Applicant’s directors have determined in good faith that no undisclosed liabilities exist. In addition, applicant will not conduct any business other than that necessary to wind up its business affairs.

7. Applicant is not a party to any litigation or administrative proceeding. Applicant will file Articles of Dissolution promptly with the State of Maryland upon the termination of the above mentioned insurance policy (i.e., 18 months after the Closing Date).

8. The dissolution expenses incurred in connection with the Reorganization totaled approximately $27,848. American Investors Money Fund, Inc., applicant’s investment adviser, bore these expenses, which consisted of printing, mailing, and solicitation expenses.

For the SEC, by the Division of Investment Management, under delegated authority. Jonathan G. Katz, Secretary.

[FR Doc. 93–11216 Filed 5–11–93; 8:45 am]
BILLING CODE 0010–16–M

[Rel No. IC–19459; 811–3648]
American Investors Money Fund, Inc.; Application

May 6, 1993.

AGENCY: Securities and Exchange Commission ("SEC").
ACTION: Notice of application of Deregistration under the Investment Company Act of 1940 (the “Act”).

APPLICANT: American Investors Money Fund, Inc.

RELEVANT ACT SECTION: Section 8(f).

SUMMARY OF APPLICATION: Applicant seeks an order declaring that it has ceased to be an investment company.

FILING DATE: The application was filed on February 5, 1993 and amended on April 28, 1993.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the SEC orders a hearing. Interested persons may request a hearing by writing to the SEC’s Secretary and serving applicant with a copy of the request, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on June 1, 1993, and should be accompanied by proof of service on applicant, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer’s interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing or request, and the issue contested.

ADDRESSES: Secretary, SEC, 450 Fifth Street NW., Washington, DC 20549. Applicant, 777 West Putnam Avenue, Greenwich, Connecticut 06836.

FOR FURTHER INFORMATION CONTACT: Marc Duffy, Staff Attorney, (202) 272–2511, or C. David Messman, Branch Chief, (202) 272–3018 (Division of Investment Management, Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained for a fee from the SEC’s Public Reference Branch.

APPLICANT’S REPRESENTATIONS

1. Applicant is a diversified open-end management company incorporated under the laws of Maryland. On May 10, 1982, applicant filed a Notification of Registration under section 8(a) of the Act. On July 16, 1982, applicant filed a registration statement under section 8(b) of the Act, and under the Securities Act of 1933, to register an indefinite number of shares. Applicant’s registration statement was declared effective on November 4, 1982, and an initial public offering was commenced immediately thereafter.

2. On November 5, 1992, applicant’s board of directors approved an Agreement and Plan of Reorganization (the “Reorganization”) between applicant and Ivy Money Market Fund (the “Ivy Fund”) and recommended that the Reorganization be approved by applicant’s shareholders. On December 20, 1992, applicant mailed proxy materials relating to the Reorganization to its shareholders. On January 28, 1993, applicant held a special shareholder meeting, at which more than the required majority of applicant’s outstanding shares voted to approve the Reorganization.

3. On January 29, 1993, applicant had 2,531,078.38 shares outstanding with a net asset value per share of $1.00. On February 1, 1993 (the “Closing Date”), applicant transferred all of its assets and known liabilities to Ivy Fund in exchange for shares of beneficial interest of Ivy Fund. The number of shares of Ivy Fund so received was determined by dividing the value of the net assets of applicant by the net asset value per share of Ivy Fund. Immediately after such transfer of assets, applicant distributed pro rata to its shareholders the Ivy Fund shares it received.

4. The Reorganization was effected as a purchase of applicant’s net assets in exchange for shares of Ivy Fund, rather than a merger, in order to protect Ivy Fund’s shareholders from any undisclosed liabilities of applicant.

5. As part of the Reorganization, applicant agreed to transfer its interest in its directors’ professional liability insurance policy to Ivy Funds, which in turn, agreed to indemnify applicant’s directors to the same extent as applicant could indemnify them under applicable law. The continued existence of this insurance policy is intended to protect applicant’s directors against post-Reorganization claims that relate to causes of action occurring prior to the Reorganization. Because the insurance carrier was unwilling to recognize an assignment of the policy, applicant agreed to retain, at the insistence of Ivy Fund, its corporate existence for the remaining policy period (18 months from the Closing Date) for the sole purpose of making any required claim under the policy on behalf of Ivy Fund.

6. At the time of filing of the application, applicant had approximately 99 shareholders. Although applicant’s shareholders retain their shares, applicant has not retained any assets and has no debts or liabilities. Applicant believes that its shareholders are not exposed to any potential liability by remaining shareholders for eighteen months after the Closing Date. Applicant’s directors have determined in good faith that no undisclosed liabilities exist. In addition, applicant will not conduct any business other than that necessary to wind up its business affairs.

7. Applicant is not a party to any litigation or administrative proceeding. Applicant will file Articles of Dissolution promptly with the State of Maryland upon the termination of the above mentioned insurance policy (i.e., 18 months after the Closing Date).

8. The dissolution expenses incurred in connection with the Reorganization totaled approximately $6,334. American Investors Advisors, Inc., applicant’s investment advisor, bore these expenses, which consisted of printing, mailing, and solicitation expenses.

For the SEC, by the Division of Investment Management, under delegated authority.

Jonathan G. Katz,
Secretary.

[FR Doc. 93–11217 Filed 5–11–93; 8:45 am]

BILLING CODE 0410–01–M

SECURITIES AND EXCHANGE COMMISSION

[Rel. No. IC–19460; 811–2578]

American Investors Income Fund, Inc.; Application

May 6, 1993.

AGENCY: Securities and Exchange Commission (“SEC”).

ACTION: Notice of application for deregistration under the Investment Company Act of 1940 (the “Act”).

APPLICANT: American Investors Income Fund, Inc.

RELEVANT ACT SECTION: Section 8(f).

SUMMARY OF APPLICATION: Applicant seeks an order declaring that it has ceased to be an investment company.

FILING DATE: The application was filed on February 5, 1993 and amended on April 28, 1993.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the SEC orders a hearing. Interested persons may request a hearing by writing to the SEC’s Secretary and serving applicant with a copy of the request, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on June 1, 1993, and should be accompanied by proof of service on applicant, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer’s interest, the reason for the request, and the issue contested. Persons who wish to be notified of a hearing or request, and the issue contested.

ADDRESSES: Secretary, SEC, 450 Fifth Street NW., Washington, DC 20549. Applicant, 777 West Putnam Avenue, Greenwich, Connecticut 06836.
FOR FURTHER INFORMATION CONTACT: Marc Duffy, Staff Attorney, (202) 272-2511, or C. David Messman, Branch Chief, (202) 272-3018 (Division of Investment Management, Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained for a fee from the SEC's Public Reference Branch.

Applicant's Representations

1. Applicant is a diversified open-end management company incorporated under the laws of Maryland. On August 28, 1972, applicant filed Articles of Incorporation with Connecticut but reincorporated in Maryland on October 4, 1989. On June 12, 1975, applicant filed a Notification of Registration under section 8(a) of the Act, and a registration statement under section 8(b) of the Act. On August 21, 1975, applicant filed a registration statement under the Securities Act of 1933 to register 1,000,000 shares of common stock, which was later amended to allow for an indefinite number of shares. Applicant's registration statement was declared effective on January 5, 1976, and an initial public offering was commenced immediately thereafter.

2. On November 5, 1992, applicant's board of directors approved an Agreement and Plan of Reorganization (the "Reorganization") between applicant and Mackenzie Fixed Income Trust ("Mackenzie") and recommended that the Reorganization be approved by applicant's shareholders. On December 20, 1992, applicant mailed proxy materials relating to the Reorganization to its shareholders. On January 28, 1993, applicant held a special shareholder meeting, at which more than the required majority of applicant's outstanding shares voted to approve the Reorganization.

3. On January 29, 1993, applicant had 1,501,239.31 shares outstanding with a net asset value per share of $5.37 and an aggregate net asset value of $8,055,365.59. On February 1, 1993 (the "Closing Date"), applicant transferred all of its assets and known liabilities to Mackenzie in exchange for shares of beneficial interest of Mackenzie. The number of shares of Mackenzie so received was determined by dividing the value of the net assets of applicant by the net asset value per share of Mackenzie. Immediately after such transfer of assets, applicant distributed pro rata to its shareholders the Mackenzie shares it received.

4. The Reorganization was effected as a purchase of applicant's net assets in exchange for shares of Mackenzie, rather than a merger, in order to protect Mackenzie's shareholders from any undisclosed liabilities of applicant.

5. As part of the Reorganization, applicant agreed to transfer its interest in its directors' professional liability insurance policy to Mackenzie, which in turn, agreed to indemnify applicant's directors to the same extent as applicant could indemnify them under applicable law. The continued existence of this insurance policy is intended to protect applicant's directors against post-Reorganization claims that relate to causes of action occurring prior to the Reorganization. Because the insurance carrier was unwilling to recognize an assignment of the policy, applicant agreed to retain, at the insistence of Mackenzie, its corporate existence for the remaining policy period (18 months from the Closing Date) for the sole purpose of making any required claim under the policy on behalf of Mackenzie.

6. At the time of filing of the application, applicant had approximately 1,070 shareholders. Although applicant's shareholders retain their shares, applicant has not retained any assets and has no debts or liabilities. Applicant believes that its shareholders are not exposed to any potential liability by remaining shareholders for eighteen months after the Closing Date. Applicant's directors have determined in good faith that no undisclosed liabilities exist. In addition, applicant will not conduct any business other than that necessary to wind up its business affairs.

7. Applicant is not a party to any litigation or administrative proceeding. Applicant will file Articles of Dissolution promptly with the State of Maryland upon the termination of the above mentioned insurance policy (i.e., 18 months after the Closing Date).

8. The dissolution expenses incurred in connection with the Reorganization totaled approximately $9,132. American Investors Advisors, Inc., applicant's investment advisor, bore these expenses, which consisted of printing, mailing, and solicitation expenses.

For the SEC, by the Division of Investment Management, under delegated authority.

Jonathan G. Katz,
Secretary.

[FR Doc. 93-11218 Filed 5-11-93; 8:45 am] BILLING CODE 8010-01-M

[Rel. No. IC-19457; 812-8356]


Dean Witter American Value Fund, et al.; Application

AGENCY: Securities and Exchange Commission ("SEC").

ACTION: Notice of application for exemption under the Investment Company Act of 1940 (the "Act").

RELEVANT ACT SECTIONS: Exemption requested under section 6(c) from the provisions of section 22(d).

SUMMARY OF APPLICATION: Applicants seek an order amending certain contingent deferred sales charge (“CDSC”) orders to waive the imposition of a CDSC in connection with certain additional types of redemptions.

FILING DATE: The application was filed on April 19, 1993.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the SEC orders a hearing. Interested persons may request a hearing by writing to the SEC’s Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be accompanied by proof of service on applicants, in the form of an affidavit or, for lawyers of service. Hearing requests should state the nature of the writer’s interest, the reason for the request, and the issues contested. Persons who wish to be notified of a request, and the issues contested. Hearing requests should be received by the SEC by 5:30 p.m. on June 1, 1993, and should be mailed to the SEC at 450 Fifth Street, NW., Washington, DC 20549. Applicants, Two World Trade Center, New York, New York 10048.

FOR FURTHER INFORMATION CONTACT: Marc Duffy, Staff Attorney, (202) 272-2511, or C. David Messman, Branch Chief, (202) 272-3018 (Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained for a fee at the SEC’s Public Reference Branch.

Applicants’ Representations

1. The Funds are registered under the Act as open-end management investment companies. InterCapital is registered as an investment adviser under the Investment Advisers Act of 1940 (the “Advisers Act”) and is the investment adviser to the DW Funds. TCW Funds Management Inc (“TFM”) is registered as an investment adviser under the Adviser Act and is the investment adviser for the TCW/DW Funds. The Distributor is a registered broker-dealer and provides distribution services to the Funds.

2. InterCapital is a wholly-owned direct subsidiary of Dean Witter Reynolds Inc. (“DWR”), a Delaware corporation, which is a wholly-owned subsidiary of Dean Witter, Discover & Co. (“DWDC”). Approximately 80% of DWDC shares are owned by Sears, Roebuck & Co. and the remaining 20% are owned directly by the public. In an internal reorganization that took place in January 1993, InterCapital assumed the investment advisory, management, and administrative activities previously performed by the InterCapital Division of DWR. InterCapital now provides administrative services to the TCW/DW Funds.

3. In 1983, the SEC issued an order to Dean Witter Developing Growth Securities Trust (“DWDGST”) and DWR to permit DWDGST and DWR to impose a CDSC on certain redemptions of shares and waive the CDSC in certain circumstances. That order was amended also in 1983 to extend CDSC relief to other open-end management investment companies for which DWR served, or in the future would serve, as investment adviser or principal underwriter. In 1992, the SEC issued an order amending the 1983 orders to extend the relief granted by the 1983 orders to each of the Funds and any open-end management investment company for which DWR or any person controlling, controlled by, or under common control with DWR within the meaning of section 2(a)(9) of the Act (a “DWR Entity”) serves or may in the future serve as investment adviser or principal underwriter (collective, the “Prior Orders”).

4. Under the Prior Orders, a CDSC is imposed on shares redeemed within six years of purchase, unless a waiver of the CDSC is applicable. However, no CDSC is imposed on an amount that represents an increase in the value of Fund shares due to capital appreciation. In addition, no CDSC is imposed on shares purchased through reinvestment of dividends or capital gains distributions, or shares acquired in exchange for shares of other Funds on which a front-end sales charge was paid. Generally, the percentage rate used in calculating the CDSC declines during the six year period with a five percent CDSC applicable for shares redeemed within one year of purchase and a one percent CDSC applicable for shares redeemed during the sixth year. The CDSC is waived, under certain circumstances, with respect to redemptions of shares of the Funds held by: (a) Employees and former employees of DWR or any DWR Entity; (b) employee benefit plans in which such employee or former employees are participants; and (c) directors/trustees of the Funds.

5. Applicants now propose also to waive the CDSC with respect to redemptions of shares of the Funds held by: (a) Employees and former employees of TFM or any persons controlling, controlled by, or under common control with TFM within the meaning of section 2(a)(9) of the Act, and (b) employee benefit plans in which such employees are participants (collectively, “TFM Employee Redemptions”). InterCapital, the Distributor, or any DWR Entity will determine whether and the extent to which these waivers are implemented, subject to the approval of the directors/trustees for each Fund adopting such waiver, including a majority of the directors/trustees of each Fund who are not “interested persons” of the Fund, InterCapital, the Distributor, or any DWR Entity, as such term is defined in section 2(a)(19) of the Act, as being in the best interest of the Fund and its shareholders. Any waivers implemented pursuant to the terms of the order requested herein will be made uniformly available to all persons and plans eligible for the waiver and will be disclosed in the prospectuses and statements of additional information of the Funds.

Applicants’ Legal Analysis

1. Section 22(d) of the Act provides, in pertinent part, that no registered investment company or principal underwriter thereof shall sell any redeemable security issued by such company to any person except at a current public offering price described in the prospectus. Applicants recognize that waiving the CDSC in connection with TFM Employee Redemptions could be viewed as causing such shares to be sold at other than a uniform offering price in violation of section 22(d). The waivers of the CDSC will not harm the Funds or their shareholders, nor will such waivers unfairly discriminate among shareholders or purchasers. Thus, should the SEC waive the CDSC under the Act.

2. Applicants submit that the requested amendment of the Prior Orders is necessary and appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act.

Applicants’ Condition

As a condition of the requested relief, applicants agree to comply with the provisions of proposed rule 6c-10 under

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the Act (Investment Company Act Release No. 16619 (Nov. 2, 1988)) as such rule is currently proposed and as it may be reproposed, adopted, or amended.

For the SEC, by the Division of Investment Management, pursuant to delegated authority.
Jonathan G. Katz,
Secretary.

[Rel. No. 1C–19461; 812–6024]
May 6, 1993.

Great Hall Investment Funds, Inc., et al.; Notice of Application

AGENCY: Securities and Exchange Commission ("SEC").

ACTION: Notice of application for exemption under the Investment Company Act of 1940 (the "Act").

APPLICANTS: Great Hall Investment Funds, Inc ("Great Hall") for and on behalf of Great Hall National Tax-exempt Fund ("National Fund") and Great Hall Minnesota Insured Tax-Exempt Fund ("Minnesota Fund"), two series of Great Hall, and all future series of Great Hall and other registered open-end investment companies or series thereof for which Insight Investment Management, Inc. ("Insight Management") in the future serves as investment adviser, that are offered in the same "group of investment companies," as that term is defined in rule 11a–3 under the Act, and that offer their shares for sale to the public at their net asset value per share plus a front-end sales load (individually, a "Fund" and collectively, the "Funds"), Insight Management, Dain Bosworth Incorporated, and Rauscher Pierce Refsnes, Inc.

RELEVANT ACT SECTIONS: Exemption requested pursuant to section 6(c) from the provisions of sections 2(a)(32), 2(a)(35), 22(c), and 22(d) and rule 22c–1.

SUMMARY OF APPLICATION: Applicants seek an exemption under section 6(c) of the Act permitting the Funds to impose and, under certain circumstances, waive a contingent deferred sales load ("CDSC") on certain redemptions of their shares. Filing Date: The application was filed on October 26, 1992, and amended on November 25, 1992, and April 29, 1993. Hearing or Notification of Hearing: An order granting the application will be issued unless the SEC orders a hearing. Interested persons may request a hearing by writing to the SEC's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on June 1, 1993, and should be accompanied by proof of service on applicants, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the SEC's Secretary.

ADDRESSES: Secretary, SEC, 450 5th Street, NW., Washington, DC 20549. Applicants, 60 South Sixth Street, Minneapolis, MN 55402.

FOR FURTHER INFORMATION CONTACT: Nicholas D. Thomas, Staff Attorney, at (202) 504–2263 or Elizabeth G. Osterman, Branch Chief, at (202) 272–3016 (Division of Investment Management, Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained for a fee at the SEC's Public Reference Branch.

Applicants' Representations
1. Great Hall, a Minnesota corporation, is an open-end management investment company that currently offers five series. Insight Management serves as the investment adviser for each series of Great Hall. Dain Bosworth Incorporation ("DBI") and Rauscher Pierce Refsnes, Inc., ("RPR") (hereafter, the "Co-Distributors") serve as principal underwriters of the shares of each series of Great Hall. Insight Management, DBI, and RPR are each wholly owned subsidiaries of Inter-Regional Financial Group, Inc., a publicly held investment and financial services company.

2. Three of Great Hall's series are offered to the public at their net asset value per share with no sales charge. The other two series (National Fund and Minnesota Fund) are offered for sale at their net asset value plus a front-end sales load ("FESL") on sales of less than $1 million. No FESL is imposed on sales of $1 million or more.

3. With regard to sales of $1 million or more, applicants propose to assess a CDSC if such shares are redeemed within a specified period following the purchase date (the "CDSC Period"). The CDSC Period may be up to twenty-four months, and the CDSC percentage may be up to one percent. Within such parameters, any Fund may in the future institute break points so that shareholders that hold shares for a specified period of time or invest a specified amount may qualify for a reduction or a waiver of the maximum permitted CDSC percentage. Additionally, any Fund may decide to temporarily or permanently discontinue the CDSC in the future. The Funds anticipate that the initial CDSC percentage will be one percent and the initial CDSC Period will be twenty-four months. Any changes, variations, discontinuation, or reinstatements of the proposed CDSC, the CDSC percentage, or the CDSC Period will be disclosed in each affected Fund's prospectus, and any such change, variation, discontinuation, or resinstatement will not affect the shares of such Fund that were issued prior to such disclosure.

4. In calculating the amount of the CDSC, the CDSC percentage will be applied to the lesser of the net asset value of shares subject to the CDSC at the time of purchase, or the net asset value of such shares at the time of redemption. The CDSC shall not be applied to shares representing amounts attributable to any increase in the value of a shareholder's account due to capital appreciation or shares acquired through reinvestment of income dividends or capital gain distributions.

5. In determining whether a CDSC is payable with respect to any redemption, it will be assumed that shares that are not subject to a CDSC are redeemed first, shares that are subject to a reduced CDSC are redeemed next, and that other shares are then redeemed on a last-in, first-redemption basis.

6. Applicants intend to waive the CDSC with respect to each of the following classes of purchasers: (a) Officers and directors of the Funds; (b) Officers, directors, and full-time employees of Insight Management and the Co-Distributors, and officers, directors, and full-time employees of parents and subsidiaries of the foregoing companies; (c) Spouses and lineal ancestors and descendants of the officers, directors, and employees referenced in clauses (a) and (b) and lineal ancestors and descendants of their spouses; (d) Registered representatives and other employees of banks and dealers that have selling agreements with the Co-Distributors and parents, spouses, and children under the age of twenty-one of such registered representatives and other employees; (e) Trust companies and bank trust departments for funds held in a fiduciary, agency, advisory, custodial, or similar capacity;
(f) Any state, county, or city, or any instrumentality, department, authority, or agency thereof, that is prohibited by applicable investment laws from paying a sales charge or commission in connection with the purchase of shares of any registered management investment company;

(g) Partners and full-time employees of the Funds' general counsel; and

(h) Private account clients of Insight Management.

7. Applicants also intend to waive the CDSC in connection with purchases of Fund shares that are funded by the proceeds from the sale or redemption of shares of a closed-end investment company. To exercise this privilege, the order for a Fund's shares must be received by the Fund within sixty days after such sale or redemption.

8. Applicants further intend to waive the CDSC in connection with purchases of Fund shares funded by the proceeds from the redemption of shares of any unrelated open-end investment company that charges an FESL, provided there was no deferred sales load, fee, or other charge imposed in connection with such redemption. In order to exercise this privilege, the order for a Fund's shares must be received by the Fund within sixty days after such redemption of shares of the unrelated investment company. Prior to waiving the CDSC in this context, the Funds and the Co-Distributors will take such steps as may be necessary to determine that the shareholder has not paid a deferred sales load, fee, or other charge in connection with such redemption. Including, without limitation, requiring the shareholder to provide a written representation that no deferred sales load, fee, or other charge was imposed in connection with such redemption and, in addition, either requiring such shareholder to provide an activity statement that supports the shareholder's representation or reviewing a copy of the current prospectus of the unrelated investment company and determining that such company does not impose a deferred sales load, fee, or other charge in connection with the redemptions of its shares.

9. Applicants also intend to waive the CDSC on redemption of shares in the event of the death or disability of the shareholder within the meaning of section 72(m)(7) of the Internal Revenue Code of 1986, as amended. Applicants will apply the waiver for death or disability to shares held at the time of death or the initial determination of disability of either an individual shareholder or one who owns the shares as a joint tenant with the right of survivorship or as a tenant in common.

10. The Co-Distributors intend to provide a pro rata refund, out of their own assets, of any CDSC paid in connection with a redemption of any Fund's shares (by crediting such refunded CDSC to such shareholder's account) if, within sixty days of such redemption, all or any portion of the redemption proceeds are reinvested in shares of one or more of the Funds. Any reinvestment within sixty days of a redemption to which a CDSC was paid shall be made without the imposition of a FESL but shall be subject to the same CDSC to which such amount was subject prior to the redemption, provided, however, that the CDSC Period shall run from the original investment date but shall be extended by the number of days between the redemption and the reinvestment dates (inclusive).

11. The CDSC will not be imposed at the time of the exchange of one Fund's shares for shares of another Fund, but the acquired Fund shares will continue to be subject to the CDSC and to the CDSC Period applicable to the Fund shares being exchanged therefor. Additionally, the CDSC will not be imposed at the time that Fund shares subject to the CDSC are exchanged for shares of any fund managed by Insight Management and offered to the public without the imposition of a FESL or a CDSC ("No-Load Funds") or at the time such No-Load Fund shares are re-exchanged for shares of any Fund subject to the CDSC, provided, however, that in each such case the shares acquired will remain subject to the CDSC, and the CDSC Period applicable to such shares will be extended by the period during which such shares represent shares of any No-Load Fund.

Applicants' Condition

If the requested exemptive relief is granted, applicants agree to comply with the provisions of proposed rule 6c-10 under the Act, Investment Company Release No. 16619 (Nov. 2, 1988), as currently proposed and as it may be reproposed, adopted, or amended.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Jonathan G. Katz,
Secretary.

[FR Doc. 93-11222 Filed 5-11-93; 8:45 am]

BILLING CODE 6010-01-M

SMALL BUSINESS ADMINISTRATION

[Declaration of Disaster Loan Area #2629]

California; Amendment #4; Declaration of Disaster Loan Area

The above numbered Declaration is hereby amended, in accordance with notification by the Federal Emergency Management Agency dated March 29 to extend the termination date for filing applications for physical damage to May 5 and further, by a subsequent notice dated May 3, to extend the termination date to June 1.

All other information remains the same i.e., the termination date for filing applications for economic injury remains November 3, 1993.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008)


Bernard Kulik,
Assistant Administrator for Disaster Assistance.

[FR Doc. 93-11162 Filed 5-11-93; 8:45 am]

BILLING CODE 6052-01-M

[Declaration of Disaster Loan Area #2639]

New York; Amendment #1; Declaration of Disaster Loan Area

The above number Declaration is hereby amended to include Oneida County and the contiguous counties of Herkimer, Lewis, Madison and Otsego as a disaster area as a result of damages caused by flooding which began on April 2, 1993.

All other information remains the same, i.e., the termination date for filing applications for physical damage is June 21, 1993 and January 21, 1994 for economic injury.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008)


Dayton J. Walkins,
Acting Administrator.

[FR Doc. 93-11161 Filed 5-11-93; 8:45 am]

BILLING CODE 6025-01-M
**Due Date for Answers, Conforming Applications, or Motion to Modify Scope:** May 24, 1993

**Description:** Application of British Airways PLC, pursuant to section 402 of the Act and subpart Q of the Regulations applies for amendment and reissuance of its Foreign Air Carrier Permit issued by Order 90-5-14 to enable it to engage in scheduled foreign air transportation of persons, property and mail over the following routes: 1. Between Birmingham, England and New York, New York 2. Between Manchester, England and Los Angeles, California 3. Between London, England and Charlotte, North Carolina 4. Between London, England and Baltimore, Maryland

**Docket Number:** 48777

**Date filed:** April 27, 1993

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**Due Date for Answers, Conforming Applications, or Motion to Modify Scope:** May 25, 1993

**Description:** Application of Air France, pursuant to section 402 of the Act and subpart Q of the Regulations applies for renewal or grant of a permanent scheduled (inclusive of charter authority) foreign air carrier permit, or permits, or, under any circumstance a permit or permits of no less than five years duration, to be able to continue to operate the authorities listed in Appendix A and for whatever other, similar relief the Department deems necessary under the circumstances, consistent herewith.

**Docket Number:** 48781

**Date filed:** April 30, 1993

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**Due Date for Answers, Conforming Applications, or Motion to Modify Scope:** May 28, 1993

**Description:** Application of AOM-Minerve, S.A., pursuant to section 402 of the Act and subpart Q of the Regulations, requests the continuation, extension, renewal or grant of its foreign air carrier permit which authorizes it to engage in charter foreign air transportation of persons, property and mail between a point or points in France and its territories and a point or points in the United States.

**Docket Number:** 48782

**Date filed:** April 30, 1993

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**Due Date for Answers, Conforming Applications, or Motion to Modify Scope:** May 11, 1993

**Description:** Joint Application of USAir, Inc. and Metropolitan Nashville Airport Authority pursuant to section 401(h) of the Act and subpart Q of the Regulations requests renewal of its foreign air carrier permit authorizing it to provide charter foreign air transportation or property and mail between Ireland and the United States.

**Docket Number:** 48739

**Date filed:** April 30, 1993

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**Due Date for Answers, Conforming Applications, or Motion to Modify Scope:** May 28, 1993

**Description:** First Amendment to the Application of Kitty Hawk, hereby amends its application for a certificate of public convenience and necessity authorizing scheduled foreign air transportation of property and mail, filed April 2, 1993 in this Docket, to replace its initial proposal for U.S.-Mexico service with a U.S.-Dominican Republic service proposal.

Phyllis T. Kaylor,
Chief, Documentary Services Division.

**Docket Number:** 48786

**Date filed:** April 30, 1993

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**Draft Environmental Impact Statement; Long Beach, CA**

**AGENCY:** Coast Guard, DOT.

**ACTION:** Notice of intent.

**SUMMARY:** The Coast Guard, as Federal lead agency and in cooperation with the Port of Los Angeles, intends to prepare a Draft Environmental Impact Statement (DEIS)/Draft Environmental Impact...
Report (DEIR) for a proposed modification of the Henry Ford (Badger) Avenue Railroad Bridge over Cerritos Channel, Long Beach Harbor between Terminal Island and Wilmington in Los Angeles County, CA. A Coast Guard bridge permit amendment is required before construction may begin.

DATES: Comments must be received on or before June 11, 1993.

ADDRESSES: Comments should be mailed to Commander (oan-br), Eleventh Coast Guard District, Bldg. 10, room 214, Coast Guard Island, Alameda, CA 94501–5100.

FOR FURTHER INFORMATION CONTACT: Susan Worden, Bridge Administrator, Eleventh Coast Guard District, telephone: (510) 437–3514.

SUPPLEMENTARY INFORMATION: This notice of intent is published as required by regulations of the Council on Environmental Quality under 40 CFR 1501.7.

The Port of Los Angeles has applied for a Coast Guard bridge permit amendment to modify the Ford (Badger Avenue) Railroad Bridge. The proposed modification would involve replacing the existing double-leaf bascule span with a vertical-lift span. A double track and a single maintenance lane would be provided on the span. The primary purpose of this project is to replace the 67-year-old, substandard, movable span to improve rail safety across the bridge and insure reliable access and safe passage through the movable span for mariners. The existing bridge provides a vertical clearance of 9 feet above mean high water in the closed to navigation position and unlimited clearance in the open position. The proposed bridge will provide a vertical clearance of 9 feet above mean high water in the closed position and 183 feet in the open position. Horizontal clearance is 180 feet and will remain the same. The current drawbridge operating regulation will remain the same (the bridge remains in the open to navigation position except for the passage of trains).

The State Historic Preservation Officer has determined that the existing bridge is eligible for the National Register of Historic Places. It is an example of a Strauss-arched bascule bridge, constructed in 1924, that has survived several natural disasters and is a historical and architectural achievement. It is also associated with the development of the Port of Los Angeles and surrounding communities of Wilmington, San Pedro and Long Beach, CA. Replacement of the existing bascule span would deplete an historic resource.

The purpose of this notice is to improve the public’s awareness of, and participation in, this aspect of FAA’s regulatory activities. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of any petition or its final disposition.

DATES: Comments on petitions received must identify the petition docket number involved and must be received on or before May 31, 1993.

ADDRESSES: Send comments on any petition in triplicate to: Federal Aviation Administration, Office of the Chief Counsel, Attn: Rule Docket (AGC–10), Petition Docket No. 11197, 800 Independence Avenue, SW., Washington, DC 20591.

The petition, any comments received, and a copy of any final disposition are filed in the assigned regulatory docket and are available for examination in the Rules Docket (AGC–10), room 915G, F.A.A. Headquarters Building (FOB 10A), 800 Independence Avenue, SW., Washington, DC 20591; telephone (202) 267–3252.

The significant impact identified with this bridge proposal would be the loss of an historic resource. Other potential impacts, such as air quality, noise, rail and end water safety, and water quality, will be analyzed.

A scoping meeting is scheduled to be held on Tuesday, May 25, 1993 at 3 p.m. and 7 p.m. in the Port of Los Angeles boardroom, 2nd Floor, 425 S. Palos Verdes Street, San Pedro, CA. Written comments are invited from all interested parties to assure that all significant issues are identified and the full range of alternatives and impacts of the proposed bridge modification are addressed.

The DEIS/DEIR is scheduled to be available in November 1993 for agencies and public review and comment. A public hearing may be scheduled after the DEIS/DEIR is issued.


A. Cattalini, Captain, U.S. Coast Guard, Acting Chief, Office of Navigation Safety and Waterway Services.

[FR Doc. 93–11197 Filed 5–11–93; 8:45 am]

BILLING CODE 4910–14–M

Federal Aviation Administration
[Summary Notice No. PE–93–21]

Petitions for Exemption; Summary of Petitions Received; Dispositions of Petitions Issued

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of petitions for exemption received and of dispositions of prior petitions.

SUMMARY: Pursuant to FAA’s rulemaking provisions governing the application, processing, and disposition of petitions for exemption (14 CFR part 11), this notice contains a summary of certain petitions seeking relief from specified requirements of the Federal Aviation Regulations (14 CFR chapter I), dispositions of certain petitions previously received, and corrections. The purpose of this notice is to improve the public’s awareness of, and participation in, this aspect of FAA’s regulatory activities. Neither publication of this notice nor the inclusion or omission of information in the summary

Docket No.: 24770

Petitioner: Flight Safety International

Sections of the FAR Affected: 14 CFR 61.56(b)(1); 61.57(a)(1), (c) and (d); 61.58(b)(2), (c) (1) and (d); 61.67(d)(2); 61.163(a); section 61 Appendix B and section 121, Appendix H.

Description of Relief Sought: To extend Exemption 5324 to allow Flight Safety International (FSI) to continue to train and check pilots in an FAA approved helicopter simulator in accordance with existing conditions and limitations.

Docket No.: 26740

Petitioner: New York Helicopter

Sections of the FAR Affected: 14 CFR 333.244(a)(1)

Description of Relief Sought: To allow New York Helicopter (NYH), on an on-going basis, to reduce the operating experience for previously qualified 5K58T captains, who also serve as pilots in command in the Bell 206 helicopter, to two hours of operating experience on the New York Helicopter routes.

Docket No.: 27235

Petitioner: United Air Lines, Inc. (United Airlines or United)
Disposition of Petitions

Petitioner: United Airlines to use its 747 #2 simulator, qualified at level C (Phase II), as if it were qualified at level D (Phase III). This simulator has a fully qualified level D (Phase III) visual system; however, it cannot meet the objective comparison requirements for buffet and sound.

Docket No.: 27243

Petitioner: Chalk's International Airlines

Sections of the FAR Affected: 14 CFR part 111, Appendix C, and F

Description of Relief Sought: To allow Chalk's International Airline to conduct passenger carrying operations under day, visual flight rules (VFR) conditions without a ground proximity warning system (GPWS) installed.

Disposition of Petitions

Docket No.: 22469

Petitioner: Parks College of St. Louis University

Sections of the FAR Affected: 14 CFR part 141 Appendices A, C, D, and F

Description of Relief Sought/Disposition: To extend Exemption No. 3495 to allow students of Parks College of St. Louis University to be trained to a performance standard in lieu of the minimum flight experience requirements of section 141 Appendices A, C, D, and F. This exemption does not allow a reduction of the minimum flight experience requirements for solo cross-country flight of section 141. Grant, April 28, 1993, Exemption No. 3495F

Docket No.: 22690

Petitioner: Boeing Commercial Airplane Group

Sections of the FAR Affected: 14 CFR 61.57 (c) and (d)

Description of Relief Sought/Disposition: To permit pilots of Air Tractor models AT-802 and AT-802A to operate these airplanes without a type rating, although the maximum gross weight of these airplanes exceeds 12,500 pounds. Grant, April 30, 1993, Exemption No. 5651

Docket No.: 27131

Petitioner: AIREVAC FOR TULSA, INC.

Sections of the FAR Affected: 14 CFR 135.153 (c) and (g)

Description of Relief Sought/Disposition: To permit AIREVAC FOR TULSA, INC (AET) to operate without a TSO-C112 (Mode S) Transponder installed on AET’s aircraft operating under the provisions of section 135. Grant, April 27, 1993, Exemption No. 5648.

[FR Doc. 93-11286 Filed 5-11-93; 8:45 am]

BILLING CODE 4910-13-M

Aviation Rulemaking Advisory Committee Meeting on Aircraft Certification Procedures Issues

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of meeting.

SUMMARY: The FAA is issuing this notice to advise the public of a meeting of the Federal Aviation Administration’s Aviation Rulemaking Advisory Committee to discuss aircraft certification procedures issues.

DATES: The meeting will be held on May 27, 1993 at 8:30 a.m., and adjourn at 11 a.m. If the agenda is not completed by that time, the meeting will resume at 2 p.m. Arrive for oral presentations by May 27, 1993.

ADDRESSES: The meeting will be held at the General Aviation Manufacturers Association, suite 801, 1400 K Street NW, Washington, DC 20005.

FOR FURTHER INFORMATION CONTACT: Ms. Kathy Ball, Aircraft Certification Service (AIR-1), 800 Independence Avenue SW, Washington, DC 20591, telephone (202) 267-8235.

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-362; 5 U.S.C. App. I), notice is hereby given of a meeting of the Security R&D Subcommittee of the Federal Aviation Administration (FAA) Research, Engineering and Development Advisory Committee to be held Wednesday, June 2, 1993, at 9:15 a.m. The meeting will take place at the Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC, in the MOC Room on the tenth floor (adjacent to Room 1015A).

The agenda for this meeting will include: (1) A review of responses to the draft white paper on immediate procurement of equipment; (2) a detailed discussion of the FAA’s response to the June 2, 1992 report; (3) a detailed discussion of the FAA’s response to the June 2, 1992 report; (3) a review of the task statement and continued mission of the panel; and (4) an opportunity for public comment.

Openings are to the interested public but limited to spaces available. With the approval of the Chairman, members of the public may present oral statements at the meeting. Persons wishing to present oral statements, obtain information, or access FAA Headquarters to attend the meeting should contact Dr. Lyle Malotky, the Panel’s Designated Federal Official.
Persons wishing to present oral comment, scheduling overview briefings to define presentations/topics to be reviewed; recommendations; determining effort to develop a report and include: Discussing the task statement

The meeting will take place at TRW, 12900 Federal Systems Park Drive, Fairfax, VA 22033, in Conference Room 7150–C.

The agenda for this meeting will include: Discussing the task statement for the subcommittee; organizing the effort to develop a report and recommendations; determining presentations/topics to be reviewed; scheduling overview briefings to define the dimensions of the problem, and providing an opportunity for public comment.

Attendance is open to the interested public but limited to space available. With the approval of the Subcommittee Chairman, members of the public may present oral statements at the meeting. Persons wishing to present oral statements, obtain information, or plan to access the building to attend the meeting should contact Mrs. Eleanor Dex at TRW, telephone (703) 968–1700.

Members of the public may present a written statement to the committee at any time.

Issued in Washington, DC, on May 3, 1993.

Martin T. Rozesky, Executive Director, Research, Engineering and Development Advisory Committee.

[FR Doc. 93–11262 Filed 5–11–93; 8:45 am]
BILING CODE 4910–13–M

DEPARTMENT OF THE TREASURY
Office of the Secretary

List of Countries Requiring Cooperation With an International Boycott

In order to comply with the mandate of section 999(a)(3) of the Internal Revenue Code of 1986, the Department of the Treasury is publishing a current list of countries which may require participation in, or cooperation with, an international boycott (within the meaning of section 999(b)(3) of the Internal Revenue Code of 1986).

On the basis of the best information currently available to the Department of the Treasury, the following countries may require participation in, or cooperation with, an international boycott (within the meaning of section 999(b)(3) of the Internal Revenue Code of 1986):

Bahrain, Iraq, Jordan, Kuwait, Lebanon, Libya, Oman, Qatar, Saudi Arabia, Syria, United Arab Emirates, Yemen, Republic of.


Sam Sessions,
Deputy Assistant Secretary for Tax Policy

[FR Doc. 93–11262 Filed 5–11–93; 8:45 am]
BILING CODE 4910–25–M

Fiscal Service

Surety Companies Acceptable on Federal Bonds Liquidation; Covenant Mutual Insurance Co.

Covenant Mutual Insurance Company, a Connecticut Corporation, formerly held a Certificate of Authority as an acceptable surety on Federal bonds and was last listed as such at 57 FR 29368, July 1, 1992. The Company’s authority was terminated by the Department of the Treasury effective March 3, 1993. Notice of the termination was published in the Federal Register of March 24, 1993, on page 15896.

On March 1, 1993, upon petition by the Insurance Commissioner of the State of Connecticut, the Superior Court of the Judicial District of Hartford/New Britain at Hartford, of the State of Connecticut, issued an Order placing Covenant Mutual Insurance Company into Rehabilitation. Mr. Robert R. Googins, the Insurance Commissioner of the State of Connecticut, was appointed as the Rehabilitator of the Company. By subsequent order dated March 16, 1993, the Connecticut Court authorized the Rehabilitator to liquidate the Florida claims. On March 17, 1993, upon a petition by the Insurance Commissioner of the State of Florida, the Circuit Court of the Second Judicial Circuit, in and for Leon County, Florida, issued an Order of Liquidation with respect to Covenant Mutual Insurance Company. Mr. Tom Gallagher, the Insurance Commissioner of the State of Florida, was appointed as the Ancillary Liquidator of the Company. All persons having claims against Covenant Mutual Insurance Company must file their claims, by September 17, 1993, or be barred from sharing in the distribution of assets.

All claims must be filed in writing and shall set forth the amount of the claim, the facts upon which the claim is based, any priorities asserted, and any other pertinent facts to substantiate the claim. It is recommended that Federal Agency claimants asserting priority status under 31 U.S.C. 3713 who have not yet filed their claim should do so, in writing, to: Department of Justice, Civil Division, Commercial Litigation Branch, P.O. Box 875, Ben Franklin Station, Washington, DC 20044–0875, Attn: Ms. Sandra P. Spooner, Deputy Director.

The above office will be consolidating any and all claims against Covenant Mutual Insurance Company, on behalf of the United States Government. Any questions concerning filing of claims may be directed to Ms. Spooner at (202/FTS) 724–7194.

Questions concerning this notice may be directed to the Department of the Treasury, Financial Management Service, Funds Management Division, Surety Bond Branch, Washington, DC 20227, Telephone (202/FTS) 674–6905.


Charles F. Schwan III,
Director, Funds Management Division,
Financial Management Service.

[FR Doc. 93–11203 Filed 5–11–93; 8:45 am]
BILING CODE 4810–35–M

UNITED STATES INFORMATION AGENCY

U.S. Advisory Commission on Public Diplomacy Meeting

AGENCY: United States Information Agency.

ACTION: Notice.

SUMMARY: A meeting of the U.S. Advisory Commission on Public Diplomacy will be held on May 12 in room 600, 301 4th Street, SW., Washington DC from 10–11 a.m.

The Commission will meet with Ms. Jodie Lewinsohn, Director, Office of East Asia and Pacific Affairs, USIA, to discuss public diplomacy issues in the East Asia/Pacific area.

FOR FURTHER INFORMATION:
Please call Gloria Kalamets, (202) 619-4468, if you are interested in attending the meeting. Space is limited and entrance to the building is controlled.

Dated: May 6, 1993.

Rose Royal,
Management Analyst, Federal Register Liaison.

[FR Doc. 93–11202 Filed 5–11–93; 8:45 am]
BILLING CODE 6235–01–M
Sunshine Act Meetings

This section of the FEDERAL REGISTER contains notices of meetings published under the “Government in the Sunshine Act” (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

COMMODITY FUTURES TRADING COMMISSION

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: 58 FR 26812.

PREVIOUSLY ANNOUNCED TIME AND DATE OF MEETING: 10:00 a.m., Tuesday, May 25, 1993.

CHANGES IN THE AGENDA: The Commodity Futures Trading Commission has added to the agenda applications of the Minneapolis Grain Exchange for contract designation in Frozen Shrimp futures and options on that futures contract.

CONTACT PERSON FOR MORE INFORMATION: Jean A. Webb, 254-6314.
Jean A. Webb,
Secretary of the Commission.
[FR Doc. 93–11355 Filed 5–10–93; 2:14 pm]
BILLING CODE 6351–01–M

FOREIGN CLAIMS SETTLEMENT COMMISSION

F.C.S.C. Meeting Notice No. 9–93

Announcement in Regard to Commission Meetings and Hearings

The Foreign Claims Settlement Commission, pursuant to its regulations (45 CFR Part 504), and the Government in the Sunshine Act (5 U.S.C. 552b), hereby gives notice in regard to the scheduling of open meetings and oral hearings for the transaction of Commission business and other matters specified, as follows:

Date, Time, and Subject Matter

Tues., May 25, 1993 at 10:30 a.m.—Consideration of Proposed Decisions on claims against Iran.

Hearings on the record on objections to
Proposed Decisions in the following claims against Iran:
IR–0899—Hugh E. Butler
IR–0900—John Christopher Butler
IR–0901—Patricia R. Butler
IR–1256—Patricia G. Parks
IR–1259—Perry M. Parks
IR–1346—Langston, A Division of Molins Machine Company, Inc.
IR–1737—Thomas J. Temple
IR–2091—Robert B. McCormick

Subject matter listed above, not disposed of at the scheduled meeting, may be carried over to the agenda of the following meeting.

All meetings are held at the Foreign Claims Settlement Commission, 601 D Street, NW., Washington, DC. Requests for information, or advance notices of intention to observe a meeting, may be directed to: Administrative Officer, Foreign Claims Settlement Commission, 601 D Street, NW., Room 10000, Washington, DC 20579. Telephone: (202) 208–7727.


Judith H. Lock,
Administrative Officer.
[FR Doc. 93–11408 Filed 5–10–93; 2:11 pm]
BILLING CODE 4410–01–M

FEDERAL DEPOSIT INSURANCE CORPORATION

Notice of a Matter To Be Withdrawn From Consideration at an Agency Meeting

Pursuant to the provisions of the “Government in the Sunshine Act” (5 U.S.C. 552b), notice is hereby given that the following will be withdrawn from the agenda for consideration at the open meeting of the Board of Directors of the Federal Deposit Insurance Corporation scheduled to be held at 10:00 a.m. on Tuesday, May 11, 1993, in the Board Room on the sixth floor of the FDIC Building located at 550–17th Street, NW., Washington, D.C.:

Memorandum and resolution re: Study of savings bank life insurance which makes a finding whether savings bank life insurance activities of insured banks pose or may pose any significant risk to the insurance fund of which such banks are members.

Requests for further information concerning the meeting may be directed to Mr. Robert E. Feldman, Deputy Executive Secretary of the Corporation, at (202) 898–6757.

Dated: May 7, 1993.

Federal Deposit Insurance Corporation.
Robert E. Feldman,
Deputy Executive Secretary.
[FR Doc. 93–11313 Filed 5–10–93; 9:04 am]
BILLING CODE 6714–0–M

NATIONAL CREDIT UNION ADMINISTRATION

TIME AND DATE: 9:30 a.m., Wednesday, May 19, 1993.

PLACE: Filene Board Room, 7th Floor, 1776 G Street, N.W., Washington, D.C. 20456.

STATUS: Open.

BOARD BRIEFINGS:


MATTERS TO BE CONSIDERED:

1. Approval of Minutes of Previous Open Meeting.
2. Request by Florida Horizons Federal Credit Union for a Community Charter Conversion.
5. Appeal by Farm Credit Employees Federal Credit Union, St. Paul, Minnesota, of Regional Director’s Decision to Disapprove Request for Overlap of Field of Membership.

RECESS: 10:45 a.m.

TIME AND DATE: 11:00 a.m., Wednesday, May 19, 1993.

PLACE: Filene Board Room, 7th Floor, 1776 G Street, N.W., Washington, D.C. 20456.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Approval of Minutes of Previous Closed Meeting.
2. Administrative Actions under Section 206 of the Federal Credit Union Act. Closed pursuant to exemptions (8), (9)(A)(ii), and (9)(B).
3. Personnel Actions. Closed pursuant to exemptions (2) and (6).

FOR MORE INFORMATION CONTACT: Becky Baker, Secretary of the Board, Telephone (202) 682–9600.
Becky Baker, Secretary of the Board.
[FR Doc. 93–11433 Filed 5–10–93; 2:57 pm]
BILLING CODE 7535–01–M
Environmental Protection Agency

40 CFR Part 82
Protection of Stratospheric Ozone; Proposed Rule
ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 82
[FRL-4625-7]

Protection of Stratospheric Ozone

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed rulemaking.

SUMMARY: This action proposes the U.S. Environmental Protection Agency's (EPA) program for evaluating and regulating substitutes for the ozone-depleting chemicals being phased out under the stratospheric ozone protection provisions of the Clean Air Act (CAA).

In section 612 of the amended CAA, the Agency is authorized to identify and restrict the use of substitutes for Class I and II ozone-depleting substances where other alternatives exist that reduce overall risk to human health and the environment. EPA is referring to the program that would provide these determinations as the Significant New Alternatives Policy (SNAP) program.

The intended effect of this action is to expedite movement away from ozone depleting compounds.

In this Notice of Proposed Rulemaking (NPRM), EPA is both issuing preliminary decisions on the acceptability of certain substitutes and introducing its plan for administering the SNAP program. To arrive at determinations on the acceptability of substitutes, the Agency completed a cross-media analysis of risks to human health and the environment from use of various substitutes in different industrial applications. This analysis is summarized in today's proposal, and covers substitutes in the refrigeration, foam blowing, solvents cleaning, fire extinguishing, tobacco puffing, adhesives, coatings and inks, aerosols and sterilants sectors. These sectors comprise the principal industrial sectors that historically consume large volumes of ozone-depleting compounds.

DATES: Written comments or data provided in response to this document must be submitted by June 21, 1993. Any data submitted can be designated as Confidential Business Information. (See Section V.C. for more detail.) EPA will conduct a public hearing on this NPRM on May 28, 1993 beginning at 9 a.m. The record of this hearing will remain open for 30 days after the hearing for the submission of rebuttals and other supplementary material.

ADDRESSES: Written comments and data should be sent to Docket A-91-42, Central Docket Section, South Conference Room 4, U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460. The docket may be inspected between 8 a.m. and 3:30 p.m. on weekdays. As provided in 40 CFR part 2, a reasonable fee may be charged for photocopying. To expedite review, a second copy of the comments should be sent to Drusilla Hufford, Substitutes Analysis and Review Branch, Stratospheric Protection Division, Office of Atmospheric Programs, Office of Air and Radiation, 401 M Street, SW., 6205J, Washington, DC 20460. Information designated as Confidential Business Information (CBI) under 40 CFR, part 2, subpart B must be sent directly to the contact person for this notice. However, the Agency is requesting that all respondents submit a non-confidential version of their comments to the docket as well. The public hearing on this NPRM will be held at the EPA auditorium in Washington, DC. Please call the contact person listed below for details regarding the public hearing.

FOR FURTHER INFORMATION CONTACT: Drusilla Hufford at (202) 233-9101. Substitutes Analysis and Review Branch, Stratospheric Protection Division, Office of Atmospheric Programs, Office of Air and Radiation, Washington, DC.

SUPPLEMENTARY INFORMATION:

I. Overview of This Action

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II. Background

A. Regulatory History

The stratospheric ozone layer protects the earth from dangerous ultraviolet (UV-B) radiation. Depletion of stratospheric ozone allows more UV-B radiation to penetrate to the earth's surface. Increased radiation, in turn, has been linked to higher incidence of certain skin cancers and cataracts, suppression of the immune system, damage to crops and aquatic organisms, and increased formation of ground-level ozone. Further, increased radiation can cause economic losses from materials damage such as more rapid weathering of outdoor plastics. (See 53 FR 30566, August 12, 1988, for more information on the effects of ozone depletion.)

In response to scientific concerns and findings on ozone depletion, the United States and twenty-three other nations' signed the Montreal Protocol on Substances that Deplete the Ozone Layer on September 16, 1987. The original agreement set forth a timetable for reducing the production and consumption of specific ozone-depleting substances, including CFC-11, CFC-12, CFC-113, CFC-114, CFC-115, Halon-1211, Halon-1301, and Halon-2402. EPA implemented the original Protocol through regulations allocating production and consumption allowances equal to the total amount of production and consumption granted to the United States under the Protocol. (See final rule promulgated on August 12, 1988; 53 FR 30566.)

The parties to the Montreal Protocol met in London June 27-29, 1990 to consider amendments to the Protocol. In response to scientific evidence indicating greater than expected stratospheric ozone depletion, the Parties agreed to accelerate the phase-out schedules for the substances already controlled by the Protocol. They also added phase-out requirements for other ozone-depleting chemicals, including...
methyl chloroform, carbon tetrachloride, and other fully-halogenated chlorofluorocarbons (CFCs).

On November 15, 1990, the President signed the Clean Air Act Amendments of 1990. Title VI, section 604 of the amended CAA requires a phase-out of CFCs, halons, and carbon tetrachloride by 2000, which is identical to the London Amendments, but with more stringent interim reductions. Title VI also differs from the London Amendments in mandating a faster phase-out of methyl chloroform (2002 instead of 2005), a restriction on the use of hydrochlorofluorocarbons (HCFCs) after 2015, and a ban on the production of HCFCs after 2030. In Title VI, section 602, the CFCs, halons, carbon tetrachloride, and methyl chloroform are defined as Class I substances; HCFCs are referred to as Class II substances. Appendix A lists the Class I and Class II substances identified in the CAA.

In addition to the phase-out requirements, Title VI includes provisions to reduce emissions of Class I and Class II substances to the "lowest achievable level" in all use sectors and to maximize the use of recycling and recovery upon disposal (section 608). It also requires EPA to ban nonessential products containing ozone-depleting substances (section 610); establish standards and requirements for the servicing of motor vehicle air conditioners (section 609); mandate warning labels on products made with or containing Class I or containing Class II substances (section 611); and establish a safe alternatives program (section 612). The development and implementation of the safe alternatives program under section 612 is the subject of this action.

In October 1991, the National Aeronautics and Space Administration (NASA) announced several new findings documenting ozone depletion over the last decade that was more severe than had previously been predicted by atmospheric modeling or measurements. In particular, NASA found 2.9 per cent ozone depletion over the northern mid-latitudes over the past decade in summertime—the first time a trend showing ozone depletion had been detected in the U.S. during that time of year, when risks from depletion are greatest.

Partly in response to these findings, on February 11, 1992, President Bush announced an accelerated phase-out schedule for Class I substances as identified in the CAA. This schedule has recently been published in the Federal Register (57 FR 15014; March 18, 1993). The President also ordered an accelerated review of substitutes that do less damage to the ozone layer than ozone-depleting compounds. The existence of the expedited phase-out schedule and the President's directive regarding alternatives adds a new urgency to EPA's effort to review and list substitutes for Class I and II substances under section 612.

B. Subgroup of the Federal Advisory Committee

In 1989, EPA organized the Stratospheric Ozone Protection Advisory Committee (STOPAC) in accordance with the requirements of the Federal Advisory Committee Act, 5 U.S.C. App. section 9(c). The STOPAC consists of members selected on the basis of their professional qualifications and diversity of perspectives and provides representation from industry, academia, Federal, state, and local government agencies, and environmental and international organizations. Since its formation, the STOPAC has provided advice and counsel to the Agency on policy and technical issues related to the protection of stratospheric ozone.

In 1991, the Agency asked STOPAC members to participate in subgroups to assist in developing regulations under Title VI of the CAA. EPA established a subgroup of the standing STOPAC to guide the Agency specifically on development of the safe alternatives program. To date, the subgroup on safe alternatives has met twice. At the first meeting in May 1991, subgroup members reviewed a detailed description of EPA's plans for implementing section 612. At this meeting, there was general agreement on the need to issue a request for data to provide the general public with an opportunity to furnish the Agency with information on substitutes. The group also agreed on the need to review substitutes as quickly as possible to avoid any delay in industry's efforts to phase out of ozone-depleting substances.

At the second meeting of the subgroup, in July 1991, subgroup members provided EPA with comments on a draft of the Advance Notice of Proposed Rulemaking (ANPRM), which was prepared in response to the conclusions of the first meeting. The comments focused primarily on the draft discussion of EPA's plans for implementing section 612 and refinements to a list of preliminary substitutes that the Agency intended to review. Based on comments received from the subgroup and other offices within EPA, a final ANPRM was prepared which was published in the Federal Register on January 18, 1992 (57 FR 1984; January 16).

III. Section 612 Program

A. Statutory Requirements

Section 612 of the Clean Air Act authorizes EPA to develop a program for evaluating alternatives to ozone-depleting substances. EPA is referring to this new program as the Significant New Alternatives Policy (SNAP) program.

The major provisions of section 612 are:

- Rulemaking—Section 612(c) requires EPA to promulgate rules by November 15, 1992, making it unlawful to replace any Class I or Class II substance with any substitute that the Administrator determines may present adverse effects to human health or the environment where the Administrator has identified an alternative that: (1) reduces the overall risk to human health and the environment, and (2) is currently or potentially available.

- Listing of Unacceptable/Acceptable Substitutes—Section 612(c) also requires EPA to publish a list of the substitutes prohibited for specific uses. EPA must publish a corresponding list of acceptable alternatives for specific uses as well.

- Petition Process—Section 612(d) grants the right to any person to petition EPA to add a substance to or delete a substance from the lists published in accordance with section 612(c). The Agency has 90 days to grant or deny a petition.

- 90-day notification—Section 612(e) requires EPA to require any person who produces a chemical substitute for a Class I substance to notify the Agency not less than 90 days before new or existing chemicals are introduced into interstate commerce for significant new uses as substitutes for a Class I substance. The producer must also provide the Agency with the producer's unpublished health and safety studies on such substitutes.

- Outreach—Section 612(b)(1) states that the Administrator shall seek to maximize the use of Federal research facilities and resources to assist users of Class I and II substances in identifying and developing alternatives to the use of such substances in key commercial applications.

- Clearinghouse—Section 612(b)(4) requires the Agency to set up a public clearinghouse of alternative chemicals, product substitutes, and alternative manufacturing processes that are available for products and manufacturing processes which use Class I and II substances.
B. Guiding Principles

EPA has followed several guiding principles in developing the SNAP program:

1. Evaluate substitutes within a comparative risk framework. The Agency's risk evaluation examines risks of continued use of ozone-depleting compounds as well as risks associated with other substitutes as reference points. This evaluation will consider factors such as effects due to ozone depletion as well as effects due to direct toxicity across all substitutes. Other risk factors considered include effects on water and air quality, direct and indirect contributions to global warming, and occupational health and safety. Where such effects could be of concern, the evaluation will assess these effects. However, EPA does not believe that a numerical scheme producing a single index to rank all substitutes based on risks is appropriate. A strict quantitative index would not allow for sufficient flexibility in making appropriate risk management decisions that consider issues such as the quality of information supporting the decision, the degree of uncertainty in the data, the availability of other substitutes, and economic feasibility.

2. Do not require that substitutes be risk-free to be considered "safe". Section 612(c) requires the Agency to publish a list of safe alternatives where the Agency has identified unacceptable substitutes. The Agency interprets this as a mandate to identify substitutes that reduce risks when compared to use of Class I or II compounds or other substitutes for Class I and II substances, rather than a mandate to list as acceptable only those substitutes with zero risks. In keeping with this interpretation, the Agency believes that a key goal of the SNAP program is to promote the use of substitutes for Class I and II chemicals that minimize risks to human health and the environment relative to other alternatives. In some cases, this approach may involve designating a substitute as acceptable even though the compound may be toxic, or pose other environmental risk of some type.

3. With the exception of those substitutes that are significantly worse. As a corollary to the point above, EPA does not intend to restrict a substitute if it poses only marginally greater risk than another substitute, all things considered. Drawing fine distinctions concerning the acceptability of substitutes would be extremely difficult given the variability in how each substitute can be used within a specific application and the resulting uncertainties surrounding potential health and environmental effects. The Agency also does not want to interfere in the market's choice of available substitutes, unless a substitute has been proposed to be used that is clearly more harmful to human health and the environment than other alternatives.

4. Evaluate risks by use. Section 612 requires that substitutes be evaluated by use. Environmental and human health exposures can vary significantly depending on the particular application of a substitute. Thus, the risk characterization of the SNAP program is designed to represent differences in the environmental and human-health effects associated with diverse uses.

5. Provide the regulated community with information as soon as possible. The Agency recognizes the need to provide the regulated community with information on the acceptability of various substitutes as soon as possible. Given this need, EPA has decided to expedite the review process by conducting initial risk characterizations for the major substitutes now known to the Agency. The results of the risk characterizations will be used, as discussed in the previous section, to propose determinations regarding the acceptability of the substitutes.

6. Do not endorse products manufactured by specific companies. While the goal of the SNAP program is to identify acceptable substitutes, the Agency will not issue company-specific product endorsements. In some cases, the Agency may base its analysis on data received from individual products, but the addition of a substitute to the approved list based on that analysis does not represent a preference for that company's product over comparable products offered by other manufacturers.

7. Defer other environmental regulations when warranted. In some cases, EPA and other federal agencies have developed extensive regulations under other statutes or other parts of the CAA that address any potential cross- or inter-media transfers that may result from the use of alternatives to Class I and II substances. For example, cessing to use an ozone-depleting compound may in some cases entail increased use of chemicals that increase tropospheric air pollution. These chemicals, such as volatile organic compounds (VOCs) or hazardous air pollutants (HAPs), are already regulated under other sections of the CAA, and determinations under the SNAP program will take these existing regulations into account. Where necessary, the Office of Air and Radiation will confer with other EPA program offices or federal agencies to ensure that any regulatory overlap is handled efficiently.

C. Implementation Strategy

Implementation of the SNAP program is directed towards fulfilling the general policy contained in section 612 of identifying substitutes that can serve as replacements for ozone-depleting substances, evaluating their effects on human health and the environment, and encouraging the use of those substitutes believed to present low risks to human health and the environment. Implementation of this policy involves three key activities. The first is to develop, promulgate, and administer a regulatory program for identifying and evaluating substitutes. The second activity is to undertake a review of the existing substitutes based on criteria established for the program and then to publish a list of acceptable and unacceptable substitutes by application. The third activity is to review additional substitutes as they are developed and to allow their timely introduction into the marketplace.

To expedite implementation of the SNAP program, EPA has developed not only a process for examining the alternatives, as discussed in today's proposal, but has completed an initial analysis of many key substitutes based on the criteria being proposed. Section IX summarizes the results of this initial assessment. More detail on the steps leading up to today's proposal and the anticipated implementation of the SNAP program is given below.

1. Issue ANPRM and Request for Data

In January of this year, EPA published in the Federal Register an Advance Notice of Proposed Rulemaking (ANPRM) and Request for Data (57 FR 19924, June 15, 1992). The ANPRM described in general terms EPA's plans for developing the SNAP program and solicited public comment on the Agency's planned approach. The ANPRM also included an appendix listing substitutes that the Agency planned to include in its initial substitute determinations. The ANPRM invited industry to submit information on these substitutes and to identify additional alternatives to be considered in the SNAP program. The Agency received approximately one hundred comments from industry, trade groups, and other federal agencies. These comments contained information on potential substitutes for ozone-depleting chemicals, as well as comments on the SNAP program as described in the ANPRM. In some cases, the information provided on substitutes...
did not contain sufficient data for the Agency to immediately incorporate these alternatives into the risk characterizations. The Agency is working now to gather additional information on these alternatives to ensure that they can be included in the list of reviewed substitutes in the final rule.

Comments on the SNAP program itself focused primarily on issues such as effective dates, small uses, the desirability of assured minimum periods of use for substitutes, how mixtures will be handled by the SNAP program, and how specific the lists of “acceptable” and “unacceptable” substances will be. These comments, and the Agency’s response to them, are addressed in later sections of today’s proposal.

2. Develop Preliminary Determinations on Substitutes

To arrive at its SNAP determinations, the Agency has been collecting and evaluating information on substitutes since the President’s signing of the Clean Air Act Amendments in November 1990. In some cases, this information has been furnished directly by companies manufacturing, selling, or using the substitutes. In others, the Agency has initiated its own studies to characterize, for example, worker exposures where toxicity was anticipated to present a potential problem. Response to the request for data in the January ANPRM augmented the Agency’s available data, both by helping to identify substitutes that merit consideration in the SNAP program and by providing additional information on substitutes already under consideration. There are, however, still omissions in the Agency’s list of substitutes under consideration. In some cases, engineering and use profile data are missing; in others, information on potential market applications may not yet be available. The Agency today is repeating the data request issued in the ANPRM, and is encouraging companies that manufacture substitutes to provide information.

3. Publish Proposed SNAP Process and Proposed Determinations

This NPRM represents the third implementation step, which is to describe the proposed structure and process for administering the SNAP program and to propose determinations on the acceptability of key substitutes. The notice also contains the proposed regulatory language that will serve as the legal basis for administering and enforcing the SNAP program.

EPA believes that notice-and-comment rulemaking procedures are necessary to establish these regulations governing the SNAP program. EPA further believes that rulemaking is also required to place any substance on the list of prohibited substances, to list a substance as acceptable only under certain conditions, or to remove a substance from either the list of prohibited or acceptable substitutes. EPA requests comment, however, on the need to include a substitute from the list of acceptable substitutes through rulemaking.

EPA does not believe that rulemaking procedures are required to list alternatives as acceptable with no limitations. Such listings do not impose any sanction, nor do they remove any prior license to use a substance. Consequently, once this rule is promulgated, EPA will be adding substances to the list of acceptable alternatives without first requesting comment on new listings.

Because EPA’s SNAP regulations are not yet final, however, manufacturers and users may have additional information that could help EPA in making this first round of SNAP determinations. Recognizing this, EPA has elected to propose the list of acceptable alternatives identified in this notice, and to request public comment on these listings. This should not in any way be taken as a precedent for future listings of acceptable substitutes. Once the SNAP program regulations are finally adopted and EPA has received SNAP notices from manufacturers and users, EPA will add substances to the list of acceptable substitutes without notice-and-comment procedures.

Any approvals or prohibitions on substances described in this notice are preliminary and will not be final until the SNAP program is promulgated. Even though they are preliminary, the Agency is issuing the SNAP decisions now because many companies are awaiting Agency guidance before switching out of ozone-depleting substances. The Agency believes that by publishing these preliminary determinations, it has met the intent of section 612 to inform the public of Class I and II substitutes believed to present minimal risks to human health and the environment. Moreover, given the accelerated pace of the phase-out of Class I compounds, the Agency wants to encourage the earliest possible shift to the alternatives identified on today’s list of acceptable substitutes.

The Agency may revise these decisions in the future as it reviews additional substitutes and receives more data on substitutes already covered by the program. However, EPA expects future changes to the SNAP lists to be minor, and thus not to represent an undue burden on the regulated community. The principal types of changes the Agency expects to make in the future would be to add new substitutes or sectors to the lists, rather than to change a substitute’s approval status. Further, once a substitute has been finally placed on either the acceptable or the unacceptable list, EPA will conduct notice-and-comment rulemaking to subsequently remove a substitute from either list, as described below in Section VII. Again, the Agency requests comment on whether formal rulemaking is necessary to remove a substance from the acceptable list.

4. Issue Final Regulation

As discussed above, the final rule will promulgate the SNAP process and the first set of determinations on SNAP substitutes. The final regulation will address comments that the Agency receives on today’s NPRM, and will also incorporate any further data on substitutes that are received during the comment period.

5. Maintain and Update SNAP Determinations

Three mechanisms exist for revising or expanding the list of SNAP determinations published in the final regulation. First, under section 612(d), the Agency will review and either grant or deny petitions to add or delete substances from the SNAP list of acceptable or unacceptable alternatives. Section VIII of this notice presents EPA’s proposed method for handling petitions.

The second means of revising or expanding the list of SNAP determinations is through the notifications, which must be submitted to EPA 90 days before introduction of a chemical into interstate commerce for significant new use as an alternative to Class I or Class II substances. These 90-day notifications are required by section 612(e) of the CAA and by EPA regulations today proposed to be issued under sections 114 and 301 of the Act to implement section 612(c). In Section VII, this notice discusses the Agency’s proposed approach for processing these notifications, including a proposed strategy for integrating the SNAP notifications with other chemical review programs already being implemented by EPA under authorities provided in the Toxic Substances Control Act (TSCA) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Other parts of this action also explain how the Agency will address the overlap...
between SNAP regulations and regulations issued under other titles of the Clean Air Act.

Finally, the Agency believes that section 612 authorizes it to initiate changes to the SNAP determinations independent of any petitions or notifications received. These amendments can be based on new data on either additional substitutes or on characteristics of substitutes previously reviewed.

6. Perform Outreach and Operate Clearinghouse

Outreach and the clearinghouse comprise the technical assistance component of the SNAP program. The purpose of this effort is to provide information for companies to use in selecting among the approved substitutes. Section VII.A.3.f. describes the Agency's proposed approach for establishing the clearinghouse and performing outreach.

IV. Scope of Coverage

A. Definition of Substitute

1. Statutory Language

Based on the language of section 612(a) of the CAA, the Agency is proposing in the SNAP program to define a "substitute" as any chemical, product substance, or alternative manufacturing process, whether existing or new, that could replace a Class I or Class II substance. Subsequent subsections of section 612 refer only to "substitute substances" or "substitute chemicals." EPA is proposing a definition that interprets these provisions as incorporating the general definition of substitute presented in 612(a). The Agency believes that this definition is consistent with the overall intent of section 612 and is necessary to enable EPA to identify and analyze the universe of substitutes for Class I and II substances.

Section 612(c) prohibits users from replacing Class I or II substances with any substitute substance which the Administrator determines may present adverse effects to human health and the environment, where the Administrator has identified an alternative to such replacement that (1) reduces overall risk to human health and the environment, and (2) is currently or potentially available. EPA believes that in addition to authorizing the Agency to ban the use of a given substitute substance, section 612 confers the legal authority to allow the use of a substitute only under certain use conditions, such as with mitigation measures. EPA only intends to use this authority where a viable substitute exists, but would otherwise have to be disallowed because of risk associated with its uncontrolled use. EPA anticipates imposing use conditions only in the rare instances where clear regulatory gaps exist, and where an unreasonable risk exists in the absence of any condition.

In imposing conditions, EPA does not intend to preempt other regulatory authorities, such as those exercised by the Occupational Safety and Health Administration (OSHA), or other standard setting bodies. Rather, EPA hopes to fill existing regulatory gaps during the interim period of substitution away from ozone-depleting compounds, and provide the needed margin of protection to human health and the environment until EPA enforce regulatory controls or standards are developed under appropriate authorities. Once existing gaps are filled, EPA will rescind any conditions which have become redundant. The mechanism for informing the public of this change will be the quarterly Federal Register notices updating the status of the SNAP lists. These are discussed further below in section VII.A.

The Agency, however, requests comment on the general issue of the need for use conditions. In particular, EPA requests comment on whether section 612 in fact confers upon the Agency the authority to go beyond the listing of acceptable and unacceptable alternatives and to set such use conditions. Further, EPA requests comment on the capability and practicality of EPA to enforce regulatory controls or standards which may, for example, closely resemble workplace safety standards, which are typically within the enforcement purview of other regulatory authorities.

EPA also requests comment on whether, when an unreasonable risk might exist due to a gap in regulatory coverage, the appropriate means to address these risks is through the existing regulatory framework of other federal authorities. For example, rather than using EPA's use conditions to address existing gaps in workplace safety standards, EPA could refer the matter to the appropriate OSHA authorities and request appropriate action to mitigate an otherwise unreasonable risk.

Alternatively, where the length of time required to address a problem under another authority may be unacceptably long given the nature of the risk, there may be cases in which EPA would simply consider unacceptable the use of a given substitute, pending the development of a regulatory framework to control the risk it poses in its use as a substitute for an ozone-depleting compound.

Section 612(e) makes clear that a chemical can be a substitute whether it is existing or new. Also, the language in section 612(c) clearly states that a substitute may be "currently or potentially available." The Agency is proposing to define as potentially available any alternative that the Agency reasonably believes to be technologically feasible and economically viable, even if not all testing has yet been completed and it is not yet produced and sold in commercial quantities. EPA solicits comment on this approach.

The language included in section 612 is written broadly to allow for an all-encompassing evaluation of substitutes that will be introduced as replacements for ozone-depleting chemicals. However, additional clarification is presented below to further explain the Agency's definition of a "substitute" based on section 612.

2. Additional Clarification

(a) Chemicals Already Listed as "Existing" under TSCA. Many commenters have expressed the view that any compound already existing (e.g., listed on the TSCA inventory, either through the grandfathering provisions or by undergoing new-chemical review under section 5 of TSCA) is not subject to review under section 612. Nothing on the face of section 612(c), however, suggests that any "new" compound can be considered a substitute for purposes of that subsection. Moreover, section 612(e) explicitly requires producers of chemicals, both "new and existing," to notify the Agency before introducing such chemicals into interstate commerce for significant new uses as Class I alternatives. In addition, section 612(c) requires the Agency to produce lists of acceptable and unacceptable substitutes, without regard to the status of each chemical, whether new or existing.

These interrelated provisions of section 612 serve as the basis for the Agency's belief that all substitutes, whether "new or existing" chemicals, are subject to SNAP review. This regulatory purview would thus necessarily extend to those chemicals already listed on the TSCA inventory. EPA believes SNAP review is critical given the differing statutory objectives of TSCA and the CAA, and the new and
expanded applications of many existing chemicals as Class I and Class II replacements, which could alter existing release and exposure profiles.

b. Expanded Use of Existing Alternatives. There has also been some question regarding whether an existing alternative already being sold (e.g., methyl chloroform used to replace CFC-113), it is clear that these compounds can be used as substitutes for other Class I and II substances. Since section 612 authority extends to other substitutes, they are subject to review under the SNAP program just as any other substitute. Given the potential for the Class I and Class II chemicals to continue depleting stratospheric ozone and thus affect human health and the environment, a close examination of these alternatives in the context of both their effect on the environment and the availability of other substitutes for particular uses is warranted under section 612.

c. Authority to Review Substitutes for Class II Compounds. Section 612(c) authorizes the Administrator to prohibit the use of substitutes for Class II, as well as Class I substances, and requires the Agency to compile lists of substitutes for Class II as well as Class I compounds upon making the requisite findings. This is in part because of the considerable overlap in sectors that use Class I and II substances. More importantly, this mirrors the statute's general emphasis on moving away from Class I compounds to one where they do not cause new and unintended environmental problems. Clearly, for the same reasons Class I substitutes require review, Class II substitutes should also be reviewed.

To obtain the data necessary to analyze Class II substitutes, the Agency is proposing to use statutory authority provided in sections 114 and 301 of the CAA with 612(c). These sections authorize the Administrator to promulgate regulations needed to require companies to provide information EPA may reasonably require to identify acceptable and unacceptable substitutes for Class II substances. EPA proposes to exercise this authority so that Class I and Class II substitutes are subject to the same information reporting requirements and listing process.

d. Designation of Class I and Class II Chemicals as Substitutes. EPA believes that the review authority under section 612 extends also to use of Class I and Class II chemicals as substitutes, even though these chemicals are subject to the phase-out provisions of the CAA.

While some comments received by the Agency in response to the ANPRM question EPA's authority under section 612 to review Class I and Class II chemicals as substitutes (e.g., methyl chloroform used to replace CFC-113), it is clear that these compounds can be used as substitutes for other Class I and II substances. Since section 612 authority extends to "any" substitutes, they are subject to review under the SNAP program just as any other substitute. Given the potential for the Class I and Class II chemicals to continue depleting stratospheric ozone and thus affect human health and the environment, a close examination of these alternatives in the context of both their effect on the environment and the availability of other substitutes for particular uses is warranted under section 612.

e. Alternative Substances and Manufacturing Processes. Section 612(c) broadly charges EPA to identify alternatives to ozone-depleting substances. For example, EPA believes that alternative substances can include no-clean fluxes for solvent cleaning, alternative manufacturing and/or processing equipment that can minimize environmental releases. Accordingly, alternative manufacturing processes will also be examined under section 612 in the context of use and emissions of substitutes. Section 612's reference to "alternative", instead of "alternative chemical" implies a statutory intent that "alternative" be read broadly.

EPA will encourage, where appropriate, alternative processes that reduce environmental and human health effects. In many applications, reliance on alternative processes and/or equipment may be associated with the use of substitute chemicals. In these instances, EPA encourages the filing of joint submissions where information is provided by both the chemical manufacturer and, for example, an equipment manufacturer. Such joint filings will provide the most comprehensive data on an alternative and its effect on human health and the environment.

f. Feedstock Substitutes. Other commenters have questioned the applicability of section 612 to substitutes that could replace Class I chemicals which are used solely as intermediates in the production of other chemicals. To the extent that any feedstock substitutions occur, the Agency believes that there will be no increased risk to human health and the environment. This is because intermediate substitutes are used as inputs in production of other compounds, and as a result are largely consumed in the chemical manufacturing process. For instance, in using carbon tetrachloride as a feedstock, the Agency determined that greater than 99 per cent of this chemical was consumed in the production process. The Agency is therefore proposing that feedstock substitutes be exempt from reporting and review under section 612.

g. Second-Generation Substitutes. A key issue is whether there exists a point at which an alternative should no longer be classified as a Class I and Class II substitute as defined by section 612. The Agency believes that as long as Class I and Class II chemicals are being used, any first-generation substitute designated to replace these applications is subject to the regulatory provisions implemented under section 612.

However, the Agency is proposing today that second-generation replacements, if they are replacing non-ozone depleting first-generation alternatives, are exempt from reporting requirements under section 612. Other regulatory programs' (e.g., other sections of the CAA, or section 6 of TSCA) exist to ensure protection of human health and the environment in these situations.

Several commenters agreed with the need to exempt second-generation substitutes. On the other hand, EPA is proposing that second-generation substitutes replacing first-generation substitutes that deplete stratospheric ozone (e.g., HCFCs) should be bound by the same notification and review requirements under section 612 as first-generation substitutes.

For example, if a hydrofluorocarbon (HFC) is introduced as a first-generation refrigerant substitute for either a Class I (e.g., CFC-12) or Class II chemical (e.g., HCFC-22), it is subject to review and listing under section 612. However, future substitutions to replace the HFC would be exempt from reporting under section 612 because the first-generation alternative did not deplete stratospheric ozone. However, if a Class I (interim only) or Class II chemical is used as a first-generation substitute (e.g., use of HCFC-141b as a transitional replacement in foam blowing), the second-generation substitute is still subject to review under section 612.
because it is replacing a Class I or II chemical.

b. Formulation Changes Accompanying the Use of Class I and Class II Substitutes. In general, the Agency believes that changes in formulation needed to accommodate replacement of Class I and II compounds are not subject to the provisions of section 612. Such auxiliary changes may be necessary, for example, when a new blowing agent in foam blowing necessitates the replacement of the catalyst formerly used in conjunction with the Class I blowing agent.

This position was also supported by comments received in response to the ANPRM. However, if the potential SNAP notice submitters have reason to believe that such changes will significantly influence the environmental and human health risk characteristics associated with the use of any Class I or Class II substitute, this must be communicated to the Agency. Alternatively, if the EPA has reason to suspect such concerns may exist, it may request the review of any such changes in formulation in connection with review of substitute compounds.

B. Who Must Report


As required by section 612(e), anyone who produces a substitute for a Class I substance must provide the Agency with that person’s unpublished health and safety studies on the substitute, as well as notify the Agency at least 90 days before introducing the substitute into interstate commerce for significant new use as an alternative. Also, as discussed in section IV.A.2.c of this notice, pursuant to sections 114, 301 and 612(c), producers of Class II substitutes must abide by the same reporting requirements.

Under the authority of sections 114, 301(a) and 612(c), the EPA is proposing that in certain cases, formulators or end-users of substitutes could be considered to be producers and would therefore be subject to reporting requirements. This approach is discussed in the following section, IV.A.2.j.(2). To analyze alternative substitutes under section 612(c), the Agency finds it necessary under section 301(a) to require all producers of substitutes, whether a chemical manufacturer, formulator, or end-user, to submit information under section 114 describing such substitutes. With respect to substitutes for both Class I and II substances, the EPA needs all of the types of information described below, not just health and safety studies. This is needed to allow the Agency to fully analyze the overall risks to human health and the environment presented by alternative substitutes, as required by section 612(c).

2. Designated Submitters

a. Chemical Manufacturers. Chemical manufacturers making a substitute for direct commercial sale are required to notify the Agency about the existence of that substitute. This requirement is especially applicable to chemical manufacturers who have developed new compounds for specific, targeted uses as substitutes for Class I or II substitutes. For instance, if a chemical manufacturer intends to market a new chemical as a substitute foam blowing agent to companies that manufacture insulation products, that manufacturer would be required to notify the Agency about the existence of the substitute. The reporting requirement would also apply to chemical manufacturers that intend to sell an existing chemical to a particular user group.

b. Formulators. A formulator is a person or an organizational entity engaged in the preparation or formulation of a substitute, after chemical manufacture of the substitute or its components, for distribution or use in commerce. Formulators usually only sell substitutes based on existing chemicals, since they do not ordinarily possess chemical manufacturing capabilities. Chemicals used in such substitutes are frequently in common use and have already been approved for general use through other chemical review programs such as under TSCA or FIFRA.

However, to the extent that these formulators are required to be directly responsible for production of the substitute, for example by offering a tailored formulation or blend for an industrial cleaning process, these formulators would be subject to reporting requirements as outlined in this proposal. In such cases, the formulator is best suited in the manufacture-to-use chain to present information on the substitute or its components, for distribution or use in commerce. In such cases, the formulator is best suited in the manufacture-to-use chain to present information on the substitute.

In cases where the manufacturer of a chemical is also the formulator, the manufacturer would then be responsible for meeting reporting requirements on the chemical. Similarly, if an end-user has developed a process to replace an ozone-depleting compound, this end-user would be required to provide EPA with information on the substitute.

The simplest approach to allocating responsibility for reporting requirements would be to place the reporting burden in all cases on chemical manufacturers. However, the Agency believes that the approach outlined above provides the best correlation between burden for reporting and benefit from securing approval for a substitute. For instance, it would be inappropriate to require a manufacturer of a chemical in widespread industrial use to report on every possible application for that chemical as a substitute. The Agency requests comment on this aspect of the proposed reporting requirements.

c. End-users. In general, end-users of substitutes will not be obligated to meet the reporting requirements discussed in this proposal, except in rare cases where the end-user and the producer of the substitute are one and the same company and the company intends to sell that substitute into inter-state commerce. While the Agency expects that this situation will occur only seldom, it has already received notices from several large companies who developed a substitute for use in their own manufacturing process and subsequently decided to offer that substitute for commercial sale. The Agency hopes that evaluating and listing such substitutes will help provide other potential end-users with information on viable substitutes, rather than stifling research and development innovations by end-users. The Agency solicits comment on this aspect of today’s proposal.

3. Exemptions from Reporting

The Agency has identified several situations in which notification under the provisions of section 612(e) will not be required. These exemptions from reporting are discussed as follows:

a. Substitutes Already Listed by EPA.

As part of today’s proposal, the Agency has already completed a preliminary review of several Class I and Class II alternatives and has proposed that these substitutes be either acceptable or unacceptable. In preparing these proposed determinations, the Agency evaluated information either on file or supplied in response to the ANPRM published in the Federal Register on January 16, 1992. The preliminary substitutes list and the supporting risk screen are described in more detail in Section IX. No submission is needed for those substitutes and applications already proposed as acceptable in today’s NPRM.

Any specific comments on the proposed substitute determinations found in this action should be provided to the Agency, along with any supporting information, during the comment period. If information is not received by the Agency during the comment period, a formal submission to...
add substitutes will be required once the final rule is promulgated.

b. Small Sector and Application Use. Most ozone-depleting substances have been or are currently used in large industrial sectors such as refrigeration or fire extinguishing. However, there are also numerous small uses of Class I or II substances that fall outside of these major uses sectors. Most of these small uses of ozone-depleting compounds are for solvents in applications other than industrial cleaning operations, such as solvents used as book preservers, drilling and machining coolants, extraction or bearing media, or mold release agents. While small-use applications for Class I and Class II compounds are varied and numerous, in the aggregate these small uses do not contribute substantially to ozone depletion. The Agency estimates that across all sectors, including the solvents sector, these varied but small volume uses comprise in aggregate at most seven per cent of total U.S. consumption of ozone-depleting substances.

Because the potential for adverse effects on human health and the environment is related to the aggregate amount of ozone-depleting material consumed in an end-use or sector, the Agency proposes to focus the SNAP determinations on large-volume applications in major use sectors. Given the breadth of EPA's required "overall" risk assessment, the emphasis is on small sectors, and on small uses within any sector, of a full SNAP submission for each small use seems unjustified by the potential for risk posed by these small uses.

Moreover, a key policy interest of EPA's in designing and implementing the SNAP program is promoting the quickest possible shift from the phase-out compounds into alternatives posing lower overall risk. The speed and orderliness of this shift depends in part on clear early determinations from EPA on the acceptability of key substitutes. Focusing the SNAP program on all possible substitutes in every conceivable use could diminish EPA's ability to provide an early and clear message on those substitutes which constitute the bulk of the problem SNAP is aimed at ameliorating.

Accordingly, eight major industrial use sectors are covered in today's proposal. They are refrigeration, foam blowing, fire extinguishing, solvent cleaning, adhesives, coatings, and inks, aerosols, sterilization, and tobacco puffing. Analysis of substitutes in a ninth sector, pesticides, will be completed, and the resulting decisions will be added to the SNAP determinations in the final rule. EPA does not plan to add sectors other than the nine principal sectors listed above to the formal analyses performed under SNAP, unless the Agency in future receives data indicating that inclusion of additional sectors is warranted based on the potential for high risks to human health and the environment.

Further, the Agency does not plan individual analyses of all small uses within major industrial sectors. Specifically, EPA is today proposing not to review any uses of substitutes of less than 10,000 lbs per year within a sector as defined in the SNAP determinations. Companies producing, formulating or using substitutes for ozone-depleting compounds in annual quantities under 10,000 lbs per year need not notify EPA of their activities under SNAP. However, the Agency encourages companies to maintain documentation describing the basis for their view that any substitute being used meets this small use definition. This documentation could be necessary in the event the Agency receives a petition to add such substitutes to its evaluation.

The Agency's decision to focus the SNAP program on high-volume sectors does not imply the complete absence of any risk from use of substitutes in small use applications. Instead, the Agency believes that focusing the listing decisions on the largest sectors and uses will allow the Agency to target its regulatory efforts to those applications that offer the maximum risk reduction potential. If other sectors are subsequently added to the Agency's analysis, the Agency will provide notice in the Federal Register of the need to furnish the Agency with data on substitutes. The Agency requests comment on this approach to small sectors and small uses within all sectors of substitutes for ozone-depleting compounds. In particular, EPA requests comment and data on risks associated with small sector and small volume uses.

c. Test Marketing. Use of alternatives for the sole purpose of test marketing is exempt from any reporting requirements under section 612. However, once a company decides to sell an alternative as a Class I or II substitute, it must provide the Agency with notification at least 90 days prior to the introduction of the substitute into interstate commerce for significant new use as a substitute for a Class I or Class II chemical.

For new substitute chemicals that are being test marketed, the producer must abide by the provisions of section 5(b)(1) of TSCA, which authorizes the EPA, upon application, to grant exemptions from TSCA-reporting requirements, provided that test marketing will not present an unreasonable risk to human health or the environment. When submitting the TSCA application, it would also be advantageous if the producer would notify EPA's Office of Air and Radiation; however, such notification is not mandated under section 612.

Research. Substitutes manufactured or imported solely for research and development are exempt from notification requirements under section 612. Several commenters, including Federal agencies involved in research on CFC-related substitutes, support this exemption. Amounts used in research are assumed to be the minimum necessary for reasonable scientific experimentation. For new chemicals, the provisions of section 720.36 of the PMN rule (40 CFR Part 720) are in effect. The Agency solicits comment on appropriate use levels to allow in research applications.

d. Second-Generation Substitutes. As discussed in section IV.A.2.h., substitutes replacing first-generation alternatives that are not ozone-depleting chemicals are exempt from any additional reporting and review under section 612. However, if the second-generation substitute is replacing a compound that contributes to stratospheric ozone depletion (e.g., a HCFC), information must be submitted to the Agency for review under the SNAP program.

f. Formulation Changes. As discussed in section IV.A.2.i., the Agency is proposing that changes in formulation that accompany the use of substitutes for Class I and Class II substances need not be reviewed under section 612. The Agency believes that other regulatory mechanisms (e.g., TSCA) are available for examining and controlling, as needed, any adverse environmental and human health effects associated with subsequent formulation modifications. However, the manufacturer overseeing the formulation change is required to notify the Agency if these modifications may significantly influence the environmental and human health risk characteristics associated with the Class I or Class II substitute. Also, the Agency reserves the right to examine formulation changes if a problem appears to exist.

g. Substitutes Produced for Export. Substitute manufacturers producing solely for export and use by non-U.S. entities outside the U.S. are not subject to the requirements of section 612. EPA believes that its authority under section 612 extends only to use of substitutes in areas under the jurisdiction of the
United States government, regardless of their place of manufacture. This exemption does not apply to substitutes introduced as replacements for Class I and II chemicals offered for sale or use at offshore U.S. installations (e.g., U.S. military bases located in foreign countries) that are subject to the legal provisions of section 612, since 612(c) applies to use rather than to manufacture of substitutes.

b. Substitutes Used as Feedstock. The Agency is proposing to exempt substitutes used as feedstock from the reporting and review requirements of section 612. Because feedstock chemicals are largely consumed as intermediates, except for trace amounts, the Agency does not believe that such substitutions would cause any increase in ozone depletion or other adverse effects on human health and the environment.

V. Information Submission

A. Overview

To develop the list of unacceptable and acceptable substitutes as required by section 612(c), the Agency must assess and compare the “overall risks to human health and the environment” posed by use of substitutes, and this assessment must be performed in the context of particular applications. This “overall” examination will consider a wide range of health and environmental factors. In the section that follows, the Agency presents information that will be required in the SNAP program notice to help EPA evaluate Class I and Class II substitutes. A copy of the notification form can be obtained from the SNAP coordinator or the address listed in the beginning of this action.

B. Information Required

1. Name and description of the substitute. The substitute should be identified by its (1) commercial name, (2) chemical name, (3) trade name(s), (4) identification numbers (e.g., Chemical Abstract Service [CAS] registry number, National Institutes of Occupational Safety and Health Registry of Toxic Effects of Chemical Substances [NIOSH RTECS], EPA hazardous waste identification number, OHM-TADS, DOT/UN/NA/IMCO shipping, HSDB, National Cancer Institute [NCI]), (5) chemical formula, and (6) chemical structure.

2. Physical and chemical information. Key properties needed to characterize the substitute are: molecular weight; physical state; melting point; boiling point; density; odor threshold; solubility; partition coefficients (Log $K_w$). Log $K_o$); vapor pressure; and Henry’s Law Constant.

3. Substitute applications. Identification of the applications in which the substitutes are likely to be used is required. It is essential to provide a complete list of potential uses because the substitute listing required by section 612(c) is specific to application.

4. Process description. For each application identified, the Agency requires descriptive data on processing, including in-place pollution controls. Such information will be used to characterize workplace and environmental and indirect effects. Direct effects means the direct global warming effects of using a substitute. The Agency is requesting that all GWPs be referenced to CO$_2$ using the methodology recommended by the Intergovernmental Panel for Climate Change (IPCC). Indirect effects explicitly consider the effect on global warming arising from changes in energy consumption associated with the use of a substitute (e.g., an alternative refrigerant). This latter measure can be identified as changes in energy efficiency or demand resulting from use of the substitute relative to that of the substance being replaced. Direct effects means the direct global warming effects of using a substitute. The Agency is requesting that all GWPs be referenced to CO$_2$ using the methodology recommended by the Intergovernmental Panel for Climate Change (IPCC).

5. Ozone depletion potential. The predicted ozone depletion potential (ODP) of substitute chemicals is required. The submitter should also provide sufficient supporting documentation—either a citation or the background information used to develop the ODP. For purposes of calculating ODP, the Agency recommends the methodology used in the most recent Scientific Assessment of Ozone Depletion: 1991, which was prepared for the United Nations Environment Programme. [1]

6. Global warming potential. The Agency requires data on the total global warming potential (GWP) of the substitute in its particular application (e.g., as a refrigerant, foam blowing agent, etc.). The total GWP considers both direct and indirect effects. Direct effects means the direct global warming effects of using a substitute. The Agency is requesting that all GWPs be referenced to CO$_2$ using the methodology recommended by the Intergovernmental Panel for Climate Change (IPCC). Indirect effects explicitly consider the effect on global warming arising from changes in energy consumption associated with the use of a substitute (e.g., an alternative refrigerant). This latter measure can be identified as changes in energy efficiency or demand resulting from use of the substitute relative to that of the substance being replaced. Direct effects means the direct global warming effects of using a substitute. The Agency is requesting that all GWPs be referenced to CO$_2$ using the methodology recommended by the Intergovernmental Panel for Climate Change (IPCC). Indirect effects explicitly consider the effect on global warming arising from changes in energy consumption associated with the use of a substitute (e.g., an alternative refrigerant). This latter measure can be identified as changes in energy efficiency or demand resulting from use of the substitute relative to that of the substance being replaced.

7. Toxicity data. To assess the overall risks to human health and the environment, information is required on the acute and chronic toxicity effects of a substitute chemical, its impurities, and its degradation products on any organism (e.g., humans and other mammals, fish, wildlife, and plants). To characterize the risk to humans, the Agency is requesting a minimum submission of the following mammalian tests: a range-finding study that considers the appropriate exposure pathway for the specific use (e.g., inhalation, oral, etc.), and a 90-day subchronic repeated dose study in an appropriate rodent species (for example, rats or mice). For substitutes that are being evaluated as fire suppressants, a cardiotoxicity study, usually in the dog, is also required. Additional mammalian toxicity tests will be identified by EPA on a case-by-case basis depending on the particular substitute and application being evaluated. To sufficiently characterize aquatic toxicity, both acute and chronic toxicity data for a variety of species are required. The Agency is proposing a minimum aquatic data set to be submitted as described in “Guidelines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and Their Uses,” which is available through the National Technical Information Service (#PB 85–227049).

Other relevant hazard information and data summaries, such as the Material Safety Data Sheets, must also be submitted. Submission of the actual toxicity studies is recommended; however, it is not necessary to submit these reports if they have been supplied to the Agency as part of other regulatory submissions. If the actual studies are not submitted, however, the submitter must provide sufficiently clear references or citations that the Agency can locate the studies without delay. As discussed below in Section V.C.3., data concerning the objectives, methodology, results or significance of any toxicity, metabolism, translocation, or persistence test for a substitute and its degradation products cannot be held as CBI. Such data are also submitted under TSCA and FIFRA. The Agency is proposing that submitters providing information on new chemicals for joint review under the TSCA and SNAP programs adhere to the TSCA minimum testing requirements described in TSCA section 4.

8. Environmental Fate and Transport. Where available, EPA requests information on the environmental fate and transport of substitutes. Such data shall include information on bioaccumulation, biodegradation, adsorption, volatility, transformation, and other data necessary to characterize a substitute’s movement and reaction in the environment.

9. Flammability. Data on the flammability of a substitute chemical or mixture are required. Specifically, data on flash point and flammability limits are needed, as well as information on the procedures used for determining the flammability limits. For substitutes that will be used in consumer applications, documentation of testing results conducted by independent laboratories (e.g., Underwriters Laboratories) should
be submitted where appropriate. Detail on any suggested abatement techniques to minimize the risks associated with the use of flammable substances or blends should also be provided. The Agency recognizes that many promising alternatives may be considered marginally flammable, but can be used safely and effectively.

10. Exposure data. The submitter must provide modeling or monitoring data on exposures associated with the manufacture, formulation, transport, and use of a substitute. Descriptive process information for each substitute application, as required above, will be used to develop exposure estimates where exposure data are not readily available. Depending on the application, exposure profiles will be needed for workers, consumers, and the general population.

11. Environmental release data. Data on emissions from the substitute application and equipment, as well as pollutant releases or discharge to all environmental media (ambient air, surface and groundwater, hazardous/solid waste) are needed to complete the risk characterization. Submitters should provide information on release locations, if known. Any information on any pollution controls that are used or could be used in association with the substitute (e.g., emissions reduction technologies, wastewater treatment, treatment of hazardous waste) and the costs of such technology is also requested.

12. Replacement ratio for a chemical substitute. The Agency also requires information on the replacement ratio for a chemical substitute versus the Class I or II substances being replaced. The term "replacement ratio" refers to how much more or less of the substitute chemical is needed to substitute for the original ozone-depleting compound being replaced. This ratio will affect the estimated incremental cost and environmental effects associated with use of the substitute.

13. Required changes in technology. Data on any changes in technology needed to use the alternative are required. Such information should include a description of whether the substitute can be used in existing equipment—with or without some retrofit—or only in new equipment. Data on the cost (capital and operating) and estimated life of the technology modifications should also be submitted. These economic data are essential to understanding the near-term potential of using an alternative.

14. Cost of substitute. The Agency requires data on the expected average cost of the alternative. The cost of the substitute can be expressed, for example, in terms of $/pound (for a chemical substitute) or as incremental capital and operating costs associated with a retrofit or new equipment. In addition, information is needed on the expected equipment life for an alternative technology. Other critical cost considerations should be identified, as appropriate. For example, it is important to understand the incremental costs associated with losses or gains in energy efficiency associated with use of a substitute relative to current experience with existing substances.

15. Availability of substitute. The Agency needs to understand the extent to which a substitute is already commercially available or the date on which it is expected to become available. The timing of availability is an important factor in assessing the overall health and environmental effects of the substitutes.

16. Anticipated market share. Data on the anticipated near-term and long-term (over the next ten years) nationwide substitute sales is also required. This information can be presented in several ways, for example: a percentage of existing nationwide use of Class I or Class II chemicals in a particular application; number of units/products to be produced or pounds of substitute sold. This information is required to assess the potential effects of a substitute related to total consumption and environmental releases.

17. Applicable regulations under other environmental statutes. The submitter is required to provide information on whether the substitute(s) are regulated under other statutory authorities, in particular the Clean Water Act, Safe Drinking Water Act, the Resource Conservation and Recovery Act, the Federal Insecticide, Fungicide, and Rodenticide Act, the Toxic Substances Control Act, the Comprehensive Environmental Response, Compensation and Liability Act, the Emergency Planning and Community Right-to-Know Act, as well as other titles of the CAA. The Agency will evaluate substitutes under the SNAP program subject to existing regulatory constraints.

18. Information already submitted to the Agency. Individuals may have already submitted information being required in the SNAP program notice to the Agency as part of past regulatory and information-gathering activities. In this case, to minimize reporting burden, the submitter should provide the following information to help EPA locate the data already maintained at EPA: type of information submitted; the date of submission; the EPA office to which the data were sent; description of the regulatory program; and any document-control number, if assigned (e.g., a PMN number). If the submitter cannot provide references for data sent previously to the Agency, he or she should include all required information in the SNAP notice. To facilitate review, reports already submitted to the Agency as part of other regulatory submissions should be resubmitted if the original information was claimed as CBI.

19. Information already available in the literature. If any of the data needed to complete the SNAP program notice are available in the literature, the submitter should provide the Agency with references for such information.

Failure to provide the Agency with an accurate and complete citation may delay review of the notice. Additionally, submitters are encouraged to provide copies of any literature to expedite review, particularly if the citation is from a source not readily available. Any references from sources in foreign languages should be translated into English prior to submission.

All submissions must be provided in three complete identical copies. If information is to be claimed as confidential, all confidential information must be excised from the third copy, which will be placed in the public docket. When portions of a submission are claimed as confidential, the first two copies will include the confidential material. If no claims of confidentiality are made for the submission, the third copy should be identical to the other two. (See below, as well as Appendix C, for further guidance on handling of confidential information under SNAP.)

C. Submission of Confidential Business Information


Anyone submitting information for which Confidential Business Information (CBI) status is requested must assert a claim of confidentiality at the time of submission. Failure to assert a claim of confidentiality at the time of submission may result in disclosure of the information by the Agency without further notice. Further, it should be noted that information which is publicly available (e.g., in journals, trade magazines, product literature, etc.) cannot be claimed as CBI. Therefore, requesting CBI status for such information could delay review under section 612. All claims of confidentiality will be treated in a manner consistent with 40 CFR part 2, subpart B.
2. Substantiation of Confidentiality Claims

At the time of submission, EPA requires a substantiation of any confidentiality claims. To make these claims, the following provisions apply:

- The specific information to which the claim applies must be clearly marked in the body of the study as subject to a claim of confidentiality.
- A Supplemental Statement of Data Confidentiality Claims must be submitted, identifying each section claimed confidential and describing in detail the basis for the claim. (A list of points to address in such a statement is included in Appendix C).
- The Supplemental Statement of Data Confidentiality Claims must be signed and dated and must include the typed name and title of the official who signed it.

The submitter should be advised that under the Clean Air Act section 114(c), emissions data may not be claimed as confidential. Moreover, there are further instances in which confidentiality assertions may later be reviewed even when confidentiality claims are received. These are provided in the provisions of 40 CFR part 2, subpart B. The submitter will be contacted as part of this evaluation process. However, if required substantiation is not provided along with the submission of information claimed as confidential, EPA may make the complete submitted information available to the public without further notice to the submitter.

3. Confidential Provisions for Toxicity Data

In the event that toxicity or health and safety studies are listed as confidential, the submitter should be advised that this information may not be maintained as confidential where such data is also submitted under TSCA or FIFRA, because of specific disclosure provisions in those statutes. However, any information other than emissions data contained in the toxicity study that is not relevant to the effects of a substance on human health and the environment (e.g., discussion of process information, proprietary blends) can be maintained as confidential subject to the provisions of 40 CFR, part 2, subpart B. The Agency is therefore requesting that submitters not identify the following information as confidential when submitting information under TSCA or FIFRA: all information concerning the objectives, methodology, results, or significance of any toxicity test or experiment performed on or with a substitute or its degradation products; any information concerning the effects of the substitute on any organism (e.g., fish, wildlife, humans and other mammals) or the environment (e.g., studies related to persistence, translocation, and fate); and pharmacokinetics/metabolism studies.

4. Federal Register Requirements

As discussed below in Section VII.A.3, the Agency intends to publish quarterly notices in the Federal Register updating the list of acceptable and unacceptable alternatives. The Agency is proposing that if the name of a specific chemical contained in any studies supporting such notices must be maintained as confidential, the submitter and the Agency will together develop a generic name that will protect the proprietary nature of the chemical, but will provide sufficient detail for the public to evaluate the health and safety studies. If appropriate, the submitter may reference any generic names identified for use in the PMN program.

VI. Effective Date of Coverage

A. General Provisions

In general, EPA’s rules listing substitutes as unacceptable become effective thirty days after final rulemaking. However, EPA is authorized to permit the continuation of activities otherwise restricted where the balance of equities supports such grandfathering. Consequently, where appropriate, EPA may grandfather use of particular substitutes by setting the effective date of unacceptability listings at some future date.

The United States District Court for the District of Columbia Circuit has established a four-part test to judge the appropriateness of Agency grandfathering (see Sierra Club v. EPA, 719 F.2d 195 (D.C. Cir. 1983)). This test involves balancing the results of four analyses, including whether the new rule represents an abrupt departure from previously established practice, the extent to which a party relied on the previous rule, the degree of burden which application of the new rule would impose on the party, and the statutory interest in applying the new rule immediately. In each rulemaking listing a substitute as unacceptable where grandfathering seems appropriate, EPA will conduct these four analyses and weigh their results. Where the balance of equities favors grandfathering, EPA will set a delayed effective date for such listings.

In keeping with the discussion above, then, for restrictions on use of unacceptable substitutes, the Agency will in selected cases set the effective date differently for each banned substitute. The effect of this will be in those selected cases to tailor the implementation dates to individual applications. EPA will establish these effective dates in the rulemakings on each substitute to be banned.

Setting effective dates for specific chemicals and uses will allow the Agency to avoid penalizing those who in specific applications may have already invested in good faith in alternatives the SNAP program ultimately prohibits. For example, the Agency in this action is proposing to find unacceptable the use of HCFC-141b in certain solvent applications. New information on stratospheric ozone depletion has increased concern over possible adverse human health and environmental effects, and the Agency’s unacceptable determination in the case of HCFC-141b reflects these increased concerns. However, the Agency recognizes that some solvent users may have switched to HCFC-141b in good faith, expecting that this substitute would sufficiently lower the risk of ozone depletion relative to earlier materials. To provide for these users, the Agency is today proposing a tailored effective date for certain uses of HCFC-141b. See the listing determination narrative discussion in Section IX, as well as the listing tables in Appendix B, for a full discussion of HCFC-141b and associated effective dates. Finally, to balance the desire not to penalize those who switched early in good faith with the need to avoid creating an incentive for continued investment in alternatives the Agency wishes to discourage, the longer-term effective dates discussed above will affect only existing equipment.

Until the Agency reaches a final decision restricting the use of a substitute, vendors are not barred from selling such substitutes. However, manufacturers, formulators, users, or other individuals involved in sale or use of a substitute are still required to notify the Agency of any sale or use of a Class I or Class II substitute as required by the SNAP program.

This action includes a proposed list of acceptable substitutes and a proposed list of banned substitutes. The list of restricted substitutes becomes binding 30 days after the date of publication of the final rule. In contrast, the list of acceptable substitutes is not binding, but rather is furnished for the purpose of assisting users in understanding the full range of available, acceptable substitutes in each application. Before issuing the final rule, the Agency hopes to supplement the list of acceptable substitutes with substitutes not yet on the proposed list.
As noted above, the Agency does not believe determinations that substitutes are acceptable need be made through rulemaking. Consequently, EPA believes that it is within its discretion to supplement the list of acceptable substitutes upon making determinations consistent with the criteria to be established in this rulemaking. In the interest of informing users as soon as possible of acceptable substitutes, EPA expects to add to the list of substitutes those substitutes for which it can make such a determination during the pendency of the rulemaking, consistent with the criteria promulgated.

The Agency therefore encourages vendors and users of substitutes to use this opportunity to provide EPA with information necessary to issue a SNAP determination. Many potential users of substitutes have asserted that they want the benefit of EPA’s SNAP determinations when transitioning out of Class I and Class II compounds. In addition, vendors of substitutes have also claimed they will derive significant benefits from having their substitutes added to the SNAP lists of approved substitutes, where possible.

VII. Notice, Review, and Decision-Making Procedures

The purpose of this section is to summarize the proposed procedures for submitting the required information to the Agency, and the steps EPA will take in reviewing SNAP program submissions, and making determinations based on them. This section focuses on three procedures, summarized in Exhibit 1, depending on the nature of the submission received by the Agency. Some substitutes may already have received approval or may not need approval under other environmental statutes, especially TSCA and FIFRA. These substitutes, in consequence, would only require review under the SNAP program. Section VII.A. discusses the submission and review process for alternatives that fall into this category in greater detail. In other cases, a substitute will require approval under section 612 as well as relevant provisions of TSCA and FIFRA. In these cases, any substitute that is a new chemical (i.e., not currently listed on the TSCA inventory) must be submitted to the Agency for review under the SNAP program, as well as the PMN program. Section VII.B. describes steps for this review in more detail. For alternatives to Class I and Class II chemicals that will be used in pesticide products, the substitute manufacturer will need to file notification jointly with EPA’s Office of Pesticide Programs (OPP) and EPA’s SNAP program. Section VII.C. discusses the letter procedure. EPA has coordinated closely with each of these regulatory programs to establish a joint review process that will ensure consistency in the final decisions, while minimizing the time for review, the reporting burden, and the costs for the submitter and the Agency.

A. Substitutes Reviewed Under SNAP Only

1. Applicability

Sections IV and V describe the conditions dictating review under the SNAP program only and the general reporting requirements under section 612. If any of these conditions are met and the substitutes are not exempt from the process as described in section IV.B.3., Exemptions from Reporting, a SNAP notice must be submitted.
SNAP Determination Process

SNAP Submission* Received by EPA

SNAP Coordinator Reviews for Completeness

Is Submission Complete and CBI Substantiated? No Query Submitter

Yes

SNAP Coordinator/Regrant Program Coordinator Review

Are There Overlaps with Other Programs? No CBI Requested? If Yes, Handle as such 90 - Day Clock Starts

Yes

SNAP Coordinator

- Assigns SNAP Tracking Number
- Send Letter of Receipt to Submitter
- CBI Requested? If Yes, Handle as such
- 90 - Day Clock Starts

If PMN Review Stops for Query, SNAP Stops Too

Joint Federal Register (FR) receipt notice

TSCA

EPA Conducts Analyses

Data Complete For Analyses? No Query Submitter

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*Petitions are handled through the same process, and are subject to the same information requirements. Please see Section VIII on petitions.
Propose Adding Chemical to Unacceptable List (Rulemaking)

EPA Conducts Analyses

Yes

EPA Makes Decision

Is Submittal Approved?

No

Propose Adding Chemical to Unacceptable List (Rulemaking)

Add Chemical to Acceptable List (3-month FR notice)

Yes

Note: All determinations will be made public in EPA's quarterly Federal Register notices updating the SNAP program lists. All determinations which have the effect of changing the unacceptable list (e.g., banning a chemical for a specific application or removing it from the acceptable list), will also be subject to the rulemaking process.

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2. Pre-Notice Communication

Prior to submitting the SNAP notice, each submitter is encouraged to contact EPA's SNAP Coordinator to discuss the notification process. Among other things, the SNAP Coordinator will: (1) assist the potential submitter in determining whether a SNAP notice is needed; (2) answer questions regarding how to complete a submission; (3) provide all necessary forms and guidance manuals; (4) serve as the initial point of contact when the notice is submitted; and (5) assign a SNAP program tracking number to the notice once it is received by the Agency. A copy of the SNAP program notice may be obtained from the SNAP Coordinator. Specific data requested are described in Section V.

3. Processing of Completed SNAP Submission

a. 90-Day Review Process. As required under section 612(e), a manufacturer of a substitute for a Class I chemical must provide the Agency with notification at least 90 days prior to introducing into commerce any new or existing chemicals for significant new uses as Class I alternatives. The same requirements apply to manufacturers of substitutes for Class II substances, although in this case the Agency is drawing on general authorities contained in sections 114 and 301 in order to fulfill the purpose of section 612(c). EPA intends to review these chemicals within a 90-day period to ensure prompt response for manufacturers initiating production of substitutes. EPA's 90-day review period for SNAP submissions will begin once EPA receives a submission that includes data that are adequate, as described in Section V.B. above. If a submission does not include adequate data, EPA may return the submission to request specific additional information. Section 114 and the case of petitions section 612(d) authorizes EPA to require manufacturers to support their SNAP submissions with data adequate to facilitate EPA's review.

b. Initial Receipt of the SNAP Submission. (1) Letter of Receipt. The SNAP Coordinator will send a letter of receipt to the submitter once the Agency receives the SNAP submission.

(2) Initial Review of Submission. Once received, the SNAP Coordinator will review the notice to ensure that basic information necessary to process the submission is present (i.e., name of company, identification of substitute, etc.). A more detailed review of supporting technical data will then ensue, as well as an examination of the substantiation provided for any claim for confidentiality of information. The 90-day review period will not commence until EPA judges the submission complete, although manufacturers may begin marketing chemicals 90 days after submitting their notification to EPA. Once the data supporting the SNAP notice are deemed adequate, the SNAP Coordinator will assign to the SNAP notice a tracking number, and EPA's formal 90-day review period will begin.

c. Determination of Data Adequacy. As mentioned above, as part of reviewing the SNAP submission, the Agency will complete a determination of the scientific and technical adequacy of the data supporting the application. The Agency will issue this determination within 15 working days after receipt of the application. Any time information is not adequate to allow the Agency to reach a SNAP determination, EPA will contact the submitter and request the missing data.

EPA believes it appropriate and authorized under section 114 to place the burden on the submitter to provide all data needed to complete the review of the SNAP notice. Depending on the type of information needed and the time necessary to compile and submit the requested data to the Agency, EPA may suspend or extend the review period. This will not affect the ability of a manufacturer to begin marketing a chemical 90 days after notifying the Agency.

In a few cases, the Agency and the submitter may disagree on a schedule for furnishing additional data EPA deems necessary to determine the acceptability of the substitute. If in these cases EPA has reason to believe that such substitute may be unacceptable, the Agency may exercise the option of proposing to list the substitute as unacceptable until the necessary data are provided, due to the uncertainty of the risks associated with use of the substitute.

d. Availability of New Information During Review Period. If critical new information becomes available during the review period that may influence the Agency's evaluation of a substitute, the submitter must notify the Agency about the existence of such information within ten days of learning of such data. The submitter must also inform the Agency of new studies under way, even if the results will not be available within the 90-day review period. The Agency may extend or suspend the review period depending on the type of information at issue and the stage of review.

e. Completion of Detailed Review. Once the submission is found to be supported by adequate data, the Agency will commence a detailed evaluation of the notice. As this review proceeds, the Agency may contact the submitter for additional information to assist in the evaluation. This will ensure that the review is completed quickly and that it reflects the best available information. Final decisions will be based on the detailed analysis completed during this stage of review.

f. Vendor Lists. The Agency will use the SNAP determinations to compile a list of vendors for the convenience of potential users. Companies could then ask EPA to review their specific substitute, to ensure that it is covered by the listing decisions on approved substitutes, and to add the company to the vendor list. The Agency believes that specific information on vendors of acceptable substitutes would be useful to companies switching out of Class I and Class II compounds. The Agency solicits comment on this aspect of today's proposal.

g. Communication of SNAP Determination. (1) SNAP Determinations on 90-Day Notifications. EPA's determinations on SNAP submissions that come as a result of the 90-day notification requirement will take the form of either adding substances to the list of acceptable substitutes or of proposing to add them to the list of unacceptable substitutes. The former, as discussed in greater detail below, will be listed in a quarterly update of SNAP determinations which EPA will publish in the Federal Register. The latter will be made final through rule-making under section 307(d).

(2) Communication of SNAP Determination to the Submitter. Once review has been completed, the submitter will be notified in writing of the determination under SNAP. At this time, the submitter will also be informed if any conditions are attached to the approval of a substitute. Companies may continue uninterrupted sale or manufacture of their substitutes until the Agency places a substitute on the list of unacceptable substitutes as a result of rulemaking. Sale or manufacture may continue if the Agency fails to reach a decision or notify the submitter of that decision within 90 days of initial notification of EPA.

(3) Communication of SNAP Determination to the Public (a) Federal Register Notice. To provide the public with updated information on SNAP determinations, the Agency is proposing to publish in the Federal Register a complete list of
the acceptable and unacceptable alternatives that have been reviewed to date. This list will be published four times each year and will include recent decisions made under the SNAP program. In addition to the quarterly publications, the Agency will communicate decisions through a clearinghouse and various outreach programs, as discussed in the next section, as well as through the stratospheric ozone program hotline, which the Agency has already established.

(b) Outreach and Clearinghouse

Section 612(b) requires the Administrator to assist users in identifying alternatives to Class I and II compounds. The Agency has long operated an outreach program for users of ozone-depleting compounds, and this new mandate along with the accelerated phase-out of Class I and II substances adds impetus to these efforts. Section 612(b)(4) requires the Agency to maintain a public clearinghouse of alternative chemicals, product substitutes, and alternative manufacturing processes that are available as replacements for Class I and Class II chemicals. The clearinghouse will distribute information on those substitutes that are approved under the SNAP program. For the convenience of companies wishing to identify substitutes with low relative environmental risks, the Agency will maintain a list of vendors selling substitutes that meet EPA's criteria for approval, as discussed in section VII.A.3.f.

In addition, the Agency is proposing to enter data on substitutes into the Pollution Prevention Information Exchange System (PPIES) database, which is maintained by EPA's Office of Research and Development. This database contains information on numerous pollution prevention options for a wide variety of industrial sectors and chemicals. PPIES can also be accessed from a variety of other pollution prevention databases maintained by other Federal agencies and industry. The Agency requests comment on this proposed approach to providing the public with information on available alternatives.

4. Decision-Making Framework
a. Decisions by Substitute and Use. As required by section 612(c), the Agency must publish a list of substitutes prohibited under the SNAP program and a list of acceptable alternatives for particular applications. Given that environmental exposure and risk profiles can change significantly from one application to the next, it is essential to evaluate and list substitute decisions in the context of their intended use. The Agency has initially identified a number of use sectors by which to list substitutes, and Section IX provides preliminary risk management decisions for many substitutes in each of the principal use sectors. Other substitutes in each of these sectors exist as well, and these substitutes will be covered in subsequent analyses undertaken in the SNAP program.

In listing the substitutes, the Agency will be as specific as possible, by providing exact chemical names of substitutes. The Agency anticipates two possible exceptions to this practice. The first is where release of the chemical identity of a substitute constitutes release of proprietary information. In that event, the Agency will report generic chemical names based on chemical classes as described in Section V.C. The other exception would be in cases where the Agency believes that a more general categorization is needed to account for the diversity of possible chemicals used in a particular set of substitutes. For example, in the solvents cleaning sector, many substitutes are formulations composed of compounds drawn from several categories of chemicals. In this case, the toxicity profile of each chemical is similar to those of other chemicals in that class. Yet for most substitutes, a broad chemical classification (e.g., aromatic hydrocarbons, or HAPs) is not specific enough because of differences among chemicals belonging to each of these groups. Thus, where appropriate, EPA will provide a more specific description of the substitute by application.

b. Decision Categories. Under section 612, the Agency has considerable discretion in the risk management decisions it can make in SNAP. The Agency has identified several possible decision categories, as described below. However, these types of risk management decisions should not be construed as comprising all possible options that the Agency will exercise under section 612. Depending on the particular characteristics of the substitution, alternative approaches may be warranted.

(1) General Acceptance. Where the Agency has reviewed a substitute and found no reason to prohibit its use, it will list the alternative as acceptable for the applications listed. Where appropriate, the Agency may provide some additional comment (e.g., general recommendations encouraging recapture and recycling). However, these comments are not conditions for use of the substitute.

(2) Approval Subject to Conditions. After reviewing a notice, the Agency may determine that a substitute is acceptable only if certain conditions are met. The Agency cannot predict at this time all necessary restrictions, but already anticipates some conditions based on substitute reviews already completed.

For example, the Agency may impose conditions on the use of a substitute and require recycling equipment to limit workplace and ambient releases or require use of other control practices within a certain application.

Alternatively, EPA may approve a substitute for general use, but for use only in certain narrow applications. Clearly, any limitations imposed will depend on the risks involved and the substitute and application in question. To provide adequate opportunity for comment by the regulated community, EPA will complete notice-and-comment rulemaking before promulgating any finding to approve a substitute subject to a condition on use.

In implementing its use conditions, the Agency has sought to avoid overlap with other existing regulatory authorities. EPA has taken a number of steps to mitigate this potential for duplication. First, EPA intends to limit the use of conditions to cases in which clear regulatory gaps exist. Second, these existing regulatory gaps must render the use of a substitute an unreasonable risk in the absence of any additional controls. Third, in the limited cases in which conditions may be necessary, the Agency will impose them only after going through formal notice-and-comment rulemaking. Finally, the Agency intends to withdraw existing conditions when they are superseded by appropriate regulatory controls under other authorities.

The Agency, however, requests comment on the general issue of the need for use conditions. In particular, EPA requests comment on whether section 612 in fact confers upon the Agency the authority to go beyond the listing of acceptable and unacceptable alternatives and to set such use conditions. Further, EPA requests comment on the capability and practicality of EPA enforcing use conditions which may, for example, closely resemble workplace safety standards, which are typically within the enforcement purview of other regulatory authorities.

EPA also requests comment on whether, when an unreasonable risk might exist due to a gap in regulatory coverage, the appropriate means to address these risks is through the existing regulatory framework of other...
federal authorities. For example, rather than using EPA's use conditions to address existing gaps in workplace safety standards, EPA could refer the matter to the appropriate OSHA authorities and request appropriate action to mitigate an otherwise unreasonable risk.

Alternatively, where the length of time required to address a problem under another authority may be unacceptably long given the nature of the risk, there may be cases in which EPA would simply consider unacceptable the use of a given substitute, pending the development of a regulatory framework to control the risk it poses in its use as a substitute for an ozone-depleting compound.

For example, in this action, EPA has proposed conditions on the acceptability of certain halon substitutes when used as total flooding agents in normally occupied areas. EPA has imposed these conditions because of the risk of cardiotoxic levels of exposure to personnel in areas where substitute agents may be discharged in the event of fire. Existing OSHA standard 1910.160 applies certain general controls to the use of fixed extinguishing systems in occupied workplaces, whether gaseous, dry chemical, water sprinklers, etc., and EPA has not reproduced those. These include, for example, the requirements for discharge and pre-discharge alarms, and availability of Self Contained Breathing Apparatus (SCBA) for emergency entry into an area where agent has been discharged.3

While section 1910.162 can apply generally to gaseous agents, it includes cardiotoxic levels specific to Halon 1301. Section 1910.162 paragraphs (b)(3) and (b)(6) provide alternative workplace requirements based on specific design concentrations of Halon 1301. (These design concentrations are not identified as the cardiotoxic NOAEL or LOAEL, so one cannot generalize a rule for use with alternative agents.) For this reason, EPA is concerned that halon substitute agents could be used in the absence of enforceable compound-specific cardiotoxic exposure levels. Should OSHA create compound-specific cardiotoxicity values to be applied to the use of halon substitutes as gaseous total flooding agents in occupied spaces, these conditions would no longer be necessary and EPA would rescind them.

However, EPA is also aware that existing OSHA regulations may provide adequate coverage against exposure to toxic levels of agents or their decomposition products. Section 1910.162 (b)(3) states, "(t)he employer shall assure that employees are not exposed to toxic levels of gaseous agent or its decomposition products," and paragraph (b)(4) states, "(t)he employer shall provide a distinctive pre-discharge employee alarm ... when agent design concentrations exceed the maximum safe level for employee exposure." EPA invites comment on the adequacy of 1910.162 (b)(3) to provide workplace protection against toxic exposures to agents that differ from Halon 1301.

(3) Substitutes Pending Completion of Review. The Agency will describe submissions for which it has not yet reached a final decision as pending. For all substitutes in the pending category, the Agency will contact the submitter to determine a schedule for providing the missing information if the Agency needs to extend the 90-day review period. EPA will use the authority under section 114 to gather this information, if necessary.

(4) General Prohibition. The Agency has the authority under section 612(c) to prohibit the use of a substitute believed to present adverse effects to human health and the environment where alternatives that reduce overall risk are available. The Agency will only use this provision where it has identified other substitutes that are currently or potentially available and that have lower overall risks. Substitutes will be listed as unacceptable through the rulemaking process.

(5) Prohibition with Limited Exemptions for Critical Uses. In some applications, even though the Agency restricts the use of a substitute based on the potential for adverse effects, it may be necessary to grant a limited number of exemptions because of the lack of alternatives for specialized uses within the general application area. The Agency will refer to such exemptions as "critical use exemptions." For example, the Agency could list a substitute as generally unacceptable for solvent applications, but allow for limited exemptions for critical uses within the sector of solvent cleaning. These critical use exemptions will be granted only for the period necessary to develop and implement alternatives not yet available.

At this time, the Agency cannot know and list all critical use applications that will be exempted. Section VII.F discusses the petition process for critical use exemptions in more detail.

Critical use exemptions will be granted through notice-and-comment rulemaking.

c. Time Certainty of Decisions. In response to the ANPRM, several comments suggested that the Agency establish assured minimum periods of use for substitutes listed as acceptable. For example, one commenter recommended that the Agency consider any substitute decision, once made, valid for a minimum of fifteen years before making any changes. Clearly, there are advantages to having a guaranteed period within which a substitute can be used without concern for future changes in the acceptability of a substitute. In particular, such certainty would encourage reduced reliance on Class I chemicals in the near term.

Despite this benefit, the Agency believes that providing time certainty to its decisions on balance could discourage continued research on substitutes. In addition, the Agency believes that in certain limited cases, new data on previously approved or disapproved substitutes may warrant changes to an existing SNAP determination. Such changes, however, will only be considered in cases where new information indicates a need to reassess the risk of a previously evaluated substitute. For example, new toxicity data may become available that point to a dramatically different hazard profile for a chemical, and which changes the risk the substitute poses to human health and the environment.
relative to other substitutes. Similarly, if the Agency previously listed a high-risk substitute as acceptable only because no other alternative exists for a specific end-use, this determination may be subject to change if a new substitute with demonstrably lower overall risks becomes available. In such instances, which the Agency expects will occur infrequently, EPA will provide consideration for companies who earlier made a switch to a substitute believed to be acceptable. In particular, the Agency proposes to examine capital expenditures made by affected industries to manufacture and use a substitute to determine whether the availability of another alternative should render the first alternative unacceptable.

d. Implications of Other Regulatory Requirements. The Agency is proposing that the SNAP program in evaluating substitutes take into consideration the regulatory requirements of other environmental and health protection statutes (e.g., the Clean Water Act or the Occupational Safety and Health Act). By considering existing regulatory constraints, the Agency’s evaluation of alternatives will explicitly recognize compliance with provisions designed to reduce workplace and environmental releases. However, it will not be possible to factor in regulatory requirements that are still under development (e.g., more stringent requirements to control volatile organic compounds and hazardous air pollutants under Title I and Title III of the CAA). Clearly, in these instances, a substitute, although approved, must comply with all future regulations. Should future regulations severely limit the availability of the only substitute for a prohibited substance, EPA would reconsider the advisability of keeping that substance on the list of unacceptable substitutes.

Several commenters felt that the goal of section 612 was to encourage use of substitutes for Class I and Class II chemicals by relaxing regulatory requirements in other areas. The Agency does not believe that it was the intent of Congress to use the authority under section 612 to compromise existing regulatory requirements. Instead, EPA intends to evaluate substitutes in the framework of protection provided by current regulatory standards.

5. EPA-Generated Review of Substitutes

In addition to notices received under section 612 for substitute review, the Agency is authorized by section 612(c) to add or delete alternatives to the list of reviewed substitutes on its own initiative. EPA has many efforts under way to identify and communicate the availability of promising new alternatives. These include support for research efforts to study and focus attention on future substitutes, involvement in the United Nations Environment Programme biannual assessment of technologies for key sectors currently using ozone-depleting chemicals, and technology transfer projects with industry, other Federal agencies, and developing nations. Based on information available through these activities, EPA may initiate review of new substitutes under section 612. In each case, the next planned quarterly Federal Register notice updating the status of SNAP determinations will inform the public that EPA is initiating a review, subject to the provisions discussed in this proposal. Similarly, determinations ultimately reached as a result of these internally-generated reviews will be publicly noticed every three months.

B. Joint Review of New Substitutes under SNAP and TSCA PMN

1. Applicability

Any potential SNAP submitter who intends to introduce a new chemical (i.e., a chemical not currently included in the TSCA inventory) as an alternative for a Class I or Class II chemical must undergo review not only under section 612, but under section 5 of TSCA (the Premanufacture Notice program) as well. Because of the overlap in statutory authority, the Agency has established a joint review process between the SNAP and TSCA Premanufacture Notice (PMN) programs. This process has been structured to minimize reporting burden and to ensure consistency in decisions between the two programs. The following sections describe the joint review and decision-making process in more detail.

2. Data Submission Requirements and Process

a. SNAP and PMN Forms. The Agency has reviewed the data submission needs for the SNAP and PMN programs and found significant overlap. In general, the Agency has identified only a few additional data elements beyond those already required by the PMN program that should be included for review under the SNAP program. These elements are:

- Ozone depletion potential.
- Global warming potential.
- Explicit quantification of the cost of using the substitute, including:
  - Chemical replacement data
  - Chemical cost data
- Incremental equipment expenditures (either new or retrofit) needed to use substitute
- Information on the cost implications of changes in energy consumption (e.g., from the use of a less energy-efficient refrigerant)
- Documentation of testing results, where available, regarding the flammability of substitutes that will be used in consumer applications.

Given this overlap, the Agency is proposing that a submitter requesting a review under both the SNAP and PMN programs provide the above information by following these steps:

- Complete the PMN form (EPA Form 7710–25) following the Instructions Manual currently available through the TSCA Assistance Information Service.
- Indicate on page 11 of the PMN form, “Optional Pollution Prevention Information,” that the chemical to be reviewed is also to be considered under the SNAP program.
- Complete a SNAP addendum that requests information only on those items listed above. (The addendum can be obtained from the SNAP Coordinator.)

The completed PMN form (EPA Form 7710–25) will retain the basis for all information needed to complete review of the new chemical under section 5 of TSCA. The completed PMN form and the SNAP addendum together will comprise the data submission for section 612 review and listing decisions for new chemicals. This approach is intended to minimize the reporting burden on submitters.

The Agency will modify the PMN Instructions Manual in the future to provide more explicit direction on how to complete the SNAP addendum. A SNAP submitter may also consult the SNAP Guidance Document, which will be available for potential submitters at the time the SNAP program is promulgated. Any questions regarding the completion of these forms can be directed to either the PMN pre-notice coordinator or the SNAP Coordinator.

b. Submission of Completed Forms.

Both the PMN and SNAP programs have a review period of 90 days, subject to suspensions and extensions described in Section VII.A. for the SNAP program and in the Preamble to the PMN final rule (40 CFR 720.75). To ensure that new chemical submissions are reviewed and decided on jointly, the Agency encourages submitters to provide both the PMN form and SNAP addendum to the PMN and SNAP coordinators. Failure to provide both programs with the requested information at the same time could result in delays in the review
of a submitter’s notice seeking approval of a new chemical as a CPC substitute approved by EPA where it would result in delay of EPA’s approval under the PMN program.

c. Procedures for Handling Confidential Business Information. The Agency recognizes that, where appropriate, information submitted to the PMN and SNAP programs may need to be confidential. EPA is proposing that all CBI submitted as part of the joint PMN/SNAP review be maintained and treated in a manner consistent with TSCA requirements. Confidentiality claims will be processed and may be reviewed in a manner consistent with 40 CFR part 2, subpart B. This approach is being proposed because the majority of data provided to SNAP under the joint review process will come from the PMN form. Submitters should note that while TSCA and CAA may have different language describing CBI handling procedures, there is no substantive difference in how CBI is maintained under the two statutes.

3. Joint Review of New Substitutes Under PMN and SNAP

a. Preparation of Public Docket and Federal Register Notices. Once the letter of receipt has been issued, the PMN program will prepare a public docket and Federal Register notice, as described in the Preamble to the final rule for the PMN program (40 CFR 720.75). The PMN program manager will consult with the SNAP Coordinator in preparing the notice. The Agency is proposing this approach for joint PMN/SNAP reviews because it believes it will reduce the reporting burden imposed on manufacturers.

b. Joint Review Process. EPA is proposing to complete joint evaluations of new chemicals serving as Class I or Class II substitutes under section 5 of TSCA and section 612 of the CAA. This joint review process will be coordinated to ensure that there is consistency in the final decisions made under the PMN and SNAP programs. To ensure agreement in the decisions, Agency offices will work in concert to develop toxicity, exposure, and risk profiles for those substitutes and applications that come under joint TSCA and CAA review authority. The Agency will also coordinate its review of the completeness of the information supplied and subsequent data requests to minimize the reporting burden on the submitter.

Submitters should note that Agency decisions to restrict production of particular chemicals under TSCA will, in the case of joint PMN/SNAP applications, also have the effect of restricting production of substitutes undergoing review under the SNAP program. However, companies that produce substitutes only being reviewed under the SNAP program are not required to cease production during the SNAP review period.

As part of the review, the PMN and SNAP programs will work to arrive at a consistent decision regarding the new chemical under review. Consequently, listing decisions under SNAP will reference any conditions also incorporated into the PMN review (e.g., submission of additional toxicity information, restrictions on use, etc.). If a substitute meets the conditions for general PMN approval but not for SNAP approval, the company may produce and market the substance in question. However, EPA will commence a rulemaking to prohibit as unacceptable the description or use of the substitute as an EPA-approved Class I or II substitute. If the chemical fails to meet the conditions for PMN approval, the submitter is barred from producing the chemical and consequently also from marketing the product as a CPC substitute. Submitters should note, however, that the CAA section 612 places considerable emphasis on identifying and promoting the use of substitutes which, relative to others, reduce overall risks to human health and the environment. To the extent a substitute offers such risk reduction, EPA under the CAA will make every effort to facilitate production and use of that alternative.

c. Communication of Decision. The PMN program will use the existing TSCA regulatory framework for communicating decisions to submitters of the decision on the new substitute. The SNAP program will provide public notice of decisions regarding the acceptability or unacceptability of a substitute following the process described in Section VII.A.3.b. EPA will contact the submitter to determine how best to list the substitute under the SNAP program if necessary to protect the confidentiality of the alternative.

d. Data Submission Requirements and Process

a. Preparation of Applications. The Agency has reviewed the data submission needs for the SNAP and FIFRA pesticide amendment/registration process to prevent no significant overlap. Because there is some little overlap, the Agency is proposing that a submitter requesting review under both SNAP and the Office of Pesticide Programs’ pesticide amendment/registration process submit all information ordinarily required for the OPP process as well as a fully completed SNAP submission form. A copy of the FIFRA form should be submitted to the OPP, and a copy of the SNAP form should be submitted to the SNAP Coordinator. The SNAP form can be obtained from the SNAP Coordinator. For further guidance, SNAP submitters may also consult the SNAP Guidance Document, which will be available for review at the time the SNAP program is promulgated.
If a registrant is submitting an amendment to a product registration under FIFRA that currently contains a Class I or II substance, he or she should note in Section II ("Amendment Information") of the FIFRA form that the amendment was prompted by the CAA production phase-out. Similarly, if a registrant is submitting an application for a new pesticide registration that would otherwise have been based on a Class I or II compound, he or she should note in Section II of the FIFRA form that the registration includes a Class I or II substitute.

The submitter should also identify in Section II both the substitute chemical and the Class I or II compound it is replacing. Further, if a registrant is aware that a particular chemical intended for use as a Class I or Class II substitute in a pesticide formulation has already been approved through earlier SNAP/FIFRA determinations, the registrant should also reference the relevant part of the prior review. This additional information will allow EPA to identify quickly those registrants whose proposed substitutes have already been the subject of listing determinations under SNAP, and thereby streamline the SNAP review.

b. Review of Applications. When the Agency receives the FIFRA application and SNAP submission, it will log each into the relevant tracking systems: the Office of Pesticide Program's (OPP) tracking system for the FIFRA application and the SNAP tracking system for the SNAP submissions. If the FIFRA application is identified in Section II as a Class I or Class II substitution, the FIFRA program coordinator will contact EPA's SNAP coordinator to establish whether the substitute has been the subject of any prior SNAP reviews. If the registrant's substitute is on the list of unacceptable substitutes, EPA will notify the registrant that the amendment request cannot be granted. If the registrant's substitute is on the list of acceptable substitutes, EPA will proceed with the standard FIFRA application review. If a chemical substitute is not listed under existing SNAP determinations but is a substitute for an ozone depleting compound, EPA will inform the registrant of the need for a SNAP review.

5. Communication of Decision. Once the EPA review is complete, the Agency will notify the registrant whether the new formulation or proposed formulation change is acceptable. At the same time, the Agency will amend the SNAP determinations to reflect these findings and will publish the revised determinations in the next quarterly Federal Register notice. Submitters should note that, because of the shared authority to review substitutes under both SNAP and FIFRA, formulators may not sell amended or new formulations until they have received FIFRA approval.

D. Shared Statutory Authority With the Food and Drug Administration

The Federal Food, Drug and Cosmetic Act (FDCA), 21 U.S.C. 321, provides for the safety and effectiveness of drugs and therapeutic devices, the purity and wholesomeness of foods, and the harmlessness of cosmetics. Under this statute, the Food and Drug Administration (FDA) regulates the packaging of food products and incidental additives and requires predistribution clearance of medical devices.

As defined in the FDCA, medical devices can include any devices, diagnostic products, drugs, and drug delivery systems. Devices covered under this jurisdiction are subject to review under the FDCA. Some medical devices and food packaging currently contain Class I or II compounds. The Agency is proposing that such products be exempt from further review for human health effects under the SNAP program where FDA approval of such effects is required before a product can be introduced into commerce. EPA will rely in its SNAP determination on FDA's conclusions regarding health effects. The Agency believes this exemption is justified because of the higher burden of proof placed on submitters under the FDCA. However, the Agency will continue to evaluate all other environmental effects of the proposed substitute, and will consult with the FDA to determine the appropriate course of action.

VIII. Petitions

A. Background

1. Role of Petitions

Section 612(d) in the CAA explicitly states that "any person may petition the Administrator to add a substance . . . or to remove a substance from either of such [prohibited or safe use] lists." The petition provision serves two principal needs. The first is to permit the appeal of existing Agency determinations under the SNAP program. The second is to provide a mechanism for individuals and organizations to bring to the Agency's attention new information on substitutes that could affect existing listing determinations or result in new ones.

The opportunity for outside parties to comment on existing listing decisions is an important aspect of the petition process. As discussed in the section on notifications, companies that produce substitutes must submit specific data on the substitutes to the Agency for review. However, organizations and private citizens other than those required to submit SNAP notices may have additional information about existing substitutes or information on new substitutes not yet reviewed by the Agency. To ensure that the SNAP determinations are based on the best information on substitutes, it is essential that the Agency offer a means for such information to be incorporated into the SNAP analyses on a continuing basis.

Before individuals, organizations, or companies may initiate court action against EPA for the purpose of changing the lists of acceptable or unacceptable substitutes, they must first exhaust all administrative remedies for receiving such relief, including remedies like the petition process described in this section.

2. Types of Petitions

Four types of petitions exist:

(1) Petitions to add a substitute not previously reviewed under the SNAP program to the approved list;
(2) Petitions to add a substitute not previously reviewed under the SNAP program to the prohibited list;
(3) Petitions to delete a substitute from the approved list and add it to the prohibited list; and
(4) Petitions to delete a substitute from the prohibited list and add it to the approved list.

Petitioners should note that the first type of petition is comparable to the 90-day Notices under SNAP, and that the latter are submitted by substitute producers prior to the introduction into interstate commerce of the substitute for a significant new use as a Class I or Class II substitute. The first type of petition, by contrast, would be initiated by entities other than the company responsible for the substitute.

Companies that manufacture, formulate, or use a substitute themselves and want to have their substitutes added to the approved list should submit information on the substitute under the 90-day review program.

3. Basis for Petition

A petitioner may submit a petition for several reasons, including:

- Availability of information on substitutes or applications not covered in the existing SNAP determinations;
- New toxicity data on a substitute;
- New technologies or practices that reduce exposures to a substitute previously prohibited under SNAP due to toxicity concerns; or
Requests for approval for specialized uses for a prohibited substitute where no other technologically viable substitute can be found in a particular niche use. All of the above are examples of valid justifications for submitting a petition. Other bases for petitioning the Agency may exist as well, and all petitions with adequate supporting data will receive equal consideration under the SNAP program.

4. Nature of Response

The Agency will only review and grant or deny petitions based on the industrial use category identified in the petition. For example, simply because the Agency ultimately deletes a substitute from the list of approved substitutes for solvents cleaning does not mean the substitute is from then on prohibited for use as a refrigerant. A similar caveat applies for petitions on uses within industrial sectors. If a substitute, for instance, is approved for a specific application within a use sector, it will not automatically be approved for all other applications in that sector.

B. Content of the Petition

A petition must contain the information described in Section V.B. of this notice, which lists the items to be submitted in a 90-day notification. Information requirements for petitions and 90-day notifications are the same, since the Agency will be applying equal rigor to analyses of petitions submitted by outside parties as to notifications received from the producing companies themselves. As with SNAP submissions, the Agency will issue a determination on the completeness of the petition within 15 days of receiving the petition. For petitions, the Agency also requires the following information:

- **Action requested**: A brief statement describing the type of petition; and
- **Rationale**: A brief summary of the basis for the petition and the data that support the petition.

Specifically for petitions that request approval for substitutes on “critical use” grounds, the Agency proposes to require additional information documenting a company’s efforts to find and implement substitutes. This information is discussed below.

For petitions that request a re-examination of a substitute previously reviewed under the SNAP program, the submitter may reference the prior submittal rather than submitting separate information. In this case, the petitioner should specifically summarize in the rationale for the petition any new or additional data.

C. Sufficiency of Data

Petitioners should be aware that insufficient data may prevent the Agency from reaching a speedy decision on whether to grant or deny a petition. EPA will not consider a petition “received” for the purposes of triggering the 90-day review prescribed by section 612(d) until the submission includes as much of the information needed to rule on the petition as the petitioner can reasonably be expected to obtain. As provided in section 612(d), any petition must “include a showing by the petitioner that there are data on the substance adequate to support the petition.” Petitioners may provide citations to scientific literature, where appropriate. However, submitters are advised that furnishing copies of supporting articles, reports, or letters will expedite the review process.

Any time the Agency receives a petition with insufficient data, EPA will not commence review until the petitioner submits the missing information to the best of the petitioner’s ability. To the extent the petitioner does not have the required information, EPA may also seek data from sources other than the petitioner, including manufacturers or users of products that contain the substitute. As with the 90-day SNAP notices, EPA may also decide, based on preliminary information, to propose to list the substitute in question as unacceptable pending the receipt of additional data. In such cases, section 612(d) explicitly provides that “the Administrator shall use any authority available to the Administrator, under any law administered by the Administrator, to acquire such information.” These authorities include section 114 of the CAA as well as information collection provisions of other environmental statutes. Where EPA cannot obtain sufficient data, the Agency may deny the petition for lack of adequate technical support.

D. Criteria for Evaluating Petitions

In evaluating petitions, the Agency will follow the same criteria as for review of pre-commercialization notices. This will ensure that both petitions and notifications are judged by the same standards.

E. Petition Review Process

1. Petition Submittals. Today’s proposal describes a generic petition process. Petitions should be sent to the docket number listed in the beginning of this action as well as to the SNAP staff.

2. Petition Reviews

When the Agency receives a petition, it will log the petition into the SNAP petition tracking system. If the petition concerns a substitute previously either approved or restricted under the SNAP program, the Agency will as a courtesy contact the manufacturer of that substitute. Decisions to remove any substitutes from either list will be made as a result of notice-and-comment rulemaking. The Agency requests comment on whether notice-and-comment rulemaking procedures are required when removing a substitute from the acceptable list.

As explained above, the Agency will grant or deny the petition within 90 days of receiving a complete application. If the Agency grants a petition to either add a substitute to the list of unacceptable substitutes or remove a substance from this list, this decision will be formally promulgated as a rulemaking. Otherwise, responses to petitions including explanations of petition denials will be noticed in the next 3-month Federal Register notice updating the SNAP determinations. Regardless of the nature of the final determination, the Agency will inform petitioners within 90 days whether their request has been granted or denied.

If a petition is denied, the Agency will publish in the Federal Register an explanation of the determination. If a petition is granted, the Agency will publish the revised list incorporating the petition decision within 6 months of reaching a determination. Where EPA must complete rulemaking to alter the lists, the statute requires EPA to propose, take comment on, complete final action, and publish the revised lists within six months of the grant of the petition.

F. Critical Use Exemption Petitions

In some cases, it may be necessary to allow limited exemptions for specialized uses of a substitute that has been designated as an unacceptable for a broad application within a sector. For example, even though the Agency may restrict the general use of a compound, it could still grant exemptions for use of that compound in specific applications where it can be demonstrated that no other substitute exists. The Agency will refer to such petitions as critical use exemptions. EPA believes that it will receive few such requests for exemptions, since the Agency is not proposing broad restrictions unless other alternatives exist for the application in question.

These petitions are in a special category, since they are based on a claim
that a particular substitute should be exempted from broad regulatory restrictions because no other substitute exists that meets performance or safety standards. The Agency can either grant the critical use exemption based on information independently collected, or it can base the exemption on a petition from a vendor or end user. Any exemptions will be granted for specific uses, and companies will not have to apply for exemptions on a company-by-company basis.

Section 612 provides the Agency with the authority to grant such exemptions. In section 612(c), the Clean Air Act states that "it shall be unlawful to replace any Class I or Class II substance with any substitute substance which the Administrator determines may present adverse effects to human health or the environment, where the Administrator has identified an alternative to such replacement that—(1) reduces the overall risk to human health and the environment; and (2) is currently or potentially available." As a result, the Agency is not authorized to restrict use of a substitute if that substitute is the only currently or potentially available alternative to the Class I or Class II substance.

However, in publicizing critical use exemptions for niche applications, the Agency will encourage other companies or vendors to challenge each critical use exemption. It is EPA’s hope that this may bring to light new alternatives or processes of which the petitioner and EPA are unaware, and that these new alternatives may pose lower overall risks than the substances which have been the subject of the critical use exemption. If an exemption is revoked based on the availability of a new, lower-risk alternative, companies that have made investments in technology which was earlier deemed a "critical use" may be granted permission to extend their use for a limited period of time.

If this approach to critical use exemption petitions is adopted in the final rule, the Agency will issue guidance describing additional documentation petitioners should include. This information could include descriptions of:

- Substitutes examined and rejected;
- Process or product in which the critical use substitute is needed;
- Reason for rejection of other alternatives, e.g., performance, technical or safety standards; and/or
- Anticipated date other substitutes will be available and projected time for switching.

In addition to this basic information, the guidance will also include specific data for critical use petitions in each sector.

For example, to evaluate critical use applications for solvent cleaning substitutes, the Agency will also need information on the soils to be removed, the substrate, and the type of part being cleaned. This information is requested not only to aid the evaluation of the petition, but also so that the Agency can help the petitioner identify other potential alternatives. As noted previously, critical use exemption petitions will be processed through notice-and-comment rulemaking.

IX. Preliminary Listing of Substitutes

A. Overview

This section presents EPA’s proposed listing decisions for Class I chemical substitutes in the following applications: refrigeration, foam blowing, solvent cleaning, fire extinguishing, sterilants, aerosols, tobacco expansion and adhesives, coatings and inks. Parts D through J below present a detailed discussion of the proposed substitute listing determinations for each of the major use sectors. Tables that summarize the key proposed listing decisions in this section are included in Appendix B. As discussed earlier in this action, the Agency is proposing to exclude substitutes in other applications from the listing decisions.

To develop the lists of unacceptable and acceptable substitutes, EPA conducted screens of health and environmental risks posed by various substitutes for Class I compounds in each use sector. These screens are presented in individual background documents entitled “Risk Screen on the Use of Substitutes for Class I Ozone-Depleting Substances” for each use sector. Based on these analyses, EPA classified as “unacceptable” only uses of substitutes that pose significantly higher human health and environmental risks than those risks that would accrue through either continued use of the Class I substances themselves or through use of other available substitutes.

The assessments presented in the background documents are screens of the comparative risks posed by use of substitutes, not assessments or rankings of the absolute risks associated with use of each substitute. Designating a substitute as “acceptable” does not imply the absence of risks for that substitute, but rather that the substitute in question is believed to present lower overall risks than the Class I compound it is replacing. For instance, in some cases, ozone-depleting substances can be replaced by chemicals with known toxicity or ability to contribute to ground-level ozone formation. The Agency’s risk screen analyzes these effects, and the SNAP determinations describe as “acceptable” those substitutes for which any risks from replacements would be small compared to aggregate risks from other existing, similar sources or for which such risks could be managed by developing and implementing appropriate regulatory controls.

The risk characterization does not at present include assessment of the environmental transformation products of the substitutes. Research efforts of the Agency in cooperation with the Alternative Fluorocarbons Environmental Acceptability Study (AFEAS) are in progress and are intended to define the chemical, biological and photochemical sinks for these substances in the biosphere. Ultimately, these research activities will contribute to the development of ecological risk assessment for substitutes.

Additionally, in cases where the Agency has proposed listing a substitute as unacceptable, it has assessed—as required in section 612—the availability of other substitutes and concluded that alternatives were currently or potentially available. This assessment includes a review of the affordability of other available substitutes.

As a rule, the Agency did not evaluate the technical performance of a substitute, since the purpose of the SNAP program is to examine environmental effects of substitutes identified as being of commercial interest regardless of technical acceptability. However, certain sectors, performance of the substitute does pertain directly to environmental or health effects. For example, in refrigeration, the ability of a refrigerant replacement to serve as a coolant will directly influence the substitute’s energy efficiency, which in turn will affect the substitute’s environmental effects. Similarly, in fire extinguishing, the ability of a substitute to put out fires and thereby save human lives will directly affect a substitute’s health effects. Further, in the case of critical use exemption petitions, the Agency’s decision to grant or deny such a petition may hinge on questions of technical performance. For example, in the case of certain specialized solvents, some substitutes otherwise considered unacceptable may require critical use exemptions because they are the only available substitute offering performance characteristics deemed essential in a certain application. In
cases such as these, the SNAP analyses do consider the performance of a substitute.

EPA's evaluation of each substitute in each end use is based on the following types of information and analyses:

- Atmospheric effects are assessed by predicting ozone depletion and global warming. Ozone depletion is based on market penetration of a substitute and is measured in terms of cumulative Clx loadings and its effect in terms of increased incidence of skin cancer cases and skin cancer mortalities. Changes in global temperatures may result from releases of the substitutes themselves or from changes in fossil fuel use due to increases or decreases in energy efficiency resulting from production or use of the substitutes. The model used by the Agency's receptors may be exposed, and over what period of time. These assessments are based on personal monitoring data or area sampling data if available. Otherwise, exposures are assessed using measured or estimated releases as inputs to mathematical models. Exposure assessments may be conducted for many types of releases, including releases in the workplace and in homes, releases to ambient air and surface water, and releases from the management of solid wastes.

- Toxicity data are used to assess the possible health and environmental effects from exposure to the substitutes. If Occupational Safety and Health Administration (OSHA)-approved or EPA-wide health-based criteria such as Permissible Exposure Limits (PELs; for occupational exposure), Inhalation reference concentrations (RFCs; for noncarcinogenic effects), or cancer slope factors (for carcinogenic risk) are available for a substitute, exposure information is combined with this toxicity information to determine whether there is reason for concern. Otherwise, toxicity data are used in conjunction with existing EPA guidelines to develop health-based criteria for interim use in these risk characterizations.

- Flammability is examined as a possible safety concern for workers and consumers. EPA assesses flammability using data on flash point and flammability limits (e.g., OSHA flammability/combustibility classifications), test data on flammability in consumer applications conducted by independent laboratories (e.g., Underwriters Laboratories), and information on flammability risk minimization techniques.

- Some of the proposed substitutes are volatile organic compounds (VOCs), which contribute to tropospheric air pollution by contributing to ground-level ozone formation. Local and nationwide increases in VOC loadings from the use of substitutes are also evaluated.

In conducting these assessments, EPA made full use of previous analyses performed by the Agency, including the 1990 interim hazard assessments and supporting documentation. These analyses were modified in some cases to incorporate more recent data or to accommodate different analytical approaches as needed. Where possible, EPA incorporated data submitted in response to the ANPRM; EPA will continue to review data provided in these submissions between proposal and promulgation of the SNAP rulemaking. Finally, these analyses assume that increased community exposure complies with applicable requirements of other statutes and regulations administered by EPA (e.g., recycling requirements promulgated under the CAA) and other Federal agencies (e.g., any enforceable occupational exposure limits set by OSHA).

Where further data become available at a later date that would help characterize the risks of substitutes, the Agency will incorporate this data into its risk screens. For example, as mentioned above, the risk screen does not at present include assessment of the environmental transformation products of substitutes. Research efforts of the Agency in cooperation with the Alternative Fluorocarbons Environmental Acceptability Study (AFEAS) are in progress and are intended to define the chemical, biological and photochemical sinks for these substances in the biosphere. Ultimately, these research activities will contribute to the development of more complete ecological risk assessments for substitutes. However, the Agency generally does not believe that a more detailed characterization of risks would lead to a different listing decision for individual substitutes, since the critical comparison for policy purposes remains the adverse effects posed by continued use of a Class I compound.

The Agency requests comment on its application of the proposed decision criteria in the listing determinations proposed today, which include acceptable and unacceptable substitutes by sector. EPA further solicits additional information on substitutes. However, the decisions included in today's proposal will not be final until the SNAP program is promulgated. It should be noted that the listing of acceptable and unacceptable substitutes is an on-going process. Thus, if a company is not yet able to provide the Agency with the information needed to complete a review of a substitute, a review can be completed in the future, when data become available. Once this rule is promulgated, the substitute may be submitted to the Agency for review as part of the formal SNAP program, as discussed in Sections IV through IX of today's proposal.

B. Format for SNAP Determinations

Sections D through J below present the proposed decisions on acceptability of substitutes that EPA has made based on available information and the proposed evaluation criteria (see Section V of today's proposal). These sections describe the application (e.g., industrial-process refrigeration), the substitutes evaluated, the proposed decision (i.e., acceptable or unacceptable) and associated rationale, conditions for use of the substitute, and any general comments.

In most cases, the application descriptions have been written broadly to encompass numerous industrial uses. Based on discussions with industry, the Agency felt that this approach was preferable to listing substitutes by narrowly-defined applications, which would increase needlessly the number of SNAP notices that would be received by the Agency. The objective of section 612 is to ensure that replacements of Class I and Class II substances with available substitutes will reduce adverse effects on human health and the environment. In general, the Agency can look at exposures from very broad classifications of use (e.g., metals cleaning) and perform the screening analysis to ensure that this statutory objective is being met. It is not necessary or helpful, for example, to list acceptable substitutes by each specific type of metal being cleaned in the solvents sector. This is especially true
when conservative assumptions used in the screening analysis demonstrate the acceptability of a wide range of alternatives. EPA requests comment on the descriptions of industrial applications and solicits comment and data, in particular, on those instances where more detail may be needed.

Where possible, the substitutes presented in sections D through J have been identified by their chemical name. Generally speaking, EPA has not listed substitutes by product or company name in order to avoid implied endorsement of one substitute over another.

However, there are two instances in which specific chemical names have not been included. First, where proprietary blends have been identified as substitutes, the Agency has worked with the manufacturers to identify generic ways in which the substitute could be listed. Before a user invests in a substitute in these categories, they may wish to contact the SNAP coordinator to confirm that the substitute they intend to use has been reviewed and approved by EPA. However, if a potential user identifies the substitute by a product name that EPA has on record, but has not included on the list for the reasons stated above, EPA will confirm the listing of the substitute without violating any proprietary business information provided in confidence to the Agency. The Agency requests comment on this proposed approach for listing and disseminating information on confidential substitutes.

The second instance in which EPA does not anticipate listing specific chemicals arises in the solvent-cleaning sector, primarily for aqueous and semi-aqueous cleaners. In this area, numerous cleaning formulations exist and are comprised of a wide variety of chemicals. As discussed in the section below on solvent-cleaning alternatives (see Section IX. F.), the Agency performed its screening assessment by identifying representative chemicals. These were then used to screen a wide variety of chemicals grouped into categories of solvent-cleaning constituents (e.g., saponifiers, surfactants, etc.). Rather than require users to compare the toxicity of chemicals in the formulations they wish to use to this set of reference chemicals, the Agency is proposing to use its risk screen to establish a list of common types of chemicals found in cleaning formulations. This list could then be used by companies as guidance on the types of chemicals expected to be found in a cleaning formulation.

EPA proposes this strategy for listing acceptable aqueous and semi-aqueous cleaners for several reasons. First, it should minimize the need to submit SNAP notices for blends of compounds that are combinations of the chemicals on the cleaning formulation components list. Second, it will allow EPA to avoid listing proprietary formulations. The Agency requests comment on the usefulness of this proposed approach for listing aqueous and semi-aqueous cleaners.

Any conditions for use included in listing decisions are part of the decision to identify a substitute as acceptable. Thus, users would be considered out of compliance if using a substitute listed as "acceptable" without adhering to the conditions EPA has stipulated for acceptable use of the alternative. The conditions, if any, are listed when it is clear that a substitute can only be used safely if certain precautions are maintained. As noted previously, listing of substitutes as approved subject to conditions will be done through rulemaking.

The comments contained in the table of listing decisions found in summary form in Appendix B are intended to provide additional information on a substitute. Since comments are not part of the regulatory decision, they are not mandatory for use of a substitute. However, EPA encourages users of approved substitutes to apply any comments in their use of these substitutes. In many instances, the comments simply allude to good operating practices that have already been identified in existing industry and/or building-code standards. Thus, many of the comments, if adopted, would not require significant changes in existing operating practices for the affected industry.

C. Decisions Universally Applicable

Recently, the Agency has become aware of substitute mixtures that are being marketed as replacements for both Class I and Class II chemicals. In situations where these mixtures are a combination of Class I and Class II chemicals, they may serve as transitional chemicals because they offer environmental advantages in that they have a lower combined ODP than use of a Class I compound by itself. However, where EPA has identified an alternative in addition to the Class I and Class II mixture and that alternative reduces overall risk to human health and the environment, such mixtures shall be unacceptable.

There have been a few instances in which mixtures of Class I and Class II chemicals have been marketed as replacements for Class II chemicals. Because the ODP of these alternatives is clearly higher than the Class II substances, the Agency is proposing to prohibit the use of any Class I and Class II mixture as a replacement for a Class II chemical. Where the Agency is aware of specific mixtures falling into this category, they are listed by individual use sector below. The remainder of this section presents the initial listing decisions for each of the following end use sectors:

D. Refrigerants

F. Foams Cleaning
G. Solvents
H. Sterilants
I. Aerosols
J. Tobacco Expansion
K. Adhesives, Coatings and Inks

1. Overview

The refrigeration industry was the first to make widespread use of CFCs after this class of chemical compounds was discovered in the 1930s. In 1990, refrigeration and air conditioning accounted for almost 22 percent of the total use of Class I substances in the United States. Over 500 million pieces of refrigeration and air conditioning equipment use these chemicals as the working fluids in a vapor compression cycle.

Many Class I substances exhibit desirable thermophysical properties for use in refrigeration cycles. They are relatively nontoxic, nonflammable, and inexpensive to produce; all these characteristics have contributed to their appeal as refrigerants. CFC-12 is the most widely used refrigerant, with applications in mobile air conditioners (MACs), household refrigerators and freezers, various appliances, chillers, retail food refrigeration equipment, cold storage warehouses, refrigerated transport systems, and industrial equipment. CFC-11 is most commonly used to provide cooling for large buildings, while CFC-115, as a component in the refrigerant blend R-502, is used for low temperature applications. CFC-113 and CFC-114 are used in special application chillers.

Of the Class II controlled substances, HCFC-22 is the refrigerant of choice in small to medium air conditioning systems, and some types of retail food and industrial process refrigeration systems.

Chillers used for commercial air conditioning can be categorized by cooling capacity. The most common options for capacities below 200 tons are usually reciprocating chillers operating with HCFC-22. These chillers are usually air-cooled. Water cooling
requires the use of cooling towers and a steady supply of water.

There is a greater range of options for air conditioners in the cooling capacity range of 150 to 1200 tons. Low-pressure centrifugal chillers using HCFC-123 are available for this capacity. In addition, screw and centrifugal chillers using higher pressure refrigerants such as HCFC-22 or HFC-134a are also available for these capacities.

For chiller cooling capacities above 1200 tons, high-pressure centrifugal chillers currently dominate the market. At least two manufacturers offer factory-packaged HCFC-22 centrifugals up to roughly 2000 tons. Field-erected systems are available in larger sizes. Multiple low-pressure HCFC-123 centrifugals are also an option.

Alternative substances, such as lithium bromide/water absorption chillers, are also available with cooling capacities up to 1500 tons or more. These systems use heat, usually from steam or natural gas, to power the refrigeration cycle. Ideal applications are those where waste heat above 200 °F is available. For chiller applications is for heat recovery when a great deal of heat below 150 °F is required and there is a significant cooling load. Another application, mainly for cold storage warehouses, involves lowering the pressure at which natural gas travels through pipelines at pressure drop stations to achieve cooling of a transfer medium, such as methanol/water or ethylene glycol.

EPA has divided the refrigeration and air conditioning sector into the following general end uses:

- commercial comfort air conditioning ( chillers) — centrifugal, reciprocating, and screw chillers used to provide air conditioning;
- residential refrigerators;
- residential freezers;
- residential dehumidifiers used to control the humidity in homes;
- cold storage warehouses — public and private facilities used to store meat, produce, dairy products, frozen foods, and other perishable goods;
- commercial ice machines — equipment used to produce ice for commercial purposes;
- industrial process refrigeration systems used in the chemical, pharmaceutical, petrochemical, and other manufacturing and food processing industries, as well as industrial ice machines and ice rinks;
- transport refrigeration, including refrigerated ship holds, trucks and truck trailers, railway freight cars, and shipping containers;
- retail food refrigeration, including equipment found in supermarkets, convenience stores, restaurants, hotel and institutional kitchens, and other food service establishments;
- mobile air conditioning used to control passenger compartment humidity and temperature in cars, trucks, buses, planes and other vehicles;
- residential and commercial air conditioning and heat pumps — window units, packaged terminal air conditioners, direct-expansion air conditioners, and heat pumps.

Industry has invested heavily in the search for suitable alternative refrigerants that exhibit the favorable characteristics of the controlled substances, but that do not contribute to stratospheric ozone depletion or global warming. The hydrochlorofluorocarbons (HCFCs) and hydrofluorocarbons (HFCs) have received the most attention, along with expanded use of traditional refrigerants such as ammonia and hydrocarbons. In some cases, the most promising solution appears to be a blend of refrigerants. The 1991 report by UNEP’s Refrigeration, Air Conditioning, and Heat Pumps Technical Options Committee contains detailed information about the status of alternative refrigerants in various applications.

Clearly, an important role will be played by blends of refrigerants. There are currently multiple blends in various stages of research, testing and market development, and as the search for optimal replacements continues, the number of blends will increase. Because of the impossibility of performing full SNAP analyses for all possible blends in all conceivable permutations, the Agency, between proposal and issuance of the final rule, will explore ways to streamline EPA’s consideration of substitute refrigerant blends under the SNAP program.

One issue which EPA will be investigating further with respect to refrigerant blends is differential fractionation which may result in flammability and energy efficiency problems. For example, in a centrifugal chiller system equipped with a flooded evaporator (liquid refrigerant is situated on the outside of tubes through which water is flowing), the evaporator may act as a distillation device for the blend. The higher-pressure components may boil first and change to vapor, while the lower-pressure components remain as a liquid. This process artificially lowers the refrigerant pressure in the evaporator which, in turn, reduces the efficiency and capacity of the chiller. Similar reductions also can occur when using a low refrigerant velocity blend shellside in a condenser. In this situation, the low-pressure components condense first, leaving the vapor “rich” in high pressure components and causing an increase in condensing pressure.

The section which follows discusses specific determinations on individual substitutes by application. Appendix B at the end of this notice summarizes in tabular form the Agency’s proposed determinations on substitutes in the refrigerants sector, which are presented here in narrative form. These proposed determinations are based on the risk screening described in the draft background document entitled “Risk Screen on the Use of Substitutes for Class I Ozone-Depleting Substances: Refrigerants”.

2. Alternative Refrigerants

a. Hydrochlorofluorocarbons. EPA believes that hydrochlorofluorocarbons (HCFCs) have a potentially important role to play as transitional refrigerants, both in retrofit applications and in new equipment. HCFCs have the disadvantage that they contribute to the destruction of stratospheric ozone, although to a much lesser extent than CFCs. Use of HCFCs until safer alternatives are available will allow industry to move away from CFC refrigerants more rapidly. EPA believes that this approach will have environmental and health benefits over one that allows continued use of CFCs until equipment that uses other alternatives is available.

HCFCs are chemically similar to CFCs except that they contain hydrogen in addition to chlorine and fluorine. Because their thermophysical properties are, in many cases, similar to CFCs, equipment designed to use CFCs can sometimes be retrofitted to operate with HCFCs. HCFC-22 has been used as a refrigerant for many years. It is the primary refrigerant used in small to medium sized air conditioners, and has found increasing application in medium temperature retail food refrigeration systems. HCFC-123 holds promise as the primary replacement for CFC-11 in low pressure centrifugal chillers. HCFC-124 has potential applications in blends as a refrigerant in chillers and other refrigeration equipment.

Because they contain hydrogen, the HCFCs break down more easily in the atmosphere, and therefore have lower ODPs. They also have global warming potentials lower than the CFCs. Production of HCFCs is controlled by the Clean Air Act and was initially scheduled to be phased out by 2030. EPA, however, is reexamining these dates in response to new data indicating greater risks of ozone depletion. Based


on these new concerns, EPA may propose an earlier phase-out for some of the HCFCs, particularly those with higher ozone-depleting potentials. As noted above, EPA believes that HCFCs will play an important role as transitional refrigerants. There are clear environmental and health benefits to be gained by their use until better substitutes are developed. Future EPA analysis under the SNAP program will focus on HCFC-22 applications and substitutes.

b. Hydrofluorocarbons. Hydrofluorocarbons (HFCs) do not contain chlorine and do not contribute to destruction of stratospheric ozone. HFCs have zero ODPs, but some HFCs contribute to global warming. Their general use is one or more years away in some applications; in other applications, the shift to their use has already begun. Although a few HFCs have been in use for some time (HFC-152a is a component in the azeotropic blend CFC-500 used in smaller tonnage reciprocating equipment and large tonnage centrifugal equipment), the potential for HFCs as a replacement for CFCs has grown rapidly over the last several years. HFC-134a and HFC-152a hold the most promise as currently available replacements for Class I and Class II refrigerants and development of HFC-32 as a possible alternative has progressed.

c. Hydrocarbons. Since hydrocarbons do not contain chlorine or bromine, they do not contribute to ozone depletion. They degrade in the atmosphere, contributing to smog, but not significantly to global warming. Propane, ethane, propylene, and to some extent butane are used as refrigerants in specialized industrial applications, primarily in oil refineries and chemical plants, where they are frequently available as part of the process stream and where their use contributes only slightly to the incremental risk of fire or explosion. These systems are designed to meet rigid requirements for reliability, durability, and safety. ASHRAE Standard 15, “Safety Code for Mechanical Refrigeration,” and Standard 34, “Refrigerants,” are incorporated into building codes in most of the U.S. These standards limit use of flammable refrigerants in many applications. Hydrocarbon refrigerants are also used in limited applications in some small appliances.

d. Ammonia. Ammonia has been used as a refrigerant in vapor compression cycles for more than 100 years. It is by far the refrigerant of choice in the meat packing, chicken processing, dairy, frozen juice, brewery, cold storage, and other food processing and industrial applications. It is also widely used to refrigerate holds in fishing vessels. Industrial process refrigeration equipment uses rotary screw or reciprocating compressors. Ammonia is mainly used when moderate to low temperatures are required. Ammonia has a characteristic pungent odor, excellent refrigeration properties, no long term atmospheric drawbacks, and is low in cost. However, it is moderately flammable and toxic, although it is not a cumulative poison. OSHA standards specify a 15 minute short-term exposure limit of 35 ppm for ammonia.

e. Perfluorocarbons. Perfluorocarbons (PFCs) are fully fluorinated compounds, unlike CFCs, HCFCs, or HFCs. The principal environmental concern for these compounds is that they have extremely long atmospheric lifetimes, often orders of magnitude longer than the CFCs. These long lifetimes cause the PFCs to have very high global warming potentials. Technology for containment and recycling of PFCs is commercially available and is recommended by manufacturers to offset any possible adverse environmental effects. An important advantage of the PFCs is that, unlike CFCs or HCFCs, they do not contribute to ozone depletion. In addition, these chemicals are nonflammable, essentially nontoxic, and are exempted from Federal VOC regulations since they do not contribute to ground-level ozone formation.

Under Section 612, the Agency has completed an analysis showing the global warming that might be expected from atmospheric emissions of these compounds. The Agency further anticipates that additional, more detailed analysis of the environmental effects of PFCs will show that in widespread use, these compounds would pose higher overall risk relative to other available alternatives. Due to these concerns, the Agency has found acceptable only certain narrowly defined uses of perfluorinated compounds. EPA has described these limited acceptable uses as specifically as possible. The Agency requests comment on whether further narrative is needed to adequately describe these uses. Further, users should be aware that, because of the environmental concerns detailed above, any uses of PFCs outside those described herein should be submitted for future review and approval under SNAP.

f. Absorption refrigeration systems. Absorption refrigeration systems are the only major existing alternative to systems based on vapor compression cycles. Ammonia is also used in absorption refrigeration and air conditioning systems. Small ammonia refrigeration units are popular in recreational vehicles and in some household applications as they need no electrically driven mechanical compressor, relying instead on a propane flame as an energy source. Small refrigerators using absorption technology are produced for use in hotel rooms, where the focus is on their silent operation rather than the lack of a suitable supply of electricity. Small absorption systems use hydrogen to maintain a system pressure high enough to allow the ammonia refrigerant to evaporate at low pressure and temperature (and condense at room temperature), and are constructed to withstand high internal operating pressures. The absorption mechanism itself is a sealed unit, which usually needs no servicing over its operating life.

Commercial ammonia absorption systems are used for air conditioning, comfort cooling, particularly where waste heat is available. As with all chillers, these produce chilled water, which is circulated to the space being cooled. Lithium bromide is also used in commercial absorption systems, where it serves as an absorber. Such systems operate at very low pressure to allow water to act as a refrigerant. Lithium bromide is a relatively nontoxic, nonflammable, nonexplosive, chemically stable compound. Both types of absorption chiller systems have been traditional competitors of electrically driven CFC chillers.

New Technologies. Chlorine has been proposed as a Class I substitute refrigerant for use in chlorine liquefaction, a processing step in the manufacture of the chemical. When chilled below its boiling point, chlorine can be stored as a liquid at atmospheric pressure, a method that for safety reasons is preferable to storing the chemical as a pressurized gas at ambient temperatures. Compatibility of the refrigerant with liquid chlorine is critical because of chlorine's high reactivity; CFC-12 has been widely used because it does not react with chlorine.

Chlorine compressors would be specialized units made to resist chemical attack by liquid and gaseous chlorine. Because a chlorine refrigeration system would use part of the process stream as the refrigerant, the proposed use of chlorine as a refrigerant is analogous to that of hydrocarbon refrigerants in the oil and gas industry. EPA has determined that if the refrigeration system is placed so that any leakage or losses of chlorine would...
be contained and neutralized by the process safety mechanisms, chlorine can be used safely in these specialized applications.

3. Preliminary Listing Decisions

a. General Conditions. (1) The use of HCFCs is acceptable. This determination shall not be considered to release any user from conformance with all other regulations pertaining to Class II substances. These include: (a) the prohibition against venting during servicing under section 608, which was effective July 1, 1992; (b) recycling requirements under section 608 once they are promulgated; (c) section 609 regulations in the case of motor vehicle air conditioners; and (d) the production phase-out of Class II substances under section 605, which is currently being revised as part of EPA's efforts to accelerate the phase-out of ozone-depleting chemicals.

(2) The use of HFCs is acceptable. This determination shall not be considered to release any user from conformance with the venting prohibition under section 606(c)(2), which takes effect November 15, 1995, at the latest.

b. Acceptable Substitutes. Substitutes are listed as acceptable by end use. Accordingly, the following list of acceptable substitutes are only approved for those end uses explicitly identified as acceptable. These substitutes are not identified as acceptable alternatives in any other end use described in this section until and unless a determination of acceptability has been made for any other end use. EPA recommends that the users of HCFCs, HFCs, and any other alternative refrigerants adhere to the provisions of ASHRAE Standard 15—Safety Code for Mechanical Refrigeration, and ASHRAE Standard 34—Number Designation and Safety Classification of Refrigerants.

(1) HCFC–123 is acceptable as a substitute for CFC–11 in centrifugal chillers, both in new equipment and in retrofits. HCFC–123 is also acceptable as a substitute for CFC–12 and CFC–500 in new centrifugal chillers. As noted above, users of HCFC–123 should adhere to ASHRAE Standards 15 and 34. EPA worker-monitoring studies of HCFC–123 show that 8-hour TWA can be kept within 1 ppm (less than the interim OEL of 10 ppm) when recycling and ASHRAE standards are followed.

(2) HCFC–22 is acceptable for use in new equipment in the following end uses:

- As a substitute for CFC–11 in centrifugal chillers;
- As a substitute for CFC–12 in centrifugal chillers, reciprocating chillers, cold storage warehouses, residential dehumidifiers, residential freezers, commercial ice machines, industrial process refrigeration equipment, refrigerated transport equipment, retail food systems, vending machines, and water coolers;
- As a substitute for CFC–500 in centrifugal chillers, dehumidifiers and refrigerated transport systems;
- As a substitute for CFC–502 in cold storage warehouses, residential dehumidifiers, commercial ice machines, industrial process refrigeration systems, refrigerated transport systems, and retail food systems.

HCFC–22 is acceptable for use in existing equipment, or retrofits, in the following end uses:

- As a substitute for CFC–12 in cold storage warehouses, industrial process refrigeration equipment, retail food systems, and vending machines;
- As a substitute for CFC–502 in cold storage warehouses, industrial process refrigeration equipment, retail food systems and refrigerated transport systems.

HCFC–22 is already used in a variety of air conditioning and refrigeration end uses. As a result, it is more widely available than any of the HFC substitutes.

(3) HFC–134a is acceptable for use in refrigeration equipment, refrigerated transport, retail food, vending machines, and mobile air conditioners.

(4) HFC–124 is acceptable as an alternative to new and retrofit CFC–114 centrifugal chillers in all applications.

(5) HCFC–22/Propane/HFC–125 blend is acceptable as a substitute for CFC–500 in refrigerated transport, both in new equipment and in retrofits. This blend is also acceptable as a substitute for CFC–502 in cold storage warehouses, industrial process refrigeration, refrigerated transport, and retail food equipment, both in new equipment and in retrofits. Flammability has been studied and shown to be controllable.

As with all blends, care must be taken in recycling to avoid mixing with other refrigerants.

(6) HFC–134a is acceptable for use in new equipment in the following end uses:

- As a substitute for CFC–11 in centrifugal chillers;
- As a substitute for CFC–12 in centrifugal chillers, dehumidifiers, and refrigerated transport;
- As a substitute for CFC–500 in industrial process refrigeration and refrigerated transport.

HFC–134a is acceptable for use in existing equipment, or retrofits, in the following end uses:

- As a substitute for CFC–12 in centrifugal chillers, reciprocating chillers, cold storage warehouses, residential dehumidifiers, industrial process refrigeration equipment, refrigerated transport systems, retail food systems, vending machines, and mobile air conditioners;
- As a substitute for CFC–500 in centrifugal chillers and refrigerated transport systems; and
- As a substitute for CFC–502 in industrial process refrigeration equipment, and refrigerated transport systems.

HFC–134a is potentially the most versatile substitute identified to date as it may be possible to use it in a broad range of applications. However, HFC–134a may be less energy efficient than HCFC–22 in some end uses.

(7) HFC–152a is acceptable as a substitute for CFC–12 in new household refrigerators and residential freezers.

(8) Ammonia is acceptable for use in new equipment in the following end uses:

- As a substitute for CFC–11 in centrifugal chillers;
- As a substitute for CFC–12 in centrifugal chillers, cold storage warehouses, commercial ice machines, industrial process refrigeration equipment, and retail food systems;
- As a substitute for CFC–500 in centrifugal chillers; and
- As a substitute for CFC–502 in cold storage warehouses, retail food systems, commercial ice machines, and industrial process refrigeration equipment.

(9) Butane is acceptable for use in new equipment as a substitute for CFC–
12 in industrial process refrigeration equipment. EPA recommends but does not require that butane only be used at industrial facilities which manufacture or use hydrocarbons in the process stream.

10 Chlorine is acceptable for use in new equipment as a substitute for CFC-12 in industrial refrigeration equipment, and as a substitute for CFC-502 in new industrial process refrigeration equipment. EPA recommends but does not require that chlorine only be used at industrial facilities which manufacture or use chlorine in the process stream.

11 Propane is acceptable for use in new equipment as a substitute for CFC-12 in industrial refrigeration equipment. EPA recommends but does not require that propane only be used at industrial facilities which manufacture or use hydrocarbons in the process stream.

12 Lithium bromide is acceptable for use in absorption refrigeration systems. It is acceptable as a substitute for CFC-11, CFC-12, and CFC-500 in new centrifugal chillers.

13 High to Low Pressure Stepdown Process is acceptable for use in energy recovery systems as a substitute for CFC-12 in new cold storage warehouse equipment.

14 HCFC-142b is acceptable as a substitute for CFC-114 in new centrifugal chillers.

b. Unacceptable Substitutes. (1) HCFC-22/HCFC-142b/CFC-12 blend is proposed unacceptable in all HCFC-22 refrigeration and air conditioning end uses. Because this blend contains CFC-12 (which has an ODP 20 times that of HCFC-22), it poses a greater risk to stratospheric ozone than the use of HCFC-22 alone. (2) HCFC-141b is proposed unacceptable as a substitute for CFC-11 in new centrifugal chillers. Flammability may be an issue. Further, this material is not generally available in new equipment. Finally, the material has a high ozone depletion potential. (3) HCFC-22/HCFC-142b/isobutane blend is proposed unacceptable for use as a substitute for CFC-12 in new mobile air conditioners. Flammability may be an issue, and the Agency's final determination in this case will depend on receiving adequate data on flammability and likely fractionation through permeable hoses. Submission of information from industry groups, such as from the Society for Automotive Engineers, for example, regarding refrigerant retrofit guidelines for specific equipment in motor vehicle air conditioners, would help EPA evaluate such issues as flammability and the effect of blends on recycling and recovery efforts.

4) Hydrocarbon Blend A is proposed as unacceptable for use as a substitute for all CFC-12 refrigeration uses. Flammability may be an issue. The Agency's final determination will depend on receiving adequate data on factors such as flammability and materials compatibility. EPA has not found any other substitutes to be unacceptable but may do so at a later date based on new data.

E. Foams

1. Overview

Foam plastics accounted for approximately 18 percent of all U.S. consumption of ozone-depleting chemicals on an ODP-weighted basis in 1990. Five Class I chemicals—CFC-11, CFC-12, CFC-113, CFC-114, and methyl chloroform—are used as blowing agents in foam production. These five compounds are used in a wide variety of applications.

The manufacture of foam plastics relies on the use of gas or volatile liquid blowing agents to create bubbles, or cells, in the plastic foam structure. Suitable blowing agents must conform to a number of criteria. They must be soluble in liquid but not in solid plastic, possess a suitable boiling point and vapor pressure, and they must not react with plastic. In addition, blowing agents with low thermal conductivity are desirable for use in insulating foams. CFCs possess these desirable properties, and hence have found widespread use as blowing agents in many foam plastics. Some foam plastics are characterized by a structure of closed cells that traps the blowing agent, while others have open cells that allow the blowing agent to escape. Although some rigid polyurethane packaging foams are open celled, most rigid foams have closed-cell structures. Many of these closed-cell, rigid foams are excellent insulating materials, because the blowing agent trapped within the cells can serve as a thermal insulator. Flexible foams, on the other hand, generally have open cells and are poor thermal insulators.

Foam plastics manufactured with CFCs fall into four major categories: polyurethane, phenolic, extruded polyurethane, and polyolefin. Historically, CFC-11 and CFC-113, which remain in a liquid state at room temperature, have been used as blowing agents in polyurethane and phenolic foams. CFC-12 and CFC-114, which have lower boiling points than CFC-11 and CFC-113 and are gases at room temperature, are used in polyolefin and polyurethane foams. In addition to CFCs, methyl chloroform is used as a blowing agent in some flexible polyurethane foams.

The major applications for foams are cushioning, packaging, and thermal insulation. In general, cushioning and packaging foams include flexible polyurethane foams, polyurethane integral skin foams, polyolefin foams, and polyurethane sheet foams, while insulating foams include rigid polyurethane foams, polyurethane insulation board, and phenolic insulation board. However, some rigid polyurethane foams and extruded polyurethane board have non-insulating uses in flotation and packaging products, and certain polyolefin foams have thermal insulating applications.

Due to the wide variety of end uses that foams represent, the Agency has decided to divide its analysis of foam plastics into the following ten distinct end-use sectors:

- rigid polyurethane laminated boardstock
- rigid polyurethane appliance
- rigid polyurethane spray and commercial refrigeration, and sandwich panels
- rigid polyurethane slabs and other foams
- polyurethane extruded insulation board
- phenolic insulation board
- flexible polyurethane
- polyurethane integral skin
- polyurethane extruded sheet; and
- polyolefin

The SNAP determinations proposed today distinguish between these ten end-use sectors because the mix of potential alternatives for Class I blowing agents is different for each.

Rigid polyurethane foams, which serve primarily as insulation for appliances, buildings, and refrigerated transport containers, rely heavily on the use of CFC-11 as a blowing agent. These foams also find use as pipe and tank insulation and as flotation material. The low thermal conductivity of CFC-11 endows many rigid polyurethane foams with excellent thermal insulating qualities. Moreover, low toxicity, low flammability, and compatibility with key materials have made CFC-11 the blowing agent of choice in most rigid polyurethane applications.

Extruded polyurethane insulation board, which has traditionally used CFC-12 as a blowing agent, serves as insulation for roofs, walls, and floors in residential and agricultural buildings, as insulation against frost heave in roads and railways, and as the insulating core material in sandwich panels. Phenolic insulation board, a closed-cell insulating foam that relies primarily...
on a blowing agent mixture of CFC-113 and CFC-11 for its manufacture, accounts for only a small proportion of the total CFC consumption in foam plastics. Closed-cell phenolic foam serves mainly as building insulation. The foam’s primary use is as roof insulation, although it also finds use as wall insulation in commercial applications and as sidewall sheathing in residential applications.

CFC-11 use was, at one time, prevalent in flexible polyurethane foams. However, the period between 1986 and 1990 saw a decrease of over 90 percent in the use of CFC-11 as an auxiliary blowing agent in flexible polyurethane foams. The reduction in CFC-11 use has, to some extent, been compensated for by increases in methyl chloride use. Polyurethane flexible slabstock foam is an open-celled flexible foam manufactured in a variety of densities and degrees of firmness that finds use in many cushioning applications. Polyurethane flexible molded foam, which is also open-celled, serves primarily as cushioning in motor vehicles.

The production of integral skin foams, which has also traditionally relied on CFC-11 as a blowing agent, has seen a reduction in CFC-11 consumption in recent years. Integral skin foams combine a flexible, semi-rigid, or rigid foam core with a tough outer skin. The skin results from the tendency of physical blowing agents such as CFC-11 to condense at the mold surface during manufacture. Rigid integral skin foams have applications in products such as computer cabinets, skis, and tennis rackets, while uses for semi-rigid integral skin foams include steering wheels, head rests, arm rests, office furniture, and certain other minor applications.

Extruded polystyrene sheet foam, which traditionally used CFC-12, has already switched to non-CFC alternatives. Extruded polystyrene sheet serves as food packaging in items such as meat trays, egg cartons, and clamshell containers. The foam also finds use as loose fill packaging material and as art board.

Traditionally, CFC-114 and CFC-12 have been the main blowing agents used in the production of extruded polyolefin foams, although some CFC-114 has been used as well. Polyolefin foams include products manufactured from either polyethylene or polypropylene resins. Extruded polyethylene sheet products serve primarily as protective packaging for furniture, electronics, and other goods. Extruded polyethylene planks are mainly used as packaging for electronics and other high-value goods but have a number of other applications in areas such as military packaging, flotation, construction, and aircraft seating. Extruded polypropylene sheet serves as packaging in applications such as interleaving, protective furniture covering, and protective wrap for delicate food items.

2. Alternative Blowing Agents

The foam industry in the U.S. has been successful in identifying, developing, and introducing substitutes for CFC blowing agents. However, the choice of future alternatives for CFCs will depend on a number of factors. These include toxicity, flammability, environmental concerns, and, in the case of insulating foams, the insulating efficiency of alternatives.

Toxicity concerns associated with the use of alternative chemicals relate to the exposure of workers and consumers to the chemicals or to the decomposition products these chemicals may form slowly over time in foam products. The likely degree of human health risk associated with an alternative depends not only on the nature of a substitute chemical but also on the chemical composition, manufacturing process, and product applications that characterize the foam end-use sector into which that substitute will be introduced.

Flammability concerns, like toxicity concerns, have to do with possible danger to workers and consumers. Such danger includes possible ignition of materials during manufacturing, storage, or transportation and the fire hazard posed by the final product. Alternatives to CFCs have varying degrees of flammability. As in the case of toxicity, however, the composition, production processes, and end-use applications that characterize each foam type will dictate the potential risks associated with flammability.

In addition to posing toxicity and flammability risks, alternatives may have deleterious effects on the environment. Such deleterious effects may include stratospheric ozone depletion, global warming, and contribution to smog formation. HCFCs have, in varying degrees, the potential to deplete ozone; both HCFCs and HFCs have global warming potential; and various potential alternatives, especially hydrocarbons, are volatile organic compounds (VOCs) that contribute to the formation of ozone, or smog, in the lower atmosphere.

The use of alternative blowing agents can have an adverse effect on the insulating capability of foam products. Based on initial tests, for example, the replacement of CFCs with HCFCs in insulating foams reduced insulating efficiency. However, formulation changes and modifications to the foam technology have yielded HCFC-blown products with insulating efficiency equivalent to CFC-blown products. In fact, most efforts to replace CFC blowing agents in insulating foams over the near term involve HCFCs, although HFCs and hydrocarbons may serve as alternatives in a limited number of applications.

In the flexible and packaging foam sectors, there has already been widespread movement away from CFCs to alternative, non-HCFC auxiliary blowing agents and production processes. Water, which generates CO2, is the primary blowing agent for flexible polyurethane foams. Auxiliary blowing agents like CFC-11, methylene chloride or acetone confer certain desirable physical characteristics, such as softness or low density, to the finished product. This trend away from use of CFCs is likely to continue in light of EPA’s proposed regulations under section 610 of the CAA that would, beginning on November 15, 1993, ban the sale of CFCs in flexible and packaging foams. Also, beginning on January 1, 1994, section 610 bans sale of noninsulating foams manufactured with Class II substances. Foam used in food packaging must in addition meet the regulatory requirements of the FDA.
The continued availability of HCFCs, even those with relatively high ODPs, is necessary to ensure the continued replacement of CFC blowing agents with alternative compounds in the short term. Production of HCFCs is controlled by the Clean Air Act and under section 605 is scheduled for phase-out by 2030. However, due to new data concerning greater risks of ozone depletion, EPA has proposed an accelerated phase-out schedule. Given the technical and safety concerns associated with many non-HCFC alternatives, however, disallowing the interim use of HCFCs in all foam sectors, including the use of HCFC-141b and HCFC-22, would have adverse effects on human health and the environment.

Additional restrictions on HCFC use may be made subject to final promulgation of section 610 for nonessential uses. Section 610 states that after January 1, 1994, it shall be unlawful for any person to sell or distribute, or offer for sale, any plastic foam product which contains, or is manufactured with, a Class II substance. Section 610(d)(2) authorizes EPA to grant exceptions to the Class II ban for foam insulation products, or foam used for motor vehicle safety in accordance with section 103 of the National Traffic and Motor Vehicle Safety Act on federal motor vehicle safety standards.

b. Hydrofluorocarbons (HFCs). Hydrofluorocarbons (HFCs) represent a zero-ODP alternative to CFC blowing agents in many sectors. From the standpoint of stratospheric ozone depletion alone, HFCs are preferable to HCFCs as alternative blowing agents. However, other considerations such as flammability and cost may limit the feasibility of HFC alternatives, especially in the short term. Moreover, the relatively high thermal conductivity of HFCs is likely to hamper the insulating capabilities of HFC-blown foams. This, in turn, could result in energy efficiency losses.

Two HFCs, HFC-134a and HFC-152a, are under consideration as substitutes in a number of applications. Because both compounds have boiling points that are significantly lower than that of CFC-11, significant technical and process modifications would be required to introduce them as replacements for CFC-11. The HFCs hold more promise as near- or intermediate-term alternatives for CFC-12 in extruded polystyrene foams, particularly in extruded polystyrene sheet foams. However, issues such as flammability, cost, commercial availability, and the solubility of HFCs in polystyrene polymer remain of concern for extruded polystyrene foams. Both HFC-134a and HFC-152a have significantly higher thermal conductivities than do any of the CFCs. Although formulation changes and process modifications can be introduced to increase the thermal insulating efficiency of HFC-blown foams, it is unlikely that such changes can compensate fully for the disparity in thermal conductivity between HFCs and CFCs, especially in the near term. As a result, conversion to HFCs would likely lead to the production of foams with lower insulating efficiency and, possibly, to a reduction in the energy efficiency of buildings, appliances, refrigerated transport containers, and other insulated items.

Conversion to hydrocarbons may entail significant capital investment in order to ensure worker safety against fire hazards. Moreover, in the case of insulating foams, manufacturers will need to guarantee that foams blown with hydrocarbons meet the building code requirements that apply to the flammability of building materials.

Hydrocarbons are VOCs that contribute to the formation of ozone, or smog, in the lower atmosphere. Any use of hydrocarbon blowing agents is subject to the federal and regional restrictions that apply to VOCs, and conversion to hydrocarbons could involve the capital investment necessary to comply with these restrictions.

Hydrocarbons have proven effective as replacements for CFCs in many noninsulating foams. However, the Agency believes that, although hydrocarbons have the potential to replace CFC blowing agents in insulating foams, they are unlikely to replace CFCs in insulating foams over the short term.

d. Other. Two other blowing agents, methylene chloride and acetone, have proven effective as substitutes for CFC-11 in flexible polyurethane foams. Methylene chloride, which already serves as an auxiliary blowing agent for most grades of flexible polyurethane foam, is commercially available, has relatively low cost, and provides a technically feasible alternative to CFC-11. However, because of concerns over its high toxicity, methylene chloride use is restricted in several states and localities; and is subject to review under Title III of the CAA.

Acetone, when used as a blowing agent, is capable of yielding all grades of flexible polyurethane foam. It can serve as an alternative blowing agent where methylene chloride use is infeasible. Acetone is a VOC and must be controlled as such. In addition, plant modifications may be necessary to accommodate acetone's flammability.

The AB Technology is a commercially available and technically feasible process for replacing CFCs or other auxiliary blowing agents for most conventional flexible foam grades. AB Technology employs formic acid in conjunction with water as the blowing agent for producing flexible polyurethane foam. The process is based...
on using the reaction of formic acid with an isocyanate to produce carbon monoxide in addition to the water/isocyanate reaction normally used to generate carbon dioxide gas for the expansion of foam. OSHA has set a permissible exposure level (PEL) for carbon monoxide of 35 ppm of a time weighted average with a ceiling not to exceed 200 ppm.

Carbon dioxide (CO₂) is an acceptable substitute for all foam end-uses. One hundred percent CO₂ blowing is achieved by further increasing the water content in the foam formulation, thereby eliminating the need for a physical blowing agent. CO₂ blends acceptable as long as the other constituents of the blend are acceptable under SNAP.

3. Primary Listing Decisions

a. Acceptable Substitutes

(1) Polyurethane, Rigid Laminated Boardstock. (a) HCFC-123

HCFC-123 is acceptable as an alternative blowing agent to CFC-11 in rigid polyurethane laminated boardstock foam. From the standpoint of technical feasibility, HCFC-123 represents a viable alternative to CFC-11 as a potential blowing agent. More specifically, the physical properties, thermal conductivity, and aging of foams blown with HCFC-123 are similar to those blown with CFC-11. As a result, HCFC-123, which has an ozone depleting potential significantly lower than that of CFC-11, has the potential to replace CFC-11 in many applications. Nonetheless, availability of HCFC-123 is limited at present, and furthermore industry may be unable to meet the relatively low interim OEL of 10 ppm set by the manufacturer. However, recent worker monitoring studies indicate that an interim OEL of 10 ppm can be achieved through the use of increased ventilation, good housekeeping and work practices, and dust collection. HCFC-123 is subject to the phase-out of Class II compounds under section 605 of the CAA.

(b) HCFC-141b

HCFC-141b is acceptable as an alternative to CFC-11 in rigid polyurethane laminated boardstock foam. Although its ODP of 0.11 is relatively high, HCFC-141b, because it can serve as a virtual drop-in substitute for CFC-11, offers almost immediate transition out of CFCs in this sector. Not only does HCFC-141b offer a technically feasible alternative to CFC-11, but it is currently available or will soon be available in sufficient quantities to meet industrial demand. The Agency has proposed restricting the use of HCFC-141b in the proposed accelerated phase-out of HCFCs in light of its relatively high ODP and the fact that other zero-ODP substitutes should be available by the phase-out dates. HCFC-141b is currently subject to the phase-out of Class II compounds under section 605 of the CAA.

(f) HCFC-22/HCFC-142b

The HCFC-22/HCFC-142b blend is acceptable as a substitute for CFC-11 in rigid polyurethane laminated boardstock foam. The blend offers an alternative with significantly less potential to deplete ozone than CFC-11. Nevertheless, certain technical problems persist. Namely, plant modifications are required to allow use of blowing agents like HCFC-22 and HCFC-142b that have low boiling points, and the blend's chemical and physical characteristics may lead to rapid aging of the foam. Finally, use of the blend results in potentially significant losses in thermal insulating efficiency. The HCFC-22/HCFC-142b blend is subject to the phase-out of Class II compounds under section 605 of the CAA.

(g) HCFC-141b/HCFC-123

The HCFC-141b/HCFC-123 blend is acceptable as an alternative to CFC-11 in rigid polyurethane laminated boardstock foam. As noted above, HCFC-141b, because of its commercial availability and ability to serve as a virtual drop-in substitute for CFC-11, offers an immediate opportunity to replace CFC-11. HCFC-123, although it has the technical requirements necessary to replace CFC-11, suffers from limited availability and concerns over whether the interim OEL can be met. The HCFC-141b/HCFC-123 blend offers an opportunity to use HCFC-123 while at the same time allaying those concerns to some degree. Moreover, because the ODP of HCFC-123 is lower than that of HCFC-141b, the blend has a lower ODP than HCFC-141b alone. Nevertheless, the blend, because of the HCFC-141b component, is subject to the proposed accelerated phase-out of HCFCs. The HCFC-141b/HCFC-123 blend is also currently subject to the phase-out of Class II compounds under section 605 of the CAA.

(h) HFC-134a

HFC-134a is acceptable as a substitute for CFC-11 in rigid polyurethane laminated boardstock foam. HFC-134a offers the potential for a non-ozone-depleting alternative to CFC-11 blowing agents in rigid polyurethane laminated boardstock foams. The use of HFC-134a as a blowing agent in rigid polyurethane laminated boardstock foams is currently not commercially feasible. Plant modifications may be necessary to accommodate the use of HFC-134a because its boiling point is lower than that of CFC-11. In addition, there are
concerns over commercial availability, the cost of HFC-134a is likely to be high, and the use of HFC-134a may cause significant increases in thermal conductivity, with a concomitant loss in the insulating capacity of foams blown with HFC-134a.

(i) HFC-152a

HFC-152a is acceptable as a substitute for CFC-11 in rigid polyurethane laminated boardstock foam. HFC-152a offers the potential for a non-ozone-depleting alternative to CFC-11 blowing agents in rigid polyurethane laminated boardstock. The use of HFC-152a as a blowing agent in rigid polyurethane laminated boardstock foam is currently not commercially feasible, and there are concerns over the potential for significant increases in thermal conductivity. Process changes may be necessary to accommodate the use of HFC-152a, and plant modifications may be necessary to manage its flammability. Also, foams blown with HFC-152a will need to conform with building code requirements that relate to flammable materials.

(j) Hydrocarbons

Hydrocarbons are acceptable as substitutes for CFC-11 in rigid polyurethane laminated boardstock foam. Of the hydrocarbons, pentane has the greatest potential as a replacement for CFC-11 in this sector of the foam industry. However, the use of pentane as a blowing agent in rigid polyurethane laminated boardstock foam is currently not commercially feasible. Moreover, extensive plant modifications may be necessary to accommodate the use of pentane and other hydrocarbons. In addition, these materials pose flammability concerns. Further, there is a potential for significant increases in thermal conductivity that could reduce insulating capacity; studies suggest that pentane could increase thermal conductivity by 15 to 20 per cent over CFC-11, for example. Foams blown with hydrocarbons will need to conform with building code requirements that relate to flammable materials. Finally, pentane and other hydrocarbons are VOCs and must be controlled as such under Title I of the CAA.

(k) 2-Chloropropane

2-Chloropropane is acceptable as a substitute for CFC-11 in rigid polyurethane laminated boardstock foam. At present, because 2-chloropropane is a proprietary technology, its commercial availability may be limited. Moreover, 2-chloropropane is flammable and its use may require extensive modification of existing equipment.

(i) Carbon Dioxide

Carbon dioxide is acceptable as a substitute for CFC-11 in rigid polyurethane laminated boardstock foam.

(2) Polyurethane, Rigid Appliance Foam

(a) HFC-123

HCFC-123, for the reasons described and with the caveats outlined in the section on rigid polyurethane laminated boardstock, is acceptable as an alternative to CFC-11 in rigid polyurethane appliance foam.

(b) HCFC-141b

HCFC-141b, for the reasons described and with the caveats outlined in the section on rigid polyurethane laminated boardstock, is acceptable as a substitute for CFC-11 in rigid polyurethane appliance foam.

(c) HCFC-22

HCFC-22, for the reasons described and with the caveats outlined in the section on rigid polyurethane laminated boardstock, is acceptable as a substitute for CFC-11 in rigid polyurethane appliance foam.

(d) HCFC-142b

HCFC-142b is acceptable as a substitute for CFC-11 in rigid polyurethane appliance foam. HCFC-142b offers an alternative with significantly less potential to deplete ozone than CFC-11. Nevertheless, certain technical problems persist. Namely, plant modifications are required to allow the use of blowing agents like HCFC-142b that have low boiling points. HCFC-142b is subject to the phase-out of Class II compounds under section 605 of the CAA.

(e) HCFC-22/HCFC-142b

The HCFC-22/HCFC-142b blend is acceptable as a substitute for CFC-11 in rigid polyurethane appliance foam. The blend offers an alternative with significantly less potential to deplete ozone than CFC-11. Foams blown with the blend have been developed that have thermal insulating capabilities equivalent to foams blown with CFC-11. However, technical problems remain. New plastic materials may be needed for appliances to counteract the solvent characteristics of HCFC-22, and significant process changes would be necessary to accommodate the low boiling point of the HCFC-22/HCFC-142b blend. The blend is subject to the phase-out of Class II compounds under section 605 of the CAA.

(f) HCFC-22/HCFC-141b

The HCFC-22/HCFC-141b blend is acceptable as a substitute for CFC-11 in rigid polyurethane appliance foam. Because both components of the blend are commercially available in large enough quantities to meet industry demand, it offers a near-term vehicle for replacing CFC-11 in rigid appliance foams. Use of the blend, because of its HCFC-141b component, will be restricted under the proposed accelerated phase-out of HCFCs, since other non-ODP substitutes should become available. The problem of toxic decomposition byproducts, although present, is controllable. However, new plastic materials may be needed for appliances to accommodate the use of HFC-134a as a blowing agent in rigid polyurethane appliance foam. However, technical problems exist over the potential for significant increases in thermal conductivity, with a concomitant loss in insulating capacity; studies suggest that pentane could increase thermal conductivity by 15 to 20 per cent over CFC-11, for example. Foams blown with hydrocarbons will need to conform with building code requirements that relate to flammable materials.
with building code requirements that relate to flammable materials. Hydrocarbons are VOCs and will be subject to control as such under Title I of the CAA.

(k) Carbon Dioxide

Carbon dioxide is acceptable as a substitute for CFC-11 in rigid polyurethane appliance foam.

(3) Rigid Polyurethane Commercial Refrigeration Foam, Spray Foam, and Sandwich Panels (a) HCFC-123

HCFC-123, for the reasons described and with the caveats outlined in the section on rigid polyurethane laminated boardstock, is acceptable as an alternative to CFC-11 and CFC-12 in rigid polyurethane commercial refrigeration foam, spray foam, and sandwich panels.

(b) HCFC-141b

HCFC-141b, for the reasons described and with the caveats outlined in the section on rigid polyurethane laminated boardstock, are acceptable alternative blowing agents for CFC-11 and CFC-12 in rigid polyurethane commercial refrigeration foam, spray foam, and sandwich panels.

(h) Hydrocarbons

Hydrocarbons, for the reasons described and with the caveats outlined in the section on rigid polyurethane laminated boardstock, are acceptable alternative blowing agents for CFC-11 and CFC-12 in rigid polyurethane commercial refrigeration foam, spray foam, and sandwich panels.

(i) Carbon Dioxide

Carbon dioxide is an acceptable alternative blowing agent for CFC-11 in rigid polyurethane commercial refrigeration foam, spray foam, and sandwich panels.

(a) Polyurethane Slabstock and Other Foams (a) HCFC-123

HCFC-123 is acceptable as an alternative to CFC-11 in rigid polyurethane slabstock and other foams.

(b) HCFC-141b

HCFC-141b is acceptable as an alternative to CFC-11 in rigid polyurethane slabstock and other foams, provided that these foams are used for insulating or flotation purposes. Although its ODP of 0.11 is relatively high, HCFC-141b, because it can serve as a virtual drop-in substitute for CFC-11, offers almost immediate transition out of CFCs in this sector. Not only does HCFC-141b offer a technically feasible alternative to CFC-11, it is currently available in sufficient quantities to meet the demands of industry. The Agency will be proposing to restrict the use of HCFC-141b in the accelerated phase-out of HCFCs because other non-ODP substitutes should become available. The problem of toxic decomposition byproducts, although present, is controllable. With the exception of flotation foams, EPA believes that HCFC-141b is not acceptable for use in noninsulating applications, such as rigid polyurethane packaging or floral foams. The Agency has decided to allow the use of HCFC-141b in rigid polyurethane flotation foams until January 1, 1994, the effective date of the section 610 ban on Class II noninsulating foams manufactured with HCFCs becomes effective. HCFC-141b is also subject to the phase-out of Class II compounds under section 605 of the CAA.

(c) HCFC-22

HCFC-22 is acceptable as a substitute for CFC-11 and CFC-12 in rigid polyurethane commercial refrigeration foam, spray foam, and sandwich panels.

(d) Hydrocarbons

Hydrocarbons, for the reasons described and with the caveats outlined in the section on rigid polyurethane laminated boardstock, are acceptable alternative blowing agents for CFC-11 and CFC-12 in rigid polyurethane slabstock and other foams.

The HCFC-22/HCFC-142b blend, for the reasons described and with the caveats outlined in the section on rigid polyurethane laminated boardstock, is acceptable as an alternative to CFC-11 and CFC-12 in rigid polyurethane commercial refrigeration foam, spray foam, and sandwich panels.
(e) Carbon Dioxide

Carbon dioxide is an acceptable alternative blowing agent for CFC-11 and CFC-12 in rigid polyurethane slabstock and other foams.

(5) Extruded Polystyrene Insulation Board. (a) HCFC–22

HCFC–22 is an acceptable alternative blowing agent for CFC–12 in extruded polystyrene boardstock foam. HCFC–22 offers an alternative with significantly less potential to deplete ozone than CFC–12. HCFC–22, however, has a relatively high permeation rate out of polystyrene thus affecting insulation performance. HCFC–22 is subject to the phase-out of Class II compounds under section 605 of the CAA.

(b) HCFC–142b

HCFC–142b is an acceptable alternative blowing agent for CFC–12 in extruded polystyrene boardstock foam. HCFC–142b offers an alternative with significantly less potential to deplete ozone than either CFC–11 or CFC–12. HCFC–142b is subject to the phase-out of Class II compounds under section 605 of the CAA.

(c) HCFC–22/HCFC–142b

The HCFC–22/HCFC–142b blend is acceptable as a substitute for CFC–12 in extruded polystyrene boardstock foam. The blend offers an alternative with significantly less potential to deplete ozone than CFC–12. The blend is subject to the phase-out of Class II compounds under section 605 of the CAA.

(d) HFC–134a

HFC–134a is acceptable as a substitute for CFC–12 in extruded polystyrene insulation board foam. HFC–134a offers the potential for a non-ozone-depleting alternative to CFC–12 blowing agents in extruded polystyrene insulation board. HFC–134a, because of its low flammability and encouraging performance in toxicological testing, exhibits definite advantages from the standpoints of environmental risk and worker and consumer safety. However, HFC–134a has relatively high thermal conductivity and cost. In addition, the compound has poor solubility in polystyrene polymer, which could limit its usefulness as an alternative blowing agent from a technical standpoint.

(e) HFC–152a

HFC–152a is acceptable as a substitute for CFC–12 in extruded polystyrene insulation board foam. HFC–152a offers the potential for a non-ozone-depleting alternative to CFC–12 blowing agents in extruded polystyrene boardstock. However, the high flammability of HFC–152a when combined with its properties of high thermal conductivity, low solubility in polystyrene polymer, and high permeability through polystyrene limit the extent to which HFC–152a is likely to replace CFC–12. Plant modifications may be needed to accommodate the flammability of HFC–152a, and foams blown with HFC–152a will need to conform with building code requirements that relate to flammable materials.

(f) Hydrocarbons

Hydrocarbons are acceptable as substitutes for CFC–12 in polystyrene insulation board foam. Of the hydrocarbons, pentane, isopentane, butane, and isobutane have been demonstrated as feasible blowing agents in polystyrene. In fact, hydrocarbons have been used for years in the manufacture of extruded polystyrene sheet products. However, hydrocarbons have several disadvantages as blowing agents in extruded polystyrene boardstock. Replacement of CFC–12 blowing agents with hydrocarbons is likely to reduce significantly the insulating efficiency of extruded polystyrene boards. Moreover, hydrocarbon-blown foams cannot presently attain the thickness that CFC-blown foams do. Controlling the flammability of hydrocarbons entails significant investment in plant conversion to accommodate them as alternatives to CFC–12. Also, foams blown with hydrocarbons will need to conform with building code requirements that relate to flammable materials. Finally, hydrocarbons are VOCs and must be controlled as such under Title I of the CAA.

(g) HCFC–22/Hydrocarbons

Blends of HCFC–22/hydrocarbons, for the reasons described and with the caveats outlined above for HCFC–22 and hydrocarbons, are proposed as acceptable substitutes for CFC–12 in extruded polystyrene boardstock foam.

(h) Carbon Dioxide

Carbon dioxide is an acceptable alternative blowing agent for CFC–12 in extruded polystyrene boardstock foam.

(6) Phenolic Insulation Board. (a) HCFC–141b

HCFC–141b, for the reasons described and with the caveats outlined in the section on rigid polyurethane laminated boardstock, is acceptable as an alternative to CFC–11 and CFC–113 in phenolic insulation board.

(b) HCFC–142b

HCFC–142b, for the reasons described and with the caveats outlined in the section on rigid polyurethane commercial refrigeration foams, spray foams, and sandwich panels, is acceptable as an alternative to CFC–11 and CFC–113 in phenolic insulation board.

(c) HCFC–22

HCFC–22, for the reasons described and with the caveats outlined in the section on rigid polyurethane laminated boardstock, are acceptable alternatives to CFC–11 and CFC–113 in phenolic insulation board.

(d) HCFC–22/HCFC–142b

The blend HCFC–22/HCFC–142b, for reasons described above and with the caveats outlined above for HCFC–22 and HCFC–142b, is acceptable as an alternative to CFC–11 and CFC–113 in phenolic insulation board.

(e) Hydrocarbons

Hydrocarbons, for the reasons described and with the caveats outlined in the section on rigid polyurethane laminated boardstock, are acceptable alternatives to CFC–11 and CFC–113 in phenolic insulation board.

(f) HCFC–22/Hydrocarbons

HCFC–22/Hydrocarbon blends are acceptable a substitute for CFC–11 and CFC–113 in phenolic insulation board. HCFC–22/hydrocarbon blends offer an alternative with significantly less potential to deplete ozone than either CFC–11 or CFC–113. However, extensive plant modifications may be necessary to accommodate use of these blends. In addition, there are concerns about the potential for significant increases in thermal conductivity resulting from the replacement of CFC–11 and CFC–113 with a blend. Also, foams blown with hydrocarbons will need to conform with building code requirements that relate to flammable materials. Hydrocarbons are VOCs and must be controlled as such under Title I of the CAA.

(g) 2-Chloropropane

2-Chloropropane is acceptable as a substitute for CFC–11 and CFC–12 in phenolic insulation board. At present, because 2-chloropropane is a proprietary technology, its commercial availability may be limited. Moreover, 2-chloropropane is flammable and its use may require extensive modification of existing equipment.
(b) Carbon Dioxide

Carbon dioxide is an acceptable alternative blowing agent for CFC-11 and CFC-12 in phenolic insulation board.

(7) Flexible Polyurethane Foam. (a) Methylene Chloride

Methylene chloride is acceptable as a blowing agent in flexible polyurethane foams, provided that it is used in accordance with relevant OSHA standards and that its use meets future ambient air control for hazardous pollutants under Title III of the CAA. Methylene chloride is already used as an auxiliary blowing agent in the manufacture of most flexible polyurethane slabstock foams and has proven adequate in yielding foams of many densities and degrees of softness. Replacement of CFC-11 or methyl chloroform blowing agents with methylene chloride can reduce the potential for stratospheric ozone depletion resulting from the production of flexible polyurethane foams.

Nevertheless, there is widespread concern over the potential health and safety hazards that methylene chloride poses. In fact, due to these concerns, some local and regional restrictions apply to the use of methylene chloride.

The Agency solicits comment on risks associated with the use of methylene chloride in open-cell foam blowing. For further details, refer to the background document entitled “Risk Screen on Use of Substitutes for Class I Ozone-Depleting Substances: Foams”.

In light of toxicity concerns, the Agency has decided to allow the use of methylene chloride subject to existing or future restrictions. Methylene chloride use must meet all future ambient air controls for hazardous air pollutants under Title III of the CAA. In addition, use of the compound must conform to all relevant workplace safety standards; OSHA has proposed permissible exposure levels (PELs) for methylene chloride of 25 ppm on a time-weighted average (TWA).

(b) Acetone

Acetone is acceptable as a blowing agent for flexible polyurethane foams, provided that it is controlled as a VOC under Title I of the CAA. In those areas where methylene chloride use is deemed unacceptable, acetone may provide another non-ODP alternative to CFC-11 and methyl chloroform. All grades of flexible polyurethane foam produced with CFCs can be produced using acetone as an auxiliary blowing agent. Acetone does not have an ozone depletion potential, its global warming potential is negligible. Nevertheless, acetone is highly flammable and its use requires special precautions to ensure adequate ventilation. In addition, the compound may be subject to controls as a VOC under Title I of the CAA.

(c) HCFC-123

HCFC-123, for the reasons described and with the caveats outlined in the section on rigid polyurethane laminated boardstock is acceptable as a blowing agent in flexible polyurethane foams.

(d) HFC-134a

HFC-134a is acceptable as a substitute for CFC-11 in flexible polyurethane foam. HFC-134a offers the potential for a non-ozone-depleting alternative to CFC-11 blowing agents in flexible polyurethane foam. The use of HFC-134a as a blowing agent in flexible polyurethane foams is currently not commercially feasible. Plant modifications may be necessary to accommodate the use of HFC-134a because its boiling point is lower than that of CFC-11. In addition, the cost of HFC-134a is high compared to CFC-11.

(e) HFC-152a

HFC-152a is acceptable as a substitute for CFC-11 in flexible polyurethane foam. HFC-152a offers the potential for a non-ozone-depleting alternative to CFC-11 blowing agents in flexible polyurethane foam. Process changes may be necessary to accommodate the use of HFC-152a, and plant modifications may be necessary to manage its flammability.

(f) AB Technology

AB Technology is acceptable as an alternative process in flexible polyurethane foams, provided that it is used in accordance with relevant OSHA standards. The AB Technology generates carbon monoxide as the chemical blowing agent. Actions to insure the safety of workers from exposure to elevated levels of carbon monoxide should be taken, particularly at the latter phases of production where ventilation is generally not as efficient as on the foam line. OSHA has set a permissible exposure level (PEL) for carbon monoxide of 35 ppm on a time-weighted average (TWA) with a ceiling of 200 ppm.

(g) Carbon Dioxide

Carbon dioxide is an acceptable alternative process in flexible polyurethane foams.

(8) Polyurethane Integral Skin Foams. (a) HCFC-123

HCFC-123 is acceptable as an alternative to CFC-11 in integral skin foams. From the standpoint of technical feasibility, HCFC-123 represents a viable alternative to CFC-11 as a potential blowing agent in integral skin foams. More specifically, the physical properties and aging of foams blown with HCFC-123 are similar to those blown with CFC-11. As a result, HCFC-123, which has an ozone depleting potential significantly lower than that of CFC-11, has the potential to replace CFC-11 in many integral skin applications. Nonetheless, commercial availability of HCFC-123 is limited at present, and it is not clear that industry can meet the relatively low interim OEL of 10 ppm set by the manufacturer.

Nevertheless, recent worker monitoring studies indicate that an interim OEL of 10 ppm can be achieved through the use of increased ventilation, good housekeeping and work practices, and dust collection. The use of HCFC-123 is subject to the provisions of section 610 of the CAA, which bans the use of Class II substances in noninsulating foams after January 1, 1994. The ban does not apply to certain integral skin foams used to provide for motor vehicle safety. HCFC-123 is subject to the phase-out of Class II compounds under section 605 of the CAA.

(b) HCFC-141b

HCFC-141b is acceptable as an alternative to CFC-11 in integral skin foams used for automotive safety, although its use will be subject to the proposed accelerated phase-out of HCFCs. Although its ODP of 0.11 is relatively high, because it can serve as a virtual drop-in substitute for CFC-11, HCFC-141b offers almost immediate transition out of CFC-11 in integral skin foams. Not only does HCFC-141b offer a technically feasible alternative to CFC-11, but it is currently available in sufficient quantities to meet the demands of industry. The Agency has chosen to restrict the use of HCFC-141b in light of the fact that other non-ODP substitutes should become available. Section 610 of the CAA, which bans the use of Class II substances in noninsulating foams after January 1, 1994, excludes certain automotive safety foams from the ban. The allowable use
of HCFC–141b shall be limited to those integral skin foams excluded from the ban under section 610. HCFC–141b is currently subject to the phase-out of Class II compounds under section 605 of the CAA.

(c) HCFC–22

HCFC–22 is acceptable as a substitute for CFC–11 in integral skin foam, although its use will be subject to the proposed accelerated phase-out of HCFCs. HCFC–22 offers an alternative with significantly less potential to deplete ozone than CFC–11. However, process changes may be necessary to accommodate the low boiling point of HCFC–22. The use of HCFC–22 in integral skin foams shall be subject to section 610 of the CAA, which bans the use of Class II substances in noninsulating foams after January 1, 1994. The ban does not apply to certain foams used to provide for motor vehicle safety. HCFC–22 is also subject to the phaseout of Class II compounds under section 605 of the CAA.

(d) HCFC–22/HCFC–141b

HCFC–22/HCFC–141b blend, for reasons described with the caveats outlined above for HCFC–22 and HCFC–141b, is an acceptable substitute for CFC–11 in integral skin foam used for automotive safety.

(e) HFC–134a

HFC–134a is acceptable as a substitute for CFC–11 in polyurethane integral skin foam. HFC–134a offers the potential for a non-ozone-depleting alternative to CFC–11 blowing agents in polyurethane integral skin foam. The use of HFC–134a as a blowing agent in flexible polyurethane foams is currently not commercially feasible. Plant modifications may be necessary to accommodate the use of HFC–134a because its boiling point is lower than that of CFC–11. In addition, the cost of HFC–134a is high compared to CFC–11.

(f) HFC–152a

HFC–152a is acceptable as a substitute for CFC–11 in polyurethane integral skin foam. HFC–152a offers the potential for a non-ozone-depleting alternative to CFC–11 blowing agents in polyurethane integral skin foam. Process changes may be necessary to accommodate the use of HFC–152a, and plant modifications may be necessary to manage its flammability. Also, foams blown with HFC–152a will need to conform with any requirements that relate to flammable materials.

(g) Hydrocarbons

Hydrocarbons are acceptable as substitutes for CFC–11 in integral skin foams. Hydrocarbons offer the possibility of a non-ODP replacement for CFC–11 in integral skin foams. However, the use of hydrocarbon blowing agents in integral skin foams is not commercially feasible at present. Moreover, extensive process modifications would be necessary to accommodate the flammability of hydrocarbons and to make the necessary technical and process modifications. Also, foams blown with hydrocarbons will need to conform with any requirements that relate to flammable materials. Hydrocarbons are VOCs and must be controlled as such under Title I of the CAA.

(h) Methylene Chloride

Methylene chloride is acceptable as a blowing agent in integral skin foam. See methylene chloride discussion under Polyurethane Flexible Foams for additional details on toxicity.

(i) Carbon Dioxide

Carbon dioxide is acceptable as a blowing agent in integral skin foams.

(j) Extruded Polystyrene Sheet Foam

(a) HFC–134a

HFC–134a is acceptable as a substitute for CFC–12 in extruded polystyrene sheet foam. HFC–134a offers the potential for a non-ozone-depleting alternative to CFC–12 blowing agents in polyurethane sheet foam.

(b) HFC–152a

HFC–152a is acceptable as a substitute for CFC–12 in extruded polystyrene sheet foam. HFC–152a offers the potential for a non-ozone-depleting alternative to CFC–12 blowing agents in extruded polystyrene sheet foams. The compound is commercially available and its low molecular weight suggests that its blowing efficiency will be double that of CFC–12. Plant modifications may be needed to accommodate the flammability of HFC–152a.

(c) Hydrocarbons

Hydrocarbons are acceptable as substitutes for CFC–12 in extruded polystyrene sheet foam. Hydrocarbons offer the potential for a non-ozone-depleting alternative to the use of CFC–12 blowing agents in extruded polystyrene sheet. At present, pentane and butane are used extensively as blowing agents in extruded polystyrene sheet. These compounds are widely available at low cost and offer excellent solubility with the polystyrene polymer. However, extensive plant modifications may be necessary to accommodate the use of hydrocarbons in place of CFC–12. In addition, hydrocarbons are VOCs and will be subject to control as such under Title I of the CAA.

(d) Carbon Dioxide

Carbon dioxide is acceptable as a substitute for CFC–12 in extruded polystyrene sheet foam.

(e) Polyolefin Foams

HFC–134a is acceptable as a substitute for CFC–11, CFC–12, and CFC–114 in polyolefin foams. HCFC–142b offers an alternative with significantly less potential to deplete ozone than CFC–11, CFC–12, or CFC–114. The use of HCFC–22 in polyolefin foams may be restricted under section 610 of the CAA, which bans the use of Class II substances in noninsulating foams after January 1, 1994. HCFC–22 is subject to the phase-out of Class II compounds under section 605 of the CAA.

(f) HCFC–142b

HCFC–142b is acceptable as a substitute for CFC–11, CFC–12, and CFC–114 in polyolefin foams. HCFC–142b offers an alternative with significantly less potential to deplete ozone than CFC–11, CFC–12, or CFC–114. The use of HCFC–142b in polyolefin foams may be restricted under section 610 of the CAA, which bans the use of Class II substances in noninsulating foams after January 1, 1994. HCFC–142b is subject to the phase-out of Class II compounds under section 605 of the CAA.

(g) HCFC–22/HCFC–141b

HCFC–22/HCFC–141b blends are acceptable, for reasons described with the caveats outlined above, as a substitute for CFC–11, CFC–12 and CFC–114 in polyolefin foam.

(h) HFC–134a

HFC–134a is acceptable as a substitute for CFC–11, CFC–12, and CFC–114 in polyolefin foams. HFC–134a offers the potential for a non-ozone-depleting alternative to CFC–11, CFC–12, or CFC–114. The use of HCFC–142b in polyolefin foams may be restricted under section 610 of the CAA, which bans the use of Class II substances in noninsulating foams after January 1, 1994. HCFC–142b is subject to the phase-out of Class II compounds under section 605 of the CAA.
CFC-11, CFC-12, and CFC-114 in polyolefin foams.

(f) Hydrocarbons

Hydrocarbons are acceptable as substitutes for CFC-11, CFC-12, and CFC-114 in polyolefin foams. Use of hydrocarbon blowing agents in polyolefin foams is not now commercially feasible. Extensive plant modifications may be necessary to accommodate hydrocarbon use due to flammability and technical considerations. Finally, hydrocarbons are VOCs and must be controlled as such under Title I of the CAA.

(g) HCFC-22/Hydrocarbons

HCFC-22/hydrocarbons blends, for the reasons described and with the caveats outlined above, are acceptable substitutes for CFC-11, CFC-12, and CFC-114 in polyolefin foams.

(h) Carbon Dioxide

Carbon dioxide is acceptable as a substitute for CFC-11, CFC-12, and CFC-114 in polyolefin foams.

3. Proposed Unacceptable Substitutes

The final listing of a foam blowing agent as unacceptable in a specific foam use sector constitutes a ban on the use of that alternative to Class I or Class II compounds in commerce. The Agency solicits comments on these proposed decisions. These decisions will be effective 30 days after publication of the final rule.

(1) Rigid Polyurethane Slabstock and Other Foams (Rigid Polyurethane Packaging Foams). (a) HCFC-141b

The use of HCFC-141b (or blends thereof) is proposed unacceptable as an alternative blowing agent in rigid polyurethane packaging foams with the exception of insulating and flotation foams. HCFC-141b has an ODP of 0.11, almost equivalent to that of methyl chloroform, a Class I substance. The Agency believes that non-ODP alternatives, or alternatives with lower ODPs, are sufficient to render the use of HCFC-141b unnecessary in this application.

(2) Flexible Polyurethane Foams. (a) HCFC-141b

The use of HCFC-141b (or blends thereof) is proposed unacceptable as an alternative blowing agent in flexible polyurethane foams. HCFC-141b has an ODP of 0.11, almost equivalent to that of methyl chloroform, a Class I substance. The Agency believes that non-ODP alternatives are sufficiently available to render the use of HCFC-141b unnecessary in this application.

(3) Integral Skin Foams. (a) HCFC-141b

Use of HCFC-141b (or blends thereof) is proposed unacceptable as an alternative blowing agent in integral skin foams, except where used for the purpose of motor vehicle safety. HCFC-141b has an ODP of 0.11, almost equivalent to that of methyl chloroform, a Class I substance. The Agency believes that non-ODP alternatives, or alternatives with lower ODPs, are sufficient to render the use of HCFC-141b unnecessary in this application. However, the use of HCFC-141b will be allowed in those integral skin automotive foams excluded from the ban on noninsulating foams under section 610 of the CAA.

(4) Polyolefin Foams. (a) HCFC-141b

The use of HCFC-141b (or blends thereof) is proposed unacceptable as an alternative blowing agent in polyolefin foams. HCFC-141b has an ODP of 0.11, almost equivalent to that of methyl chloroform, a Class I substance. The Agency believes that non-ODP alternatives, or alternatives with lower ODPs, are sufficiently available to render the use of HCFC-141b unnecessary in this application.

4. Solvents Cleaning

1. Overview

On an ozone-depletion weighted basis, solvents constitute approximately 15 per cent of the chemicals targeted for phase-out under the Montreal Protocol. In the U.S., the two Class I chemicals used as industrial solvents are CFC-113 (C\(_2\)F\(_3\)Cl, trifluorotrichloroethane) and methyl chloroform (C\(_2\)HCl\(_3\), 1,1,1-trichloroethane). The SNAP determinations proposed today focus on substitutes for these chemicals when used as industrial cleaning solvents, since this application comprises the largest use of CFC-113 and methyl chloroform (MCF).

Other cleaning applications for CFC-113 and MCF exist as well, such as in dry cleaning of textiles. In addition, these solvents are used as bearer media (such as lubricant carriers), mold release agents, component testing agents, coolants, or in other non-cleaning applications. For the reasons described earlier in this Preamble, the Agency proposes to exclude substitutes for these smaller uses from the SNAP determinations. As a result, the Agency is not at this time issuing any determinations on acceptability of such substitutes, and will neither approve nor restrict their use.

The three major cleaning applications that use CFC-113 and MCF are metals cleaning, electronics cleaning, and precision cleaning. Metals cleaning applications usually involve removing cutting oils and residual metal filings. This sector relies principally on MCF as a cleaning solvent. In contrast, the electronics industry uses principally CFC-113, for instance, to remove flux residues left after mounting parts on printed circuit boards. Precision cleaning also uses mostly CFC-113. This last application comprises a broad category of industrial cleaning operations and can cover uses ranging from cleaning printed circuit boards to cleaning direct access storage devices on computer.

Appendix B at the end of this Preamble lists in tabular form the Agency’s proposed determinations on substitutes in the cleaning sector. These proposed determinations are based on the risk screen described in the draft background document entitled “Risk Screen on the Use of Substitutes for Class I Ozone-Depleting Substances: Solvent Cleaning.” The table also includes as “pending” a number of substitutes that the Agency will issue determinations on in the next round of SNAP analyses. This table was compiled in part based on information on substitutes that companies submitted to the Agency in response to the January 16, 1992, Advance Notice of Proposed Rulemaking. In some cases, the Agency did not have adequate engineering or environmental information on these substitutes to permit a SNAP determination. Vendors or users of cleaning substitutes not described in Appendix B should submit information on these uses, so that the Agency can issue a SNAP determination.

In general, the solvents cleaning industry has been extremely successful at finding non-ozone-depleting alternatives to cleaning with CFC-113 and MCF. Numerous alternatives are already commercially available, and ongoing research and development promises to generate additional innovative solutions. The most creative approaches focus on changing the manufacturing process to remove the cleaning stage altogether. This change, in which producers rely on “no-clean” technologies, embodies one of the success stories in the search for alternatives—a pollution prevention approach that relies on cutting out the manufacturing step that creates the environmental problem rather than simply transferring the pollutants from one medium to another. The electronics industry in particular has many such cleaning alternatives that eliminate the need for CFC-113 and MCF. In metals cleaning, few “no-clean” alternatives are currently available, since the
manufacturing process is so heavily dependent on the use of oils as lubricants. However, no-clean approaches and products, such as vanishing oils, are being developed for cleaning metal parts and may soon be more broadly available.

Finding alternatives for CFC-113 and MCF in precision cleaning has been more difficult. Here, the industry has tried where possible to find and implement other cleaning options, but in some cases currently available alternatives simply do not meet the performance or safety criteria that would permit them to be used successfully.

2. Alternatives in Solvents Cleaning

a. Hydrochlorofluorocarbons (HCFCs)

HCFC-141b or HCFC-141b blends with alcohols are the principal HCFC alternative solvents to CFC-113/MCF cleaning. These alternatives can be used in vapor degreasing equipment, principally for electronics or precision cleaning, and some existing CFC-113 or MCF equipment can be retrofitted for use with HCFC-141b alternatives. From an environmental standpoint, the critical characteristic of HCFC-141b is that it has a relatively high ODP—0.11—the highest of all the HCFCs.

Another HCFC, HCFC-123, is generally not considered to have widespread application as a cleaner. Although this HCFC has the capacity to remove many soils, it is such an aggressive cleaner that it frequently degrades the surface of the part being cleaned. Additionally, toxicity concerns have limited commercial interest in HCFC-123 as a cleaning substitute. The Agency is currently investigating whether industry exposure standards for HCFC-123 can be met, and has therefore listed this chemical as "pending" approval.

HCFC-225, a third HCFC, is widely viewed as having potential as a cleaner, especially for precision cleaning. However, this chemical is not yet in widespread production or use. Further, HCFC-225 is still undergoing toxicity testing. Preliminary findings suggest that of the two HCFC-225 isomers, HCFC-225c is and HCFC-225cb, toxicity concerns associated with the ca-isomer may limit its commercial viability.

b. Semi-Aqueous Cleaning

Semi-aqueous cleaning is an alternative for cleaning in all three cleaning sectors. This process employs hydrocarbon/surfactant cleaners either emulsified in water solutions or applied in concentrated form and then rinsed with water. Since both approaches involve water as part of the formulation, the process is commonly referred to as "semi-aqueous." The principal categories of chemicals used in this process are terpenes, petroleum distillates, or alcohols. Surfactants are sometimes added to the formulation to increase wetting, emulsification and rinsing properties. Within each category of compounds, formulators draw from a wide variety of specific chemicals. For example, even though terpene-based cleaning often uses d-limonene, other terpene cleaners formulated with terpinols or terpinenes exist. A similar range of choices is available when selecting the surfactant.

To characterize environmental releases, EPA developed model processes intended to represent generic semi-aqueous cleaning scenarios. The purpose of developing the model processes was to portray the average use scenario, rather than to depict specific examples of cleaning applications. An extensive discussion of various semi-aqueous cleaning processes may be found in the Industry Cooperative for Ozone Layer Protection (ICOLP) documents on the subject.

c. Aqueous Cleaning

Aqueous cleaning, unlike semi-aqueous cleaning, uses water as the primary solvent. This process is used mostly for metals cleaning, but companies are beginning to explore options using these substitutes in other cleaning applications.

In aqueous cleaning, detergents and surfactants are combined in water with a variety of additives such as organic solvents (e.g., high-boiling point alcohols), builders, saponifiers, inhibitors, emulsifiers, Ph buffers and antifoaming agents. Builders such as alkaline salts usually make up a large portion of the formulation (other than water), and they are often used in blends of several chemicals. Surfactants comprise the other major portion; these chemicals are chosen for their detergent, emulsification or wetting properties.

The cleaning process is comparable to that used in semi-aqueous applications and consists of combinations of a wash phase, a rinse phase, and a drying phase. An important difference is that the wash tank is frequently heated to improve soil removal. The final step, drying, can be accomplished by use of heat or a drying agent.

A critical feature of aqueous cleaning, as with semi-aqueous cleaning, is the wide variety of chemicals chosen for the formulations. For each cleaning need, a vendor can tailor a formulation to the soils and parts—a process that produces innumerable combinations of chemicals in different concentrations. To capture this diversity, the Agency has chosen to adopt a screening approach that parallels the methodology described in the section on semi-aqueous cleaners.

d. Organic Solvents

Organic solvents can be used to replace CFC-113 and MCF in certain cleaning operations. The classification of organic solvents typically includes conventional organic solvents such as alcohols, ethers, esters and ketones. These compounds are commonly used in solvent tanks at room temperature, although the solvents can also clean in-line systems or be heated to increase solvency power. If heated, the solvents must be used in equipment designed to control vapor losses.

These solvents, unlike Class I and II compounds, do not contribute to stratospheric ozone depletion, and generally have short atmospheric lifetimes. Yet many of the organic solvents are regulated as VOCs because they can contribute to ground-level ozone formation. In addition, certain of the organic solvents are toxic to human health and are subject to workplace standards set by OSHA.

e. Other Chlorinated Solvents

In addition to MCF and CFC-113, the three other commonly used chlorinated solvents are trichloroethylene ("TCE"), methylene chloride ("methyl"), and perchloroethylene ("perc"). Unlike MCF and CFC-113, these chlorinated solvents have very short atmospheric lifetimes and are not considered to contribute to ozone depletion. However, all three have known toxicity problems and are regulated as Hazardous Air Pollutants under Title III of the Clean Air Act. They are also subject to stringent workplace standards set by the Occupational Health and Safety Administration. Additionally, TCE and perc exhibit photochemical reactivity, and are regulated as smog precursors.

The phase-out of CFC-113 and MCF has prompted a renewed interest in methyl, TCE, and perc, despite these toxicity concerns. The three solvents are mostly viewed as potential metal cleaning substitutes, especially since they can be used in conventional vapor degreasing equipment. In fact, these three solvents were the preferred industrial solvents until concerns about their toxicity and anticipated lowering of the Occupational Safety and Health Administration (OSHA) Permissible Exposure Limits (PELs) resulted in a switch by some users to MCF.

In response to such concerns, equipment vendors have now developed processes for using these solvents that significantly limit their emissions. The availability of such equipment has prompted environmental agencies in other western countries, such as
Class I compounds in electronics and (VMSs) are currently undergoing and linear volatile methyl siloxanes chemical properties. The Agency mixtures, depending on desired used either in isolation or in various applications. These compounds can be chlorobenzotrifluorides. offset any possible adverse recommended containment and recycling of PFCs is refrigerants chapter. Technology for Environmental concerns associated with magnitude longer than the CFCs. that they have extremely long atmospheric lifetimes, often orders of magnitude longer than the CFCs. Although these processes have the technical potential to meet a number of cleaning needs, the expense of the PFCs may limit wide-spread commercial interest in processes that use these compounds.

The principal environmental characteristic of concern for the PFCs is that they have extremely long atmospheric lifetimes, often orders of magnitude longer than the CFCs. Environmental concerns associated with use of PFCs are discussed in the refrigerants chapter. Technology for containment and recycling of PFCs is commercially available and is recommended by manufacturers to offset any possible adverse environmental effects.

h. Monochlorotoluene/ chlorobenzotrifluorides. Monochlorotoluene and chlorobenzotrifluorides are of commercial interest as solvent substitutes in a variety of cleaning applications. These compounds can be used either in isolation or in various mixtures, depending on desired chemical properties. The Agency recently received information on these formulations, and will issue a SNAP determination for these substitutes in the next set of listing decisions.

i. Volatile Methyl Siloxanes. Cyclic and linear volatile methyl siloxanes (VMSs) are currently undergoing investigation for use as substitutes for Class I compounds in electronics and precision cleaning. Because of their chemical properties, these compounds show promise as substitutes for cleaning precision guidance equipment in the defense and aerospace industries. In addition, the volatile methyl siloxanes have high purity and are therefore relatively easy to recover and recycle. In the cleaning process using VMS, the fluids are used to clean parts in a closed header system using a totally enclosed process. The parts are drained and then dried using vacuum baking.

j. Supercritical Fluid Cleaning. Plasma Cleaning, UV-Ozone Cleaning. Supercritical fluid cleaning, plasma cleaning, UV-ozone cleaning are all three high-technology methods of cleaning parts. These substitutes are mostly of interest for cleaning electronic parts or for precision cleaning.

k. Brominated Hydrocarbons. The Agency recently received notification that brominated hydrocarbons can be used as substitute cleaning agents, and will issue a SNAP determination on these chemicals in the next set of listing decisions.

3. Preliminary Listing Decisions


To complete its modeling of the ability of aqueous and semi-aqueous substitutes to replace CFC-113 and MCF in existing applications, the Agency examined their ability to meet the cleaning requirements posed in the metals cleaning sector. Each of these alternatives has the potential to service as much as 70 percent of the metals cleaning market. To date, companies have shown the greatest interest in aqueous cleaners for metals cleaning, which is why the Agency has made every effort to include review of this option in its first round of SNAP determinations.

The concern with the water-based processes has historically been the potential for adverse effects on aquatic life following discharge of wastewaters to surface water bodies. Examples of these effects include death to aquatic microorganisms, fish teratogenicity, or ecosystem effects such as inhibition of algal growth or bioconcentration. In this case, the Agency wanted to ensure that, in restricting the use of CFC-113 and methyl chloroform, it would not simply be replacing risks from air emissions with equal risks from contaminated water effluent.

To complete its risk analysis for the aqueous and semi-aqueous cleaners, the Agency developed a screening methodology designed to characterize risks presented by typical processes using these cleaners. The diversity of chemicals used in aqueous and semi-aqueous cleaning formulations turned this exercise into a complex undertaking. To complete its screen, the Agency projected concentrations in water for the "worst" or most toxic chemical that could be used in the water-based processes. These concentrations were based on the maximum possible concentration in the formulation and case studies documenting actual release profiles for several sample processes. The predicted concentrations obtained using this approach were then compared with toxicity values for this "worst" chemical.

The risk screen performed by the Agency did show a potential for adverse effects on aquatic life due to the inherent toxicity of some of these chemicals. However, the Agency believes that most risks presented by use of water-based processes can be controlled by adhering to requirements for wastewater treatment imposed by municipal or state authorities. In addition, the screen performed by the Agency that indicated the possibility of risks to aquatic life is likely to have overstated potential risks. For example, the screen did not account for several complex biological processes, including biodegradation and volatilization. The Agency is developing scientific studies to address these factors, and believes that once these factors are incorporated into the risk screen, the adverse effects will be significantly less.

The Agency believes that this approach to screening risks, although it does not examine the toxicity of each chemical and mixture or project exposures for each possible process, provides adequate perspective on the risks of these compounds compared with risks from the CFCs. The Agency solicits comments on this approach and data that could help refine the analysis of individual chemicals and mixtures. For example, the Agency's analysis did not specifically examine risks from mixtures of various chemicals where there could be synergistic effects. Although the Agency does not anticipate that such data would change the decision to list these substitutes as acceptable, the Agency hopes that a
better understanding of ecological effects of such substitutes will enhance its ability to assist users in choosing among substitutes and among formulations.

In an effort to further assist users in choosing substitutes with low environmental impacts, the Agency is currently developing a list of chemicals commonly used in the types of cleaners deemed acceptable under the SNAP program. The Agency encourages companies to ensure that substitutes sold as CFC-113/MCF replacements be formulated based on this list.

In addition, the Agency urges companies to adopt closed-loop recycling and recovery systems wherever possible to limit discharge of these chemicals. Users should also note that EPA is preparing new effluent guidelines under the Clean Water Act for this industry. These guidelines, expected to be issued by 1994, will address any remaining, uncontrolled risks deriving from the use of water-based cleaners in this industry.

(2) Electronics Cleaning (a) Semi-Aqueous/Aqueous Cleaners

In the area of electronics cleaning, semi-aqueous and aqueous cleaners were deemed to be acceptable substitutes. The justification for this determination is described in the section on metals cleaning. In this case, the Agency estimated that up to eighty per cent of the cleaning market could be captured by semi-aqueous processes and that up to sixty per cent of the market could be served by aqueous cleaners.

As in metals cleaning, the Agency urges companies to adopt pollution prevention practices and to formulate cleaners based on the cleaner constituent list.

(b) No-Clean Substitutes. No-clean processes are acceptable substitutes for ozone-depleting chemicals used in electronics cleaning. The Agency's analysis estimates that, over time, as much as seventy per cent of the electronics cleaning market could switch to no-clean processes—a projection that is borne out by the high degree of interest shown by electronics companies in these substitutes.

Concerns for risks deriving from use of no-clean processes focus primarily on worker safety. To examine these risks, the Agency looked at critical factors that distinguish no-clean processes from conventional electronics assembly.

These differences center on changes in the proportions of chemicals used in formulations, rather than on differences in the identity of chemicals selected. The analysis determined that occupational risks deriving from these differences are already well-documented and controlled, for example, through requirements specified on key Materials Safety Data Sheets and existing workplace regulations implemented by OSHA.

Additionally, the shifts in proportions of chemicals used in the formulation result in less waste than is normally generated through the traditional manufacturing process, resulting in a lower probability of adverse effects to the general population. The Agency also investigated the production of waste before and after the actual cleaning process and found that waste generation at these points in the production process would not be affected.

(c) Organic Solvents. Organic solvents are acceptable substitutes for CFC-113 and MCF in the electronics cleaning sector. The Agency's justification for this decision is described in the section on acceptable substitutes for metals cleaning.

(d) Other Chlorinated Solvents. Trichloroethylene (TCE),
perchloroethylene (perc) and methylene chloride (meth) are all acceptable substitutes for CFC-113 and MCF in the electronics cleaning sector, for the reasons described in the metals cleaning discussion. Although these solvents have not been as much commercial interest for electronics cleaning as for metals cleaning applications, the Agency did receive a request to review and approve these chemicals for electronics cleaning.

Although the Agency's risk screen focused on uses of these chemicals in metals cleaning applications, the screen suggests that release profiles for these chemicals in electronics cleaning will be either the same or lower. As a result, the Agency has reached the same conclusion in the metals cleaning analysis, namely that any risks due to the inherent toxicity of these chemicals could be controlled by existing and future regulatory standards.

However, the Agency has received some indication from industry experts that these solvents do not fill any special cleaning niche for the electronics industry. Based on a desire to control any unnecessary use of chemicals with such high inherent toxicity, the Agency requests comment on the availability of other alternatives and on whether there is a genuine need to use these chemicals in electronics cleaning applications.

(e) Perfluorocarbons. Use of perfluorocarbons (PFCs) in spot-free cleaning and drying of high-performance computer components is an acceptable substitute in cases where no other alternative exists that meets performance and safety standards. This would not include defluxing of printed circuit boards or cleaning of standard metal parts, since many other viable alternatives exist for these applications.

Global warming concerns associated with PFC use are discussed in the refrigerators chapter. Despite these concerns, the Agency has listed this niche application as an acceptable use of perfluorocarbons because it is aware that, for certain computer components, a PFC-based process may be the only viable process available to replace use of Class I or II compounds.

For example, in manufacture of certain direct access storage devices (DASDs) for computers, spot-free cleaning and drying using PFCs appears at the present time to be the only cleaning process that yields the necessary product performance (as opposed to cosmetic appearance). To make the technical improvements demanded of the storage devices, such as faster access times and higher recording densities, companies have been required to use magnetically superior materials. These materials are extremely prone to corrosion from water and are vulnerable to any contamination introduced in the manufacturing process, such as organic or particulate matter. Consequently, the storage device itself must be a miniature "clean room" if it is to perform correctly. Manufacturers of some DASDs can use water-based cleaners in much of the production process, but may need to rely on the PFCs as water-displacement agents to achieve the required high degree of cleanliness while protecting the water-sensitive materials in the device.

Another example of components where PFC-based cleaning may be necessary is data storage media. In cases where users must rely on PFCs due to lack of other options, they should make every effort to:
- Adopt closed systems and recover, recycle and destroy where possible
- Reduce emissions to a minimum through conservation practices that address venting losses, liquid drogout, and operator variables.
- Continue to search for long-term alternatives.

Examples of appropriate measures to reduce emissions include freeboard chillers, welded piping, and programmable handling devices. The Agency believes that it is reasonable to expect users to achieve favorable CFC/PFC replacement ratios since PFCs have relatively higher boiling points. In addition, the high price of PFCs makes additional containment cost-effective.

Prospective users should also note that companies investigating PFC use currently contend that within 3-8 years, it will be possible to replace the PFCs in cleaning equipment with other chemicals that have zero ozone depletion potential and very low global warming potential. As a result, they view use of the PFCs as an important but transitional solution to their cleaning needs. If PFCs are chosen, it is important for users to begin working with chemical manufacturers to start testing and qualifying these new materials to help speed conversion when the chemicals become commercially available.

In addition to the case cited earlier, the Agency is examining other possible necessary uses for PFCs as rinse agents to follow a water-free cleaning process or as drying or rinsing agents to follow a water-based cleaning process. Parts typically cleaned in these applications are characterized by vulnerable substrates, complex geometries, and exceptionally stringent cleanliness standards and include:

- Precision mechanical or electromechanical parts such as gyroscopes and accelerometers with complex structures and capillary spaces that could trap water or solvent residue
- Plastic parts with embedded iron or parts made from steel, lead or other materials subject to corrosion, oxidation or other damage from water (e.g., gallium arsenide, silicon nitride or magnesium parts)
- Plastic parts for the medical industry where extremely rigorous standards of cleanliness are necessary to ensure patient survival (e.g., kidney dialysis, implants, etc.)
- Electro-optical devices for weapon-targeting systems
- Ceramic or other porous materials for military, medical, safety or other high-value products, where any conductive residue could interfere with the component's performance
- Temperature-sensitive materials that cannot maintain component integrity at aqueous drying temperatures (e.g., where loss of dimensional stability is at issue)
- High-performance analytical devices where any residue could interfere with equipment accuracy.

The Agency solicits comment on the need to use PFCs in these applications or in any other specialized cleaning applications. In addition, the Agency seeks comment on the availability, performance, and economic feasibility of any cleaning alternatives that would eliminate the need for PFCs in these applications.

(f) Supercritical Fluid Cleaning. Plasma Cleaning, UV-Ozone Cleaning. Supercritical fluid cleaning, plasma cleaning, UV-ozone cleaning are all approved as substitutes in electronics cleaning. The Agency did not identify any environmental issues associated with use of these substitutes. Ozone is hazardous to human health, however, the Occupational Safety and Health Administration has already set standards for use of this compound in the workplace.

(3) Precision Cleaning. (a) Semi-Aqueous/Aqueous Processes.

Semi-aqueous and aqueous processes are approved for precision cleaning. The reasons for this decision are the same as those described in the metals cleaning section. Each of these alternatives has the potential to service approximately 65 per cent of the precision cleaning market. This figure may overestimate the technical potential for water-based processes in this sector, since industry feedback indicates that this end use sector faces the greatest technical
constraints in implementing new cleaning alternatives.

The Agency did not specifically examine risks from water-based processes used in precision cleaning. Instead, the analysis assumed that these risks would be either comparable to or less than risks associated with use of water-based processes for electronics cleaning.

(b) Other Chlorinated Solvents. These alternatives, for reasons described in the section on metals cleaning, are deemed acceptable substitutes for precision cleaning. For the analysis of risks from these substitutes in the precision cleaning and use sector, the Agency made the same assumptions as in its analysis for electronics cleaning applications of water-based processes, namely that exposures would be equal or less than exposures in the metals cleaning sector. Consequently, the Agency believes that risks would also be either equal or less.

(c) Organic Solvents. Organic solvents are acceptable substitutes for CFC-113 and MCF in the precision cleaning sector. The Agency’s justification for this decision is described in the section on acceptable substitutes for metals cleaning.

(d) Perfluorocarbons. Use of perfluorocarbons (PFCs) in spot-free cleaning and drying of high-performance computer components is an acceptable substitute in cases where no other alternative exists that meets performance or safety standards. This would not include defluxing of printed circuit boards or cleaning of standard metal parts. While the Agency is concerned about increased uses of PFCs due to global warming concerns as discussed in the refrigerants chapter, it believes that cases exist where a PFC-based process may be the only process available to replace use of Class I or II compounds. These cases are discussed in the section on acceptable substitutes for electronics cleaning.

(e) Supercritical Fluid Cleaning, Plasma Cleaning, UV-Ozone Cleaning. Supercritical fluid cleaning, plasma cleaning, UV-ozone cleaning are all approved as substitutes in precision cleaning. The Agency did not identify any environmental issues associated with use of these substitutes. Ozone is hazardous to human health, however, the Occupational Safety and Health Administration has already set standards for use of this compound in the workplace.

b. Proposed Unacceptable Substitutes

(1) Metals Cleaning. (a) HCFC-141b and its Blends

HCFC-141b and its blends are proposed to be prohibited as substitutes for CFC-113/MCF in metals cleaning, with limited critical use exceptions for CFC-113 replacements. The proposed effective date for this prohibition is 30 days after the date of the final rule for new equipment and as of January 1, 1996, for existing equipment. As discussed earlier in this action in Section VI.A, the Agency is authorized to grandfather existing uses from a proposed prohibition where appropriate under the four-part test established in Sierra Club v. EPA, supra.

The Agency has conducted the four analyses required under this test, and it has concluded that the balance of equities favors a grandfathering period of two years for existing equipment in this application. The prohibition proposed in this action clearly represents a departure from previously established practice, as use of the substitute was allowed previously. Existing users of HCFC-141b who switched from Class I substances into this solvent invested in this substitute on the assumption that it would be a sufficient improvement. Prohibiting their use of the substitute immediately would impose a severe economic burden on these users. These factors taken together outweigh any statutory interest in applying the new rule immediately to existing users. This is especially true since the restriction applies immediately to new equipment using HCFC-141b, which creates no incentive for continued investment in equipment using HCFC-141b in this application.

The Agency’s basis for proposing to restrict use of HCFC-141b is that this compound has a comparatively high ODP—0.11. This is the highest ODP of all the HCFCs; in fact, the ODP for 141b is nearly equal to the ODP for MCF (0.12). For this reason, the Agency proposes not to grant any exceptions for replacing MCF with 141b, since using 141b in place of MCF would negate the environmental benefits that the phase-out was designed to achieve.

To analyze the impacts from use of 141b as a CFC-113 replacement, the Agency estimated 141b use over time in each of the cleaning end uses, and projected health effects due to ozone depletion with the help of the Atmospheric Stabilization Framework model. The modeling period starts in 1990 and measures health effects expected for people born before 2030.

The findings of this modeling show adverse health effects of the magnitude commonly associated with the use of ozone-depleting compounds. For example, in the case of metals cleaning, the Agency projected that use of HCFC-141b to replace MCF where technically feasible could yield approximately 40,000 additional skin cancer cases and approximately 1,000 additional skin cancer fatalities compared to use of non-ozone-depleting substitutes.

The Agency believes that these figures and the availability of superior substitutes as described in the section on acceptable substitutes justify the proposal to list 141b as an unacceptable substitute. The Agency believes that, in almost all applications, other solvent cleaning substitutes are available that meet industry performance and safety criteria. To reach its decision on 141b use, the Agency also took into account the cost of other alternatives. The analysis suggested that, although 141b can be used with modification to existing equipment, the capital costs for the retrofit and the materials costs in combination would be so high as to render other alternatives comparatively affordable, even though they require new equipment.

Readers should note that 141b will be restricted as a substitute only where other alternatives exist to CFC-113 for the application in question. Several companies have already contacted the Agency, indicating that they have tested available alternatives to CFC-113, and that in some cases only HCFC-141b meets performance or safety criteria. The most commonly cited reasons for needing to use HCFC-141b are either applications where a non-flammable solvent is required for cleaning operational equipment or where sensitive parts could be destroyed by use of other cleaning processes.

For these applications of 141b, which the Agency refers to as “critical uses,” users may receive an exemption from the SNAP restrictions. Procedures for receiving a critical use exemption are described in Section VII.E. of today’s Preamble. Companies interested in these exemptions who believe they may qualify are encouraged to review this section. Companies who have already notified the Agency and requested permission for continued use of 141b will be contacted after this proposal so that the Agency can issue a formal critical use determination.

Companies should note that uses of 141b in existing solvent cleaning equipment would be permitted to continue until two years after the date of the final rule, as discussed above. The
The Agency solicits comment on the proposed effective date. The Agency believes that the decision to restrict 141b use as a CFC-113/MCF substitute for metals cleaning will have little effect on industry since few vendors of HCFC 141b have been selling 141b as a metals cleaning substitute. Companies in this end use sector that want to replace CFC-113 with 141b and feel they qualify for an exemption should review the section referenced above. The Agency expects to receive few such petitions, however, since most metals cleaning is currently performed with MCF.

(2) Electronics Cleaning. (a) HCFC-141b and its Blends

HCFC-141b and its blends are proposed to be prohibited as substitutes for CFC-113/MCF in electronics cleaning, with limited critical use exceptions for CFC-113 replacements. The reasons for this prohibition are the same as those for the decision on 141b as a metals cleaning substitute. As in the metals cleaning sector, the Agency proposes to grant limited critical use exemptions to this prohibition. The proposed effective date for this prohibition is 30 days after the date of the final rule for new equipment and January 1, 1996 for existing equipment. As discussed earlier in this action in Section VI.A., the Agency is authorized to grandfather existing uses from a proposed prohibition where appropriate under the four-part test established in Sierra Club v. EPA, supra.

The Agency has conducted the four analyses required under this test, and it has concluded that the balance of equities favors a grandfathering period of two years for existing equipment in this application. The prohibition proposed in this action clearly represents a departure from previously established practice, as use of the substitute was allowed previously. Existing users of HCFC-141b who switched from Class I substances into this solvent in this substitute on the assumption that it would be considered an acceptable substitute. It would impose a severe economic burden on these users to prohibit their use of the substitute immediately, with no provision of time to allow them to recover their investment in existing equipment or acquire new equipment in a timely fashion. These factors taken together appear to outweigh any statutory interest in applying the new rule immediately to existing users, especially since the restriction would apply immediately to new equipment using HCFC-141b, which would serve to prevent further ozone depletion from use of HCFC-141b in this application.

As with metals cleaning applications for 141b, the Agency modeled potential 141b use in electronics cleaning applications over time, and projected health effects due to ozone depletion with the help of the Atmospheric Stabilization Framework model. For electronics cleaning, the maximum market penetration for 141b as a replacement for CFC-113 is 90 per cent. With this penetration, the model predicted approximately 400 additional skin cancer fatalities and 30,000 additional skin cancer cases compared to uses of non-ozone-depleting substitutes.

(3) Precision Cleaning. (a) HCFC-141b

For the same reasons described in the section on metals cleaning, HCFC-141b and its blends are proposed to be prohibited as substitutes for CFC-113/MCF in precision cleaning, with limited critical use exemptions for CFC-113 replacements. The proposed effective date for this prohibition is 30 days after the date of the final rule for new equipment and as of January 1, 1996, for existing equipment. As discussed earlier in this action in Section VI.A., the Agency is authorized to grandfather existing uses from a proposed prohibition where appropriate under the four-part test established in Sierra Club v. EPA, supra.

The Agency has conducted the four analyses required under this test, and it has concluded that the balance of equities favors a grandfathering period of two years for existing equipment in this application. The prohibition proposed in this action clearly represents a departure from previously established practice, as use of the substitute was allowed previously. Existing users of HCFC-141b who switched from Class I substances into this solvent invested in this substitute on the assumption that it would be considered an acceptable substitute. It would impose a severe economic burden on these users to prohibit their use of the substitute immediately, with no provision of time to allow them to recover their investment in existing equipment or acquire new equipment in a timely fashion. These factors taken together appear to outweigh any statutory interest in applying the new rule immediately to existing users, especially since the restriction would apply immediately to new equipment using HCFC-141b, which would serve to prevent further ozone depletion from use of HCFC-141b in this application.

In the case of precision cleaning uses of HCFC-141b, the Agency’s modeling of 141b use as a CFC-113 replacement projected approximately 5,000 additional skin cancer cases when compared to use of non-ozone-depleting substitutes.

As in the case of other cleaning applications, the Agency proposes to prohibit substitutions of 141b to replace MCF, since these compounds have nearly identical ODPs. Here again, the Agency will propose to grant a limited number of critical use exemptions. Companies in this sector wishing to replace CFC-113 with 141b that may qualify for an exemption should review the section in today’s Preamble on critical use exemption petitions. The Agency expects most requests for permission to use 141b will come from this end use sector, and has already received a number of inquiries from companies that either use or want to use 141b as a substitute for cleaning with CFC-113.

G. Halons

1. Overview. Halons are gaseous or easily vaporizable halocarbons used primarily for putting out fires, but also for explosion protection. The two halons used most widely in the United States are Halons 1211 (chlorodifluorobromomethane) and 1301 (trifluorobromomethane). Halon 1211 is used primarily in stream applications, in which it is manually dispensed through a nozzle from a hand-held or portable extinguisher. Halon 1301 is used in total flooding and explosion protection applications in which a predetermined quantity of the gas is dispensed into a fixed location in order to achieve a specific extinguishing concentration of gas.

The principal use for Halon 1211 is in hand-held extinguishers in fixed facilities such as homes, offices, and military and government buildings. A small percentage of hand-held 1211 extinguishers are also used on aircraft in accordance with FAA regulations. Portable systems are used by military and commercial “crash/rescue” teams at airports. In order to evaluate 1211 substitutes in the variety of applications described above, the Agency has divided stream applications into three categories: residential, commercial/industrial, and military. This subdivision of the sector allows the Agency to properly account for differences in the types of fires likely to be encountered and in the types of proposed extinguishers.

Halon 1301 systems are used in combination with automatic fire detection equipment as total flooding agents in contained areas. Most Halon 1301 total flooding systems are used to...
controlled and balanced against the risk evacuation of personnel. Again, possible agent, often without providing time for suppression require rapid discharge of concentration. Both inertion and explosion, or deflagration, that has agent is discharged to mitigate an to cause an explosion. In suppression, concentration for a specified amount of inerting agent must disperse uniformly needed to prevent an explosion. The atmosphere is explosion suppression. In inertion, the explosion protection applications which include large numbers of workers or large capital investments may be at risk. In this latter case, precautions must be taken to avoid exposing occupants to toxic levels of extinguishant. Typically, these chemicals are used in conjunction with fire detection devices, alarm devices to warn occupants of impending discharge, as well as manual abort mechanisms to delay discharge until occupants are evacuated or to prevent accidental discharges. Some systems also incorporates a ‘lockout’ mechanism to prevent discharge if anyone in the event personnel must enter the area in an emergency. Some occupational or military settings involve flammable liquids or vapors (Class B fires) where the speed of the potential fire event precludes evacuation prior to discharge. The design of a system that acts quickly to the threat of fire or explosion must consider the effects of human exposure to the protecting agent. Halon 1301 can also be used in explosion protection applications which include explosion inertion and explosion suppression. In inertion, the atmosphere is filled with an explosion protection agent at the concentration needed to prevent an explosion. The inerting agent must disperse uniformly and remain at the required concentration for a specified amount of time. Effective inertion systems require the timely detection of conditions likely to cause an explosion. In suppression, an agent is discharged to mitigate an explosion, or deflagration, that has already begun. The agent must surround the expanding fireball at a specified concentration. Both inertion and suppression require rapid discharge of agent, often without providing time for evacuation of personnel. Again, possible exposure of occupants to toxic levels of the compound must be carefully controlled and balanced against the risk of explosion. Some limited use of Halon 2402 also exists in the United States, but only as an extinguishant in engine nacelles (the streamlined enclosure surrounding the engine) on older aircraft and in the guidance system of Minuteman missiles. Halons also find limited application in other use sectors such as plasma etching. Decisions proposed in this notice do not address these other sectors, but instead focus on fire protection applications which comprise the vast majority of applications. Halons are used in a wide range of fire protection applications because they combine five characteristics. First, they are highly effective against solid, liquid/ gaseous, and electrical fires (referred to as Class A, B, and C fires, respectively). Second, they are clean agents; that is, they dissipate rapidly, leaving no residue and therefore do not cause "secondary damage" to the property they are protecting. Third, halons do not conduct electricity and can be used in areas containing live electrical equipment. Fourth, halons are gaseous substances that can penetrate in and around physical objects to extinguish fires in otherwise inaccessible areas. Finally, halons are generally safer for limited human exposure when used with proper exposure controls. Despite these advantages, halons are among the most ozone depleting chemicals in use today. Halon 1301 has an estimated ODP of 16; Halon 1211 has an estimated ODP of 4. Thus, while total halon production (measured in metric tons) comprised just 2 per cent of the total production of Class I substances in 1986, halons represented 25 per cent of the total estimated ozone depletion potential of CFCs and halons combined. Halons therefore make up the largest use sector in terms of ozone depleting potential. The greatest releases of halon into the atmosphere occur not in extinguishing fires, but during testing and training, service and repair, and accidental discharges. Data generated as part of the Montreal Protocol's technology assessment indicate that only 15 per cent of annual Halon 1211 emissions and 18 per cent of Halon 1301 emissions occur as a result of use to extinguish actual fires. These figures indicate that significant gains can be made in protecting the ozone layer by revising testing and training procedures and by limiting unnecessary discharges through better detection and dispensing systems for halon and halon alternative systems. Additional information on specific halon uses can be found in the Montreal Protocol 1991 Assessment or in other background material in the public docket. The initial determinations found in this section are based on the risk screen described in the draft background document entitled "Characterization of Risk from the Use of Substitutes for Class I Ozone- Depleting Substances: Fire Extinguishing and Protection (Halon Substitutes)."

2. Substitutes for Halons. The fire protection community has made considerable progress in identifying and developing substitutes for halons in fire protection applications. Several manufacturers have submitted information regarding substitute streaming and total flooding agents, and the National Fire Protection Association (NFPA) has initiated efforts to develop standards for their use in total flooding scenarios. In addition, manufacturers are seeking Underwriters Laboratories (UL) and Factory Mutual (FM) certifications for systems employing the new agents. The Agency's review of halon substitutes is intended not to replace, but to complement the guidance of the fire protection community in directing the transition away from halons to substitutes that are less destructive to the stratosphere. Most recent efforts to develop substitutes for halon have focused primarily on halocarbon chemicals. These are considered potential "replacements" for halon because they possess halonlike properties (gaseous, non-conducting) and because they can be used on Class A, B, and C fires. These halocarbon replacements can be distinguished by the mechanism by which they extinguish fires. Chemical action agents, like halons, suppress fires by interfering with the free radical chain reactions that sustain a fire. Physical action agents cool, dilute, or smother the fire (separating the air and fuel). In general, chemical action agents are much more effective fire suppressants than physical action agents. Halocarbons represent only a portion of agents available for fire protection. Water mist or fog is a newly developing technology that uses fine water droplets to suppress and extinguish fires. Studies indicate that water mist can be used in a wide variety of applications for occupied and unoccupied areas including electronics, machinery spaces, enclosed spaces, etc. Several other "alternative" agents such as water, carbon dioxide, foam, and dry chemicals are already in widespread use as fire extinguishants and can be expected to find limited use as substitutes for halon. Unlike some halocarbons, these alternative agents are not effective against all types of fire. They do not all have the same penetration capability, nor are they all non-conducting and non-toxic. Thus, each can be used only in specified applications as directed by
manufacturers and by fire protection authorities such as the NFPA. However, these alternatives should seriously be considered as appropriate replacements to halons where systems are being redesigned. Substitutes for halons, whether other halocarbons or alternatives such as water, must meet four general criteria. They must be effective fire protection agents, be readily available, have a low environmental impact, have low toxicity, and they must be relatively clean or volatile. In addition, they must be commercially available as a halon replacement in the near future.

The halon system requires special evaluation of consumer and worker exposures to discharges of halon substitutes during fire emergencies and accidental discharges. In these acute, episodic exposures to the halon substitutes, cardiac sensitization is of particular interest. The term cardiac sensitization refers to an increased susceptibility of the heart to adrenaline (or other catecholamines) which may result in potentially fatal heart arrhythmias.

Human heart arrhythmias and sudden deaths resulting from overexposure to CFCs, halons, and other halogenated hydrocarbons have been documented in workplace settings, and in volatile substance abuse (i.e., glue-sniffing). Several studies involving human exposure in a laboratory setting establish the potential significance for human health of animal data on cardiac sensitization. (See the background document "Characterization of Risk from the Use of Substitutes for Class I Ozone-Depleting Substances: Fire Extinguishing and Protection" for more details.) Evaluating the safety of potential halon substitutes requires the measurement of the No-Observed-Adverse-Effect-Level (NOAEL) and the Lowest-Observed-Adverse-Effect-Level (LOAEL) of cardiac sensitization in an appropriate species, usually the dog. The Agency uses the NOAEL value as the basis to ensure protection to the worker population.

The determination of the safety of either a flooding or streaming agent substitute is also dependent on a number of other related factors. For total flood systems, the magnitude of exposure will depend on the design concentration of the flooding agent (as determined by the substitute's extinguishing concentration plus 20 percent, as specified by NFPA guidelines) and the length of time it takes a person to evacuate the area in which the agent is released. Because total flood systems are designed to achieve a uniform concentration of agent within a space, the magnitude of exposure is independent of the size of space, size of fire, or proximity of person to the fire. In assessing exposure and consequent use restrictions, the design concentration of a total flood substitute is compared to its cardiotoxic NOAEL and LOAEL levels. Generally, if the design concentration is higher than the agent's NOAEL level, conditions are placed on the use of the agent to ensure human safety. For example, if the NOAEL is 1 percent and the LOAEL is 2.5 percent, but the substitute requires 4 percent concentration to extinguish a fire, all personnel must be evacuated from an area before the concentration exceeds the 2.5 percent LOAEL. If there is a possibility that someone must enter a room while the agent is likely to exceed the NOAEL level, Self Contained Breathing Apparatus (SCBA) must be worn in accordance with OSHA safety requirements.

In contrast, exposure to substitute streaming agents can be expected to vary greatly depending on the amount of agent released, the time needed to extinguish a fire, the size of the room or enclosure in which a fire occurs, the size of the fire, the proximity of the person to the point of discharge of the agent, the rate at which fresh air infiltrates the space, and the air exchange rate near the fire. Assessment of exposure in streaming applications is much more complicated and requires development of a model and testing of the values assumed for the variables described above. The resulting modeled peak exposure rate is compared to the NOAEL in our assessments. For some proposed substitutes, the Agency requires personal monitoring data in order to complete the assessment.

Evaluating halon substitutes also requires assessing the efficacy of substitute agents. The efficacy of a fire protection agent can be measured by the extinguishing concentration required to put out a burning fire. With substitutes for handheld extinguishers and for total flood systems on weight-constrained systems (such as aircraft and space systems), designers are also concerned with the weight of substitute required to replace the halon. This factor is referred to as the weight equivalency ratio and relates the number of pounds of substitute required to replace each pound of halon to achieve the same fire extinguishing capability. In other applications, such as with existing equipment, required storage volume for a substitute is of greatest concern. This quantity can be measured by the storage volume equivalency ratio which is defined as the ratio of the storage volume of substitute to the storage volume of halon required to achieve the same fire extinguishing capability.

These three measures will be used throughout this proposed rule to evaluate halon substitutes.

After concluding the analysis of alternatives to halon, the Agency in some cases proposes to approve the use of an agent contingent on certain conditions. In implementing its use of conditions, the Agency has sought to avoid overlap with other existing regulatory authorities. EPA has taken a number of steps to mitigate this potential for duplication. First, EPA intends to limit the use of conditions to cases in which clear regulatory gaps exist. Second, these existing regulatory gaps must render the use of a substitute an unreasonable risk in the absence of any additional controls. Third, in the limited cases in which conditions may be necessary, the Agency will impose them only after going through formal notice-and-comment rulemaking. Finally, the Agency intends to withdraw existing conditions when they are superseded by appropriate regulatory controls under other authorities.

The Agency, however, requests comment on the general issue of the need for use conditions. In particular, EPA requests comment on whether section 612 in fact confers upon the Agency the authority to go beyond the listing of acceptable and unacceptable alternatives and to set such use conditions; and on the capability and practicality of EPA enforcing use conditions which may, for example, closely resemble workplace safety standards which are typically within the enforcement purview of other regulatory authorities.

EPA also requests comment on whether, when an unreasonable risk might exist due to a gap in regulatory coverage, the appropriate means to address these risks is through the existing regulatory framework of other federal authorities. For example, rather than using EPA's use conditions to address existing gaps in workplace safety standards, EPA could refer the matter to the appropriate OSHA authorities and request appropriate action to mitigate an otherwise unreasonable risk.

Alternatively, where the length of time required to address a problem under another authority may be unacceptably long given the nature of the risk, there may be cases in which
EPA would usually consider unacceptable the use of a given substitute, pending the development of a regulatory framework to control the risk it poses in its use as a substitute for an ozone-depleting compound.

Finally, EPA requests comment on the use of conditions where no regulatory gap, per se, exists, but where the use of an alternative poses risk to the public. By imposing such conditions, EPA would be establishing a new regulatory framework where one did not previously exist. For example, explosion inertion agents are not currently regulated by OSHA or any other regulatory body. However, design concentrations for systems protecting from explosion of various gases or flammable liquids may expose personnel to cardiotoxic levels of inertion agents. While the Agency is not currently proposing to place conditions for the use of alternatives in occupied areas, it may do so in the final rule to subject to public comment as well as further analysis with agencies such as OSHA and OMB. EPA could place a condition for use of alternative agents in occupied areas which would identify the cardiotoxic LOAEL and would prohibit design concentrations that exceed that level.

The primary candidate substitutes for halons in fire protection applications are discussed below by category. No SNAP submissions have been received for substitutes to replace halons in explosion suppression applications. However, in the listing decisions, explosion suppression is included with the explosion inertion decisions. The Agency is requesting comment on this.

**a. Brominated Hydrofluorocarbons.**—Brominated hydrofluorocarbons (HBFCs) are also effective halon substitutes. Because these substances contain bromine, they act as chemical action agents in the same manner as the halons. In fact, some HBFCs are more effective than Halons 1211 and 1301 in specific applications. For this reason, HBFCs can replace Halons 1211 and 1301 on nearly a one-to-one basis and appear to have significant applicability in existing systems. However, the presence of bromine also means that these agents have higher ozone-depleting potentials than other halon substitutes.

At this time, only one HBFC, HBFC-22B1, is expected to be commercially available in the near term. Extinction testing indicates that HBFC-22B1 can replace Halon 1211 at a ratio of 1.08 by weight, making it a substitute for handheld extinguishers. HBFC-22B1 can also replace Halon 1301 at a ratio of 1.4 by weight and 1.3 by storage volume, making it technically suitable for use in existing total flood systems.

HBFC-22B1 can, however, serve only as an interim substitute for halons. The substance has an estimated ODP of 0.74 and will soon be added to the list of Class I substances in accordance with section 602(d) of the Clean Air Act. Under the Montreal Protocol, production of HBFC-22B1 is required to be completely phased out by January 1, 1996. In addition, this agent was submitted to the Agency as a Premanufacture Notice (PMN) and is presently subject to requirements contained in a Toxic Substance Control Act (TSCA) section 5(e) Consent Order and associated Significant New Use Rule (40 CFR 721.1296). The provisions of today's proposed rule do not supersede those of the TSCA regulations presently in effect, and readers should note that, at present, the terms of the TSCA requirements are more restrictive than the provisions of this rule.

**b. Hydrochlorofluorocarbons.**

A number of hydrochlorofluorocarbons (HCFCs) have also been suggested as halon replacements. These include HCFC-22, HCFC-123, and HCFC-124. These HCFCs are effective fire-fighting agents, but because they are physical action agents, they are considerably less effective than halons or HBFCs and thus exhibit higher extinguishing concentrations. Further, although the ozone depletion potential of HCFCs is considerably lower than that of either halons or HBFCs, they are listed as Class II chemicals under the Clean Air Act and their production will be phased out. As a result, these chemicals can serve only as interim halon substitutes.

HCFC-22 has been suggested as a total flooding agent. HCFC-22 has a low acute toxicity, but its ODP (0.05) is higher than other candidate HCFCs. The extinguishing concentration is 11.6 percent, the highest of the candidate HCFCs, while its cardiotoxicity LOAEL is 5.0 percent. It also is somewhat inferior in terms of weight and storage volume equivalents. For these reasons, this compound is unlikely to be used as a single agent.

HCFC-123 is being considered as a streaming agent to replace Halon 1211. Because of its relatively high effectiveness, HCFC-123 could replace Halon 1211 at a ratio of 1.8 by weight—a figure considerably better than that of most other streaming substitutes. HCFC-123 has the lowest ODP of all the HCFCs proposed as halon substitutes, and its global warming potential (GWP) is half that of other proposed HCFC substitutes. However, HCFC-123, has a cardiotoxic level of 2.0 percent in the dog, with no effect apparent at 1.0 percent. Potential users have expressed concern about using HCFC-123, or blends containing HCFC-123 as the primary constituent, in small enclosed areas. However, actual exposures were assessed using personal monitoring, and the Agency concludes that likely exposure levels do not exceed safe levels.

HCFC-124 is being considered as both a total flooding agent and a streaming agent, both alone and in blends. HCFC-124 has a lower ODP, a lower GWP, and a relatively low LOAEL. Because of its relatively low ODP and GWP values, Testing indicates that the substance may be lethal at levels ranging from 24 percent to 36 percent. Cardiototoxicity occurs in the dog at 2.5 percent with no effect apparent at 1.0 percent. Potential users express concerns regarding exposures in small enclosed spaces.

**c. Hydrofluorocarbons.**

Hydrofluorocarbons (HFCs) have also been suggested as halon substitutes. HFCs are physical action agents and are less effective than halons or HBFCs. Due to their reduced efficacy, considerably larger storage volumes are required for use in fire protection systems. Their great advantage over halons, HBFCs, and HCFCs is that HFCs have an ozone depletion potential of zero. However, when exposed to fires, HFCs potentially decompose into greater amounts of hydrogen fluoride (HF) than do HCFCs, depending on the number of fluorines in the molecule. Discharge of these chemicals onto a fire must be rapid to prevent the buildup of large amounts of these decomposition products.

In addition, some HFCs can potentially contribute to global warming. The Agency examines the atmospheric lifetime and global warming potential (GWP) of each substitute to establish a risk balanced listing decision. If an agent's atmospheric lifetime or GWP is unusually large relative to other available substitutes, the use of these agents may be allowed only for specific limited uses to prevent widespread adoption.

HFC-23, HFC-32, HFC-125, HFC-134a, and HFC-227ea have all been proposed as total flooding agents. HFC-227ea has also been proposed as a streaming agent. Required extinguishing concentrations vary from 5.9 percent for HFC-227ea to 12.4 percent for HFC-23. Required storage volumes will vary from 2.5 to 4.5 times that required for Halon 1301. Weight equivalency ratios compared to Halon 1301 vary from 1.1 for HFC-32 to 2.65...
for HFC-125. All have low acute toxicity levels. Not all of these substances have been fully investigated for commercialization. Specifically, HFC-32 is considered flammable with a flammability range that is very large, and would probably require blending with another material to make a nonflammable mixture.

d. Perfluoroalcohols.—

Perfluoroalcohols (PFAs) are effective fire protection agents, having the lowest required extinguishing concentration of any of the substitutes other than HBFCs. However, these compounds have high molecular weights which create weight and storage replacement ratios that are somewhat higher than the HCFCs and many of the HFC candidates. Two PFAs have been submitted as halon replacements: perfluorobutane (FC 3–1–10) as a total flood replacement for Halon 1301, and perfluorohexane (FC 5–1–14) as a Halon 1211 replacement primarily for USAF flightline applications.

As discussed in the section on refrigerants, PFAs are of concern due to long atmospheric lifetimes and their potential to contribute to global warming. The intent of SNAP is to reduce the overall risk to health and the environment. Since there is no other regulatory authority controlling the emissions of such long-lived agents, the Agency intends to take conservative decisions regarding substances with the potential to cause significant environmental, and ultimately human health, impacts. Therefore, the Agency is proposing to prohibit discharge testing and training with these agents, and to require recapture and recycling in order to minimize emissions of these agents. Eighty to eighty-five percent of all halon emissions prior to testing, training, leakage and accidental discharge, and it is likely that such emission patterns will occur with the alternative agents as well. In addition, the Agency proposes to allow use of PFAs only for applications involving critical military uses, the protection of public safety or national security, or life support functions. The Agency invites comment about the niche these agents can best serve in light of the fact that the Agency seeks to prevent their widespread use. The Agency specifically invites comment on the cost of these restrictions and benefits in terms of reduced potential for global warming.

e. Chlorofluoroalcohols.—

Chlorofluoroalcohols (CFCs) have also been proposed as halon alternatives, either individually or in blends. However, since production of CFCs is to be phased out by the end of 1995, sufficient quantities of recycled CFC would have to be available for halon applications, making it improbable that significant shifts to these compounds will occur. CFCs have effective fire extinguishants and have well-understood toxicity characteristics. While CFCs deplete stratospheric ozone, their ODPs are significantly lower than those of Halons 1211 and 1301.

f. Blends.—A number of manufacturers have proposed proprietary blends of chemicals for fire protection applications. These blends combine a variety of CFCs, HCFCs, HFCs, FFCs, inert gases, and other additives to achieve desired levels of effectiveness, toxicity, and decomposition products. Most of these blends have non-zero ODPs and GWPs. Toxicity varies with the exact composition of the blend.

Where possible, the Agency has examined both the blend and its individual constituents. Characteristics of the overall combination, in some cases, were examined to estimate a weighted average of the characteristics of the individual components.

g. Non-halocarbon Alternative Agents.

Non-halocarbon alternative agents such as CO₂, dry chemical, foams, inert gas and water that are currently in widespread use may also be used as substitutes for halons. However, as noted above, these agents are not as widely applicable as are the halons and must be used in end uses recommended by the manufacturers and approved by standard-setting entities such as the NFPA.

CO₂ can be used as a streaming or a total flooding agent. In the past, CO₂ systems were used in many of the applications now served by halons. As a total flooding agent, CO₂ has an extinguishing concentration ten times that of Halon 1301 and requires 1.4 times the storage volume required by 1301 systems; it is also an asphyxiant in the concentrations required for total flooding. Streaming CO₂ extinguishers must also be larger and heavier than 1211 extinguishers and have no Class A fire rating. Additionally, depending on the exposure characteristics discussed above, CO₂ may reach dangerous levels in small areas.

One manufacturer has developed a blend of CO₂ mixed with inert gases as a Halon 1301 substitute in total flood systems. This agent would not be considered a ‘drop in’ replacement due to its high extinguishing concentration. As it is a non-reactive, non-halocarbon substance, and thus is not carcinogenic, mutagenic or teratogenic, the toxicity and cardioxicity tests normally applied to halon substitutes do not apply here. Rather, this agent is a potential asphyxiant. It is designed to decrease the oxygen level to 12 to 14 per cent, at which combustion cannot be supported. OSHA requires oxygen levels to be at least 18.5 per cent for human safety. It has been suggested that this particular blend increases breathing rates, thus making the oxygen deficient atmosphere breathable for short periods of time. Data submitted by the manufacturer was peer-reviewed by pulmonary, cardiac, and stroke specialists. All have agreed that the blend does not pose significant risk to the working population and may even pose less risk than does exposure to halocarbon agents.

Dry chemical extinguishers are suitable for Class A, B, and some Class C fires. Total flooding systems using dry chemical are rare, but some “localized applications” exist around deep fat fryers and textile machines. Generally, dry chemical extinguishers are more effective than halons, but dry chemical is not a clean agent and cannot be used without potentially damaging precision machinery and other equipment.

Water is an effective fire protection agent that can be used with either total flooding or streaming systems. Water is primarily a Class A fire extinguishing, but can be used against Class B when applied as a fine mist. Water also produces a cooling effect that prevents re-ignition. Water, typically cannot be used against Class C electrical fires and may cause considerable secondary damage in some applications. However, a promising new technology incorporates fine water droplets to create a water mist or fog. It has been suggested that water mist systems are safe for use on Class A and B fires, and even on Class C electrical fires without causing secondary damage.

Foams are extremely effective in extinguishing flammable liquids (Class B fires) and to some degree against Class A fires. Portable and handheld systems are available for use as streamers agents, but high- and medium-expansion foams are also marketed for total flooding applications in inaccessible areas (such as between floors or in marine machinery spaces). Use of high- and medium-density foams can be dangerous in large, cluttered or hazardous enclosures in which people might be present, but foams are not typically considered toxic. Nevertheless, foams can cause secondary damage and, due to their water content, cannot be used with electrical fires. They do not penetrate as well as gaseous agents.
3. Preliminary Listing Decisions

In order to evaluate the acceptability of proposed halon substitutes, the Agency divided the fire protection sector into six end-uses: (1) Residential/Consumer Streaming Agents, (2) Commercial/Industrial Streaming Agents, (3) Military Streaming Agents, (4) Total Flooding Agents for Occupied Areas, (5) Total Flooding Agents for Unoccupied Areas, and (6) Explosion Inertion. The table in Appendix B provides a summary of decisions by end use.

For some substitutes, data required by the Agency to complete a risk assessment is not yet available or has not been submitted to the Agency as requested. As a result, not all candidate substitutes have been fully evaluated by the Agency. Those substitutes which the Agency is currently reviewing, but for which a final determination cannot yet be made, are listed as pending in the table in Appendix B. The Agency will make every effort to evaluate these chemicals before promulgation of the final rule.


(a) HBFC-22B1. HBFC-22B1 is proposed acceptable as a streaming agent in consumer applications for nonresidential uses only. Given the potential market penetration and the high ODP of HBFC-22B1, use of HBFC-22B1 in consumer applications was estimated to cause unacceptable damage to the ozone layer and an excessively high number of skin cancer cases and deaths. The total estimated skin cancer cases and fatalities from the use of 22B1 as a halon 1211 replacement in all uses including consumer uses is approximately 30,000 and approximately 600, respectively. In light of the availability of other fire protection agents with lower associated risks, the Agency determined that the risks posed by HBFC-22B1 were too large to justify widespread use in the consumer sector.

In addition to concern about its ODP, use of HBFC-22B1 in residential applications may present exposure risks of cardioosensitization. To assess this risk, the Agency modeled the peak concentration of HBFC-22B1 that would be expected if such an extinguishant were used to suppress a kitchen fire and estimated the decline from the peak. Such analysis indicated that peak concentrations of HBFC-22B1 would exceed 3300 ppm. This is in excess of NFPA ceilings for exposure.

Because of its effectiveness, the Agency is approving use of HBFC-22B1 as a streaming agent only for nonresidential uses only. However, it can only be considered a transitional agent, because it will be phased out as a Class I substance in accordance with the Clean Air Act and with the requirements of the Montreal Protocol.

This agent was submitted to the Agency as a Premanufacture Notice (PMN) and is presently subject to requirements contained in a Toxic Substance Control Act (TSCA) section 5(e) Consent Order and associated Significant New Use Rule (40 CFR 721.1296). Under the terms of the Consent Order, it may be used only for outdoor automotive and marine applications. In addition, to ensure safe use, the product is restricted to a size discouraging residential use, with a minimum UL rating of SBC. The unit must be properly labeled indicating that residential use is prohibited due to danger of cardiotoxicity; indicating proper space volume restrictions limiting exposure to 1 per cent; and indicating proper evacuation and reentry requirements. In addition, the agent may only be sold in rechargeable units to encourage reuse and recycling and to discourage the potential for the agent to escape to the atmosphere through improper disposal.

(b) HCFC-123. HCFC-123 is acceptable as a streaming agent for consumer applications. Because of its relatively high effectiveness, HCFC-123 could replace Halon 1211 at a ratio of 1.8 by weight—a figure considerably better than that of most other streaming substitutes. HCFC-123 has the lowest ODP of all the HCFCs proposed as halon substitutes, and its global warming potential (GWP) is half that of other proposed HCFC substitutes. However, since HCFC-123, has a cardiotoxic level of 2.0 per cent in the dog, with no effect apparent at 1.0 per cent, potential users have expressed concern about using HCFC-123 or blends containing HCFC-123 as the primary constituent. However, actual exposures were assessed using personal monitoring devices, and the Agency concludes that likely exposure levels from its use as a streaming agent do not exceed safe levels.

(c) [HCFC Blend] B

[HCFC Blend] B is acceptable as a streaming agent for consumer applications. This blend consists largely of HCFC-123, therefore, as with HCFC-123, it has been shown in tests to have a relatively high effectiveness with a weight equivalency ratio to Halon 1211 of 1.8—a figure considerably better than that of most other streaming substitutes. HCFC-123 has the lowest ODP of all the HCFCs proposed as halon substitutes, and its global warming potential (GWP) is half that of other proposed HCFC substitutes. While HCFC–123 has a cardiotoxic level of 2.0 per cent in the dog, with no effect apparent at 1.0 per cent, actual exposures from use of this blend as a streaming agent were assessed using personal monitoring devices, and the Agency concludes that likely exposure levels do not exceed safe levels.

(d) [CFC-Blend]

[CFC-Blend] is acceptable as a streaming agent for nonresidential consumer use.—While [CFC-Blend] contains CFCs, its overall ODP is 0.95, which is less than one-fourth that of Halon 1211. [CFC-Blend] is the most effective of all other halon substitutes except for HBFC-22B1 and HCFC-123, and does not pose the exposure risk of HBFC-22B1 in certain scenarios. [CFC-Blend] is generally considered non-toxic but in light of its high ODP relative to other substitute agents and the large potential market for consumer/residential extinguishers, alternative agents such as water and dry chemical are considered sufficient for residential uses. In addition, this substitute will be phased out by December 31, 1995.

(e) Dry Chemical

Dry chemical extinguishers are approved for use in residential streaming applications as a Halon 1211 substitute. Dry chemical extinguishers can be used as a substitute for Halon 1211 in most residential applications. While dry chemical extinguishers can be used on Class A, B, or C fires depending upon the type of powder used, they do not always penetrate well around obstacles, they do not inhibit reignition of fires, they do not cool surfaces, they can cause secondary damage, and discharge in confined spaces can result in temporary loss of visibility. Dry chemical extinguishers should be used only in accordance with the manufacturer's guidelines and with relevant NFPA standards.

(f) Carbon Dioxide

Carbon Dioxide extinguishers are approved for use in residential streaming applications as a Halon 1211 substitute.—Carbon dioxide can be used as a direct substitute for Halon 1211 in specified applications. Carbon dioxide systems have no rating versus Class A fires and so must be used in conjunction with another type of extinguisher to ensure that all possible fire scenarios can be appropriately handled. In addition, discharge of carbon dioxide into confined spaces may result in CO2
concentrations above the Immediately Dangerous to Life and Health (IDLH) level. Areas into which carbon dioxide is discharged should be immediately evacuated and ventilated. Carbon dioxide extinguishers should be used only in accordance with manufacturer’s guidelines and applicable NFPA standards.

(g) Water

Water extinguishers are approved for use in residential streaming applications as a Halon 1211 substitute. Users should be aware, however, that water extinguishers cannot act as a substitute for Halon 1211 in all applications. Water is primarily a Class A (solid) fire extinguisher and should not be used with Class B (flammable liquid) or C (electrical) fires. Water may damage objects onto which it is discharged. Water extinguishers should be used only in accordance with manufacturer’s guidelines and with NFPA standards.

(h) Foam

Foam extinguishers are approved for use in residential streaming applications as a Halon 1211 substitute. Foam extinguishers cannot be used as a substitute for halon in all applications. Portable foam extinguishers are intended primarily for use on flammable liquid fires and are somewhat effective on Class A fires. Foams can also cause secondary damage on objects onto which it is discharged. Foam extinguishers should be used in accordance with manufacturer’s guidelines and with NFPA standards.

(2) Streaming Agents: Commercial/Industrial Use

(a) HBFC-22B1

HBFC-22B1 is approved for use as a streaming agent in commercial/industrial applications. Despite its high ODP, this chemical will enable industry to more rapidly shift away from 1211 extinguishants which have an even higher ODP. Moreover, as the chemical will be phased out as a Class I substance on January 1, 1996, only limited use is expected to be made of this substitute.

Worker exposure may be a concern in small office areas, but in larger offices, modeling efforts indicate that HBFC-22B1 can be used safely. In most office/industrial fire scenarios, proper procedures should be in place regarding the operation of the extinguisher and ventilation of extinguishment areas after dispensing the extinguishant to minimize concerns about exposure.

This agent was submitted to the Agency as a Premanufacture Notice (PMN) and is presently subject to requirements contained in a Toxic Substance Control Act (TSCA) section 5(e) Consent Order and associated Significant New Use Rule (40 CFR 721.1296). Under the terms of the Consent Order, to ensure safe use, the sale of this product is restricted to a size discouraging residential use, with a minimum UL rating of SBC. The unit must be properly labeled indicating that residential use is prohibited due to danger of toxicity, listing proper space, volume restrictions limiting exposure to 1 per cent, and indicating proper evacuation and reentry requirements. In addition, the agent may only be sold in rechargeable units to encourage reuse and recycling and to discourage the potential for the agent to escape to the atmosphere through improper disposal. EPA invites comment on these use restrictions.

(b) [CFC-Blend]

[CFC-Blend] is acceptable as a streaming agent for use in commercial/industrial streaming applications. While [CFC-Blend] contains CFCs, its overall ODP is 0.95, which is less than one-fourth that of Halon 1211. [CFC-Blend] is the most effective of all other halon substitutes except for HBFC-22B1 and HCFC-123, and does not pose the exposure risk of HBFC-22B1 in certain scenarios. [CFC-Blend] is generally considered non-toxic and could serve as a transitional substitute in many streaming applications, but will be phased out by December 31, 1995.

(c) HCFC-123

HCFC-123 is acceptable as a streaming agent for commercial/industrial applications.

Because of its relatively high effectiveness, HCFC-123 could replace Halon 1211 at a ratio of 1.8 by weight—an effect considerably better than that of most other streaming substitutes. HCFC-123 has the lowest ODP of all the HCFCs proposed as halon substitutes, and its global warming potential (GWP) is half that of other proposed HCFC substitutes. However, since HCFC-123 has a cardiotoxic level of 2.0 percent in the dog, with no effect apparent at 1.0 percent, actual exposures from use of this blend as a streaming agent were assessed using personal monitoring devices. The Agency concludes that likely exposure levels do not exceed safe levels.

(e) Dry Chemical

Dry Chemical, for the reasons described and with the limitations suggested in the section on consumer streaming applications, are approved for use as a commercial/industrial streaming agent.

(f) Carbon Dioxide

Carbon Dioxide, for the reasons described and with the limitations suggested in the section on consumer streaming applications, is approved for use as a commercial/industrial streaming agent.

(g) Water

Water, for the reasons described and with the limitations suggested in the section on consumer streaming applications, is approved for use as a commercial/industrial streaming agent.

(h) Foam

Foams, for the reasons described and with the limitations suggested in the section on consumer streaming applications, are approved for use as a commercial/industrial streaming agent.

(3) Streaming Agents: Military Applications

(a) HBFC-22B1

HBFC-22B1 is approved for use as a streaming agent in military applications. Despite its high ODP, HCFC-22B1 will enable the military to more rapidly shift away from 1211 extinguishants which have an even higher ODP. Moreover, as this chemical will be phased out under the Montreal Protocol (with possible essential use exemptions) as a Class I substance on...
January 1, 1996, only limited use is expected to be made of this substitute. Worker exposure may be a concern in small, enclosed areas, but in larger areas and outdoor areas, modeling efforts indicate that HBFC-22B1 can be used safely. In most realistic fire scenarios, proper procedures should be in place regarding the operation of the extinguisher, workers will be properly trained in fire-fighting procedures, and ventilation of extinguishment areas can be expected after dispensing the extinguisher.

This agent was submitted to the Agency as a Premanufacture Notice (PMN) and is presently subject to requirements contained in a Toxic Substance Control Act (TSCA) section 5(e) Consent Order and associated Significant New Use Rule (40 CFR 721.1296). Under the terms of the Consent Order, to ensure safe use, the sale of this product is restricted to a size not exceeding the UL rating of 5BC. The unit must be properly labeled indicating that residual use is prohibited due to toxicity; indicating proper space volume restrictions limiting exposure to 1 percent; and indicating proper evacuation and reentry requirements. In addition, the agent may only be sold in rechargeable units to encourage reuse and recycling and to reduce the potential for the agent to escape to the atmosphere through improper disposal.

(b) HCFC-123

HCFC-123 is acceptable as a streaming agent for military applications.

Because of its relatively high effectiveness, HCFC-123 could replace Halon 1211 at a ratio of 1.8 by weight—a figure considerably better than that of other halon substitutes. HCFC-123 has the lowest ODP of all the HCFCs proposed as halon substitutes, and its global warming potential (GWP) is half of other proposed HCFC substitutes. While HCFC-123 has a cardiotoxic level of 2.0 percent in the dog, with no effect apparent at 1.0 percent, actual exposures from use of this blend as a streaming agent were assessed using personal monitoring devices. The Agency concludes that likely exposure levels do not exceed safe levels.

(d) FC 5–1–14

FC 5–1–14 is acceptable in streaming applications for military flightlines, inside military aircraft, and in military computer and telecommunication facilities.

Due to the long atmospheric lifetime of FC 5–1–14, the Agency urges that the chemical be used only in those instances in which a viable alternative is not available. The Agency proposes that only acceptable uses involve national security or public safety where no other substitute has been proven to be as effective.

For example, military flightlines are ground-based operations which typically involve fuel spills and fires in engine nacelles. Flightlines require a clean agent that is capable of extinguishing three-dimensional fires, and that is non-corrosive and leaves no residue in order to leave engines intact. These are typically smaller, easily contained fires. Crash Rescue Vehicles may have a combination of agents available, but agents such as foam are usually used for larger fires.

The Agency proposes to permit use of this agent in operational military electronics facilities such as computer and telecommunication rooms, which are critical to national security or public safety.

In order to reduce emissions of FC 5–1–14 into the atmosphere, the Agency is proposing to require that FC 5–1–14 not be used in system discharge tests or for training. In addition, the Agency is proposing to require that FC 5–1–14 be recovered before servicing and recycled for later use. In most streaming applications, the Agency believes that alternatives to FC 5–1–14 exist. These include the halocarbon replacements identified above as well as alternative agents such as water, CO₂, foam, and dry chemicals.

Users should attempt to use these other agents before deciding on a FC 5–1–14 system.

(e) [CFC-Blend]

[CFC-Blend] is acceptable as a substitute to Halon 1211 for use in military streaming applications. While [CFC-Blend] contains CFCs, its overall ODP is 0.85, which is less than one-fourth that of Halon 1211. [CFC-Blend] is the most effective of all other halon substitutes except for HBFC-22B1 and HCFC-123, and does not pose the exposure risk of HBFC-22B1 in certain scenarios. [CFC-Blend] is generally considered non-toxic and could serve as a transitional substitute in many streaming applications until it is phased out on December 31, 1995.

(f) Dry Chemical

Dry chemical, for the reasons described in the section on consumer streaming applications, is approved for use as a military streaming agent.

(g) Carbon Dioxide

Carbon Dioxide, for the reasons described and with the limitations suggested in the section on streaming applications, is approved for use as a military streaming agent.

(h) Water

Water, for the reasons described and with the limitations suggested in the section on streaming applications, is approved for use as a military streaming agent.

(i) Foam

Foams, for the reasons described and with the limitations suggested in the section on streaming applications, is approved for use as a military streaming agent.

(4) Total Flooding Agents: Occupied Areas

In analyzing the acceptability of substitutes for occupied total flooding applications, the Agency considered cardiotoxicity one of the primary decision variables. Current limitations on use of Halon 1301 in total flooding applications assure that these uses do not pose a cardiotoxic risk to personnel, if flooding does not exceed the design concentration. Halon 1301 has a cardiotoxic NOAEL of 7.5 percent, and a LOAEL of 10.0 percent; its required extinguishing concentration for total flooding is only 2.6 percent, according to testing results. OSHA promulgated a safety and health standard governing fire protection systems used at all workplaces (29 CFR 1910 Subpart L) which is designed to limit employee
exposures to toxic levels of gaseous agents used in fixed total flood systems. In addition to alerting employees of impending system discharge by suitable alarms (Section 1910.160), the standard requires that employees be provided sufficient time to leave before system discharge if the discharge is designed to exceed 10 percent (Section 1910.162). For Halon 1301, the standard prohibits the use of Halon concentration greater than 7 percent (the cardiotoxic NOAEL) where egress cannot be accomplished in less than 1 minute and prohibits the use of concentrations greater than 10.0 percent (the cardiotoxic LOAEL) where egress requires more than 30 seconds. In addition, if there is a possibility that someone must enter a room while an agent is likely to exceed the NOAEL level, Self Contained Breathing Apparatuses (SCBA) must be worn.

Since most of the proposed substitutes for use in normally occupied areas pose a risk of cardiotoxic exposure, EPA has concluded that their use must be governed by conditions similar to those for Halon 1301. While the OSHA regulation section 1910.160 generally applies to all fire protection systems, section 1910.162 addresses specific allowable concentrations only for halon. While it is not the intent of EPA to preempt OSHA regulation in this area, the Agency is seeking to ensure public safety until OSHA develops appropriate regulations for the new substitute gaseous agents. Therefore, while all agents used in normally occupied areas must meet OSHA regulations under section 1910.160, the Agency is setting conditions for use in normally occupied areas similar to those found in the OSHA regulation section 1910.162.

For example, in this action, EPA has proposed conditions on the acceptability of certain Halon substitutes when used as total flooding agents in normally occupied areas. EPA has imposed these conditions because of the risk of cardiotoxic levels of exposure to personnel in areas where substitute agents may be discharged in the event of fire. Existing OSHA standard 1910.160 applies certain general controls to the use of fixed extinguishing systems in occupied workplaces, whether gaseous, dry chemical, water sprinklers, etc., and EPA has not reproduced those. These include, for example, the requirements for discharge and pre-discharge alarms, and availability of Self Contained Breathing Apparatus (SCBA) for emergency entry into an area where agent has been discharged.

While section 1910.162 can apply generally to gaseous agents, it includes cardiotoxic levels specific to Halon 1301. Section 1910.162 paragraphs (b)(5) and (b)(6) provide alternative workplace requirements based on specific design concentrations of Halon 1301. That is, if the design concentration is 7 percent, employees must be able to egress in one minute, but if the design concentration is 10 percent, employees must be able to egress in 30 seconds. These design concentrations are not identified as the cardiotoxic NOAEL or LOAEL, so one cannot generalize a rule for use with alternative agents which have different LOAEL and NOAEL values. For this reason, EPA is concerned that halon substitute agents could be used in the absence of enforceable compound-specific cardiotoxic exposure levels. On the other hand, requiring other gaseous agents to meet the 7 percent or 10 percent requirements specified in 1910.162 will preclude their use because the design concentrations of the alternative agents vary greatly, as does their cardiotoxic values. Should OSHA create compound-specific cardiotoxicity values to be applied to the use of halon substitutes as gaseous total flooding agents in occupied spaces, these conditions would no longer be necessary and EPA would rescind them.

However, EPA is also aware that existing OSHA regulations may provide adequate coverage against exposure to toxic levels of gaseous agents and their decomposition products. Section 1910.162 (b)(3) states, "(a)(2) The employer shall provide a distinctive pre-discharge employee alarm ** when agent design concentrations exceed the maximum safe level for employee exposure." EPA invites comment on the adequacy of 1910.162 (b)(3) to provide workplace protection for agents that differ from Halon 1301.

In those relatively rare instances where explosion suppression or fireball suppression of Class B fires is immediately necessary to protect life, discharge of any suitable agent without an alarm may be necessary. The Agency solicits descriptive comments on such situations and on appropriate use restrictions of agents.

In many occupied areas, total flooding halons can be replaced by improved detection equipment and manually operated extinguishing systems. Improved detection systems, if they detect fires in their early stages, can alert occupants to the existence of a fire so they may extinguish it with handheld extinguishers. In those cases in which a total flooding system is deemed necessary, improved detection systems and the use of cross-zoning can also reduce false alarms that result in the unnecessary discharge of total flooding systems.

The following substitutes are approved by the Agency for use as total flooding agents in occupied areas:

- **HBFC–22B1**
  
  **HBFC–22B1 is acceptable as a 1301 substitute only in occupied areas from which personnel can be safely evacuated and egress can occur before concentration of HBFC–22B1 exceeds its cardiotoxic LOAEL.** The required extinguishing concentration for HBFC–22B1 is estimated at 44,000 ppm (or 4.4 percent) and its design concentration is 5.4%. The LOAEL for cardiotoxicity is 1 percent while its NOAEL is 0.3%. EPA proposes that, for occupied areas from which personnel cannot be evacuated in one minute, use is permitted only up to concentrations not exceeding the NOAEL for cardiotoxicity. For occupied areas from which personnel can be evacuated or egress can occur in 30 to 60 seconds, use is permitted up to a concentration not exceeding the LOAEL. All personnel must be evacuated before concentration of HBFC–22B1 exceeds 1

* 29 CFR 1910.160(b) includes general provisions to ensure the safety of all fixed extinguishing systems. Paragraph (c) stipulates requirements for systems with "potential health and safety hazards to employees" such as might be posed by gaseous agents.

(b)(3) "The employer shall provide a distinctive alarm or signaling system ** capable of being perceived above ambient noise or light levels ** to indicate when the extinguishing systems are discharging. Discharge alarms are not required on systems where discharge is immediately recognizable."**

(b)(4) "The employer shall provide effective safeguards to warn employees against entry into discharge areas where the atmosphere remains hazardous to employee safety or health."**

(b)(5) "The employer shall post hazard warning or caution signs at the entrance to, and inside of, areas protected by fixed extinguishing systems which use agents in concentrations known to be hazardous to employee safety and health."**

(b)(6) "The employer shall assure that fixed extinguishing systems are inspected annually ** to assure that the system is maintained in good operating condition."**

(b)(10) "The employer shall train employees designated to inspect, maintain, or operate, or repair fixed extinguishing systems. ** ** to assure that the system is maintained in good operating condition."

(b)(17) "The employer shall provide and assure the use of personal protective equipment needed for immediate rescue of employees trapped in hazardous atmospheres created by an agent discharge."

(c)(3) "On all total flooding systems the employer shall provide a pre-discharge employee alarm ** which will give employees time to safely exit from the discharge area prior to system discharge."
percent. This compound is unlikely to be feasible as a total flooding agent because its design concentration exceeds its cardiotoxic level.

While HBFC-22B1 has an ODP of 0.74 and will be phased out on January 1, 1996, the Agency believes that the substance can serve a useful role in helping users transition away from Halon 1301, which has an ODP estimated at 16. HBFC-22B1 is available immediately and can replace 1301 at a ratio of 1.1 by weight and a ratio of 1.3 by storage volume. Thus, current 1301 total flooding systems can be converted to HBFC-22B1 with only minor increases in storage volume (or losses in efficacy). Other total flooding agents, though having a lower ODP, would require much larger additions of agent weight and storage volume.

This agent was submitted to the Agency as a Premanufacture Notice (PMN) and is presently subject to requirements contained in a Toxic Substance Control Act (TSCA) section 5(e) Consent Order and associated Significant New Use Rule (40 CFR 721.1296).

(b) HCFC-22

HCFC-22 is acceptable as a total flooding agent in occupied areas from which personnel can be safely evacuated and egress can occur before concentration of HCFC-22 exceeds its cardiotoxic LOAEL.

HCFC-22 has an acute cardiotoxicity with a LOAEL of 5 percent; however its extinguishing concentration of 11.8 percent and its design concentration of 13.9 percent makes this compound unlikely to be used as a single agent because it exceeds its cardiotoxic level. EPA proposes that, for occupied areas from which personnel cannot be evacuated in one minute, use is permitted only up to concentrations not exceeding the NOAEL for cardiotoxicity. For occupied areas from which personnel can be evacuated or egress can occur in 30 to 60 seconds, use is permitted up to a concentration not exceeding the LOAEL.

All personnel must be evacuated before concentration of HCFC-22 exceeds 2.5 percent. This compound is unlikely to be feasible as a total flooding agent because its design concentration exceeds its cardiotoxic level.

(d) [HCFC BLEND] A

[HCFC BLEND] A is acceptable alternative to Halon 1301 only in occupied areas from which personnel can be safely evacuated and egress can occur before concentration of [HCFC BLEND] A exceeds its cardiotoxic LOAEL. Based on full-scale testing, the extinguishing concentration of this blend has been determined to be approximately 8.8 percent and therefore the design concentration is approximately 10.3 percent. Preliminary reports of test data indicate that the cardiotoxicity NOAEL of the blend is at least 10.0 percent, and therefore the LOAEL is likely to be greater than 10.0 percent. The Agency is awaiting the final report validating this data, but believes the preliminary report represents a conservative assessment of the cardiotoxicity of the blend. The blend has an ODP higher than other proposed HCFC substitutes, but appears somewhat more effective from a weight and storage volume equivalency basis.

EPA proposes that, for occupied areas from which personnel cannot be evacuated in one minute, use is permitted only up to concentrations not exceeding the NOAEL for cardiotoxicity.

For occupied areas from which personnel can be evacuated or egress can occur between 30 and 60 seconds, use is permitted up to a concentration not exceeding the LOAEL. All personnel must be evacuated before concentration of [HCFC BLEND] A exceeds 10 percent. This compound is a feasible candidate for use in a normally occupied area.

(e) HFC-23

HFC-23 is an acceptable alternative to Halon 1301 in occupied areas only for high value applications such as those involving the protection of public safety or national security; telecommunication or computer equipment related to public safety or national security; or life support functions; and from which personnel can be safely evacuated and egress can occur before concentration of HFC-23 exceeds its cardiotoxic LOAEL.

HFC-23 is attractive for use as a total flooding agent in occupied areas because the draft report on cardiotoxicity indicates that its cardiotoxic NOAEL is over 30 percent without added oxygen and over 50 percent with added oxygen, compared to a design concentration of 14 percent. The Agency is awaiting the final report to validate these values, but believes that the draft report adequately represents the likely cardiotoxicity of the agent. Still, in order to ensure safe evacuation, EPA proposes that, for occupied areas from which personnel cannot be evacuated in one minute, use is permitted only up to concentrations not exceeding the NOAEL for cardiotoxicity. For occupied areas from which personnel can be evacuated or egress can occur between 30 and 60 seconds, use is permitted up to a concentration not exceeding the LOAEL. All personnel must be evacuated before concentration of HFC-23 exceeds 30 percent.

While this agent has an ODP of zero, it has a relatively high GWP and an atmospheric lifetime of some 300 to 400 years. Until the Agency completes its analysis of its likely effects on global warming, it is listed as acceptable for particular critical uses only.

The weight equivalent of HFC-23 is 2.0 while its storage volume is 4.6.

(f) HFC-134a

The Agency has determined that HFC-134a is an acceptable alternative to Halon 1301 only in occupied areas from which occupants can be safely evacuated and egress can occur before concentration of HFC-134a exceeds its cardiotoxic LOAEL. HFC-134a has a cardiotoxic NOAEL of 4 percent, a LOAEL of 8 percent, and an...
extinguishing concentration of 10.5 percent. EPA proposes that, for occupied areas from which personnel cannot be evacuated in one minute, use is permitted only up to concentrations not exceeding the NOAEL for cardiotoxicity. For occupied areas from which personnel can be evacuated or egress can occur between 30 and 60 seconds, use is permitted up to a concentration not exceeding the LOAEL. All personnel must be evacuated before concentration of HFC-134a exceeds 8 percent. This compound is unlikely to be feasible as a total flooding agent in occupied areas because its design concentration exceeds its cardiotoxic level.

Like the other HFCs, HFC-134a has an ODP of zero. It also has among the lowest GWP of the candidate 1301 replacements for which GWP has been estimated. Extinguishment tests conducted with HFC-134a indicate that the substance is considerably less effective than 1301. Systems that use HFC-134a will therefore require approximately 2.5 times more extinguishant by weight and 3.1 times more storage volume than 1301 systems. Such considerations preclude HFC-134a from being used in most existing equipment.

(h) HFC-227ea

HFC-227ea is acceptable for use as a total flooding agent in occupied areas from which occupants can be safely evacuated and egress can occur before concentration of HFC-227ea exceeds its cardiotoxic LOAEL. The preliminary report on the cardiotoxicity of HFC-227ea indicates a cardiotoxic NOAEL of 8.1% and a LOAEL of at least 10.5%. The Agency is awaiting the final report to validate the data, but believes that the draft report represents a conservative estimate of its likely cardiotoxic value. The design concentration for this agent is 7.1%, which provides a sufficient margin of safety for use in an occupied area. EPA proposes that, for occupied areas from which personnel cannot be evacuated in one minute, use is permitted only up to concentrations not exceeding the NOAEL for cardiotoxicity. For occupied areas from which personnel can be evacuated or egress can occur between 30 and 60 seconds, use is permitted up to a concentration not exceeding the LOAEL. All personnel must be evacuated before concentration of HFC-227ea exceeds 10.5 percent.

HFC-227ea does not deplete stratospheric ozone. In addition, HFC-227ea is the most effective of the proposed HFC substitutes for Halon 1301. Testing indicates an extinguishing concentration of 5.9 percent. HFC-227ea can replace Halon 1301 at a ratio of 2.4 by weight and 2.55 by volume, which may limit its applicability in existing total flood systems.

(h) FC 3-1-10

FC 3-1-10 is acceptable as a total flooding agent in occupied areas only for those limited applications involving the protection of public safety or national security; telecommunications or computer equipment related to public safety or national security; or life support functions. Experimental results indicate that FC 3-1-10 can extinguish fires in a total flood application at concentrations of 5.5 percent. The cardiotoxicity NOAEL of 40% for this agent is well above its extinguishment concentration and therefore is safe for use in occupied areas. In order to ensure safe evacuation, EPA proposes that, for occupied areas from which personnel cannot be evacuated in one minute, use is permitted only up to concentrations not exceeding the NOAEL for cardiotoxicity. For occupied areas from which personnel can be evacuated or egress can occur between 30 and 60 seconds, use is permitted up to a concentration not exceeding the LOAEL. All personnel must be evacuated before concentration of FC 3-1-10 exceeds 40 percent.

Due to the long atmospheric lifetime of FC 3-1-10, the Agency urges that the chemical be used only in those limited instances described above in which a viable alternative is not available. In order to reduce emissions of FC 3-1-10 into the atmosphere, the Agency is also proposing to require FC 3-1-10 not to be used in system discharge tests. In addition, the Agency is proposing to require FC 3-1-10 to be recovered from total flooding systems before servicing and recycled for later use. Fire detection should also be cross-zoned to avoid unnecessary discharge and maintained to high reliability. In most total flooding applications, the Agency believes that alternatives to FC 3-1-10 exist. These include the halocarbon replacements identified above. As a result, EPA is proposing to restrict its use only to those applications described above.

(i) [Inert Gas Blend]

[Inert Gas Blend] is approved as a total flooding agent in occupied areas. This agent is a non-reactive, non-halocarbon substance, and thus not carcinogenic, mutagenic, or teratogenic; the toxicity and cardiotoxicity tests normally applied to halon substitutes do not apply here. Rather, this agent is a potential asphyxiant as it is designed to decrease the oxygen to a level at which combustion cannot be supported. This blend is designed to increase breathing rates, thus making the oxygen deficient atmosphere breathable for short periods of time. Data submitted by the manufacturer was peer-reviewed by pulmonary, cardiac, and stroke specialists. All have agreed that the blend does not pose significant risk to the working population and may even pose less risk than does exposure to halocarbon agents. However, to ensure safety, the Agency proposes to approve this blend under the conditions that the design concentration results in at least 14% oxygen and 4% carbon dioxide. In addition, if the oxygen concentration of the atmosphere falls below 12%, personnel must be evacuated and egress must occur within 30 seconds. Since a fire can be expected to consume oxygen and form decomposition products, personnel should treat any fire situation as an emergency and promptly exit the space.

Concerns have been raised about the decibel level of this system upon discharge. The manufacturer has submitted a report indicating the decibel level to be 117 decibels for 3 seconds followed by a decay in noise level over 5 minutes, compared to 130 decibels for a typical halon system. The Time Weighted Average (TWA) of this system is 57 decibels. These levels are in compliance with the OSHA and workplace maximum allowed peak of 140 decibels and a maximum Time Weighted Average (TWA) of 90 decibels.

(j) Carbon Dioxide

Carbon Dioxide is approved as a total flooding agent in occupied areas. The Agency is not proposing to regulate alternative fire protection agents that are currently in widespread use. However, questions have been raised about the Agency's position on the use of carbon dioxide as a total flooding agent in occupied areas.

Exposure to carbon dioxide poses an imminent threat to life. However, because it displaces oxygen, it is an effective fire protection agent. As a result, both OSHA and the National Fire Protection Association (NFPA) address CO\textsubscript{2} systems for occupied areas. OSHA 1910.162(b)(5) requires a pre-discharge alarm for systems with a design concentration of 4 percent or greater. NFPA has written a standard (NFPA 12) that explicitly controls how such CO\textsubscript{2} systems may be safely used in occupied areas. To protect life, it requires a system design such that no personnel may be present upon system discharge. The EPA recognizes both the OSHA regulation and the NFPA standard as industry practice and therefore references them in this rule.
In the review of proposed substitutes, the Agency looks at a variety of health and environmental factors, including whether the agent contributes to global warming. While carbon dioxide is a greenhouse gas, it is a byproduct of many industrial processes. We realize that carbon dioxide is recaptured and reformulated as a fire fighting agent and thus does not require new production. Therefore, the Agency has determined that its status as a greenhouse gas is irrelevant to our review.

(k) Water

Water sprinkler systems are also approved for use as a 1301 substitute in occupied areas. Such systems should not be used on Class C electrical fires or in instances in which secondary damage is considered unacceptable.

(5) Total Flooding: Unoccupied Areas.

In unoccupied areas, human exposure to potentially toxic substitutes or decomposition products are of less concern than in occupied areas. Key criteria in the decision process therefore become agent efficacy and environmental considerations. At the same time, the Agency must ensure that personnel are not exposed to toxic concentrations of fire protection agents or their decomposition products when the substances are vented or leak out from the extinguishing area. Precautions must also be taken to prevent exposures to personnel entering a normally unoccupied area after a discharge. In addition, if there is a possibility that someone must enter a room while an agent is likely to exceed the NOAEL level, Self Contained Breathing Apparatuses (SCBA) must be worn.

Based on these considerations, the Agency has determined that the following agents are acceptable substitutes to Halon 1301 in unoccupied areas:

(a) HBFC–22B1

In unoccupied areas, toxicity concerns are minimal. Thus, for the reasons outlined in the section on occupied areas, HBFC–22B1 is acceptable for use in unoccupied areas. Because of its low storage volume equivalency ratio, HBFC–22B1 can be used in existing total flooding systems to help speed the transition away from Halon 1301.

This agent was submitted to the Agency as a Premanufacture Notice (PMN) and is presently subject to requirements contained in a Toxics Substance Control Act (TSCA) section 5(e) Consent Order and associated Significant New Use Rule (40 CFR 721.1286).

(b) HCFC–22

HCFC–22 is acceptable as a total flooding agent in unoccupied areas. However, due to the low efficacy of the agent and its high ODP and GWP relative to other proposed substitutes, the Agency believes this is a less attractive replacement than other potential candidates.

(c) HCFC–124

HCFC–124 is acceptable as a total flooding agent in unoccupied areas. This agent is relatively effective for a physical action agent and has lower ODP and GWP values than other substitutes.

(d) [HCFC BLEND] A

[HCFC BLEND] A is acceptable as a substitute for Halon 1301 in unoccupied total flooding applications. [HCFC BLEND] A is not anticipated to result in toxic exposures when used in unoccupied areas. The blend has an ODP higher than other HCFC substitutes, but appears more effective on a weight and storage volume equivalency basis.

(e) HFC–23

HFC–23 is an acceptable alternative to Halon 1301 in unoccupied areas only for high value applications such as those involving the protection of public safety or national security; telecommunication or computer equipment related to public safety or national security; Armored Personnel Vehicles and related vehicles; and for explosion initiation/suppression with flammable liquids and gases. Due to the long atmospheric lifetime of FC 3–1–10 and its global warming potential, the Agency urges fire protection specialists to consider alternatives to FC 3–1–10 in unoccupied areas. Such alternatives would include other halocarbon systems, water sprinkler systems, or manually operated extinguishers in conjunction with improved and well-maintained fire detection and warning devices and the use of cross-zoning to avoid unnecessary discharge.

In those limited cases described above in which FC 3–1–10 is the optimal fire protection choice, care must be taken to limit releases of FC 3–1–10. To this end, the Agency is also proposing to require (1) that systems not be tested using FC 3–1–10, and (2) that during servicing and maintenance all FC 3–1–10 be recovered from the total flood system and recycled for later use.

(f) HFC–125

HFC–125 is acceptable for use as a Halon 1301 substitute in unoccupied areas. Specific cardiotoxicity information has not been received by the Agency regarding HFC–125. However, in unoccupied areas, it is not expected that human health would be threatened by use of HFC–125. In addition, HFC–125 does not deplete stratospheric ozone.

Despite its zero ODP, HFC–125 has one of the highest calculated GWP (100 year GWP of 2500) of any HFC or HCFC currently planned for production as a halon or CFC substitute.

(g) HFC–134a

In unoccupied areas, toxicity concerns are minimal. Thus, for the reasons outlined in the section on occupied areas, HFC–134a is acceptable for use in unoccupied areas.

(h) HFC–227ea

In unoccupied areas, it is not expected that human health would be threatened by use of HFC–227ea. In addition, HFC–227ea does not deplete stratospheric ozone. HFC–227ea is therefore acceptable for use in unoccupied areas.

HFC–227ea is the most effective of the proposed HFC substitutes for Halon 1301. Testing indicates an extinguishing concentration of 5.9 percent. HFC–227ea can replace Halon 1301 at a ratio of 2.4 by weight and 2.55 by volume which may limit its applicability in existing total flood systems.

(i) FC 3–1–10

FC 3–1–10 is acceptable as a total flood agent in unoccupied areas only for those limited applications involving the protection of public safety or national security; telecommunication or computer equipment related to public safety or national security; Armored Personnel Vehicles and related vehicles; and for explosion initiation/suppression with flammable liquids and gases. Due to the long atmospheric lifetime of FC 3–1–10 and its global warming potential, the Agency urges fire protection specialists to consider alternatives to FC 3–1–10 in unoccupied areas. Such alternatives would include other halocarbon systems, water sprinkler systems, or manually operated extinguishers in conjunction with improved and well-maintained fire detection and warning devices and the use of cross-zoning to avoid unnecessary discharge.

In those limited cases described above in which FC 3–1–10 is the optimal fire protection choice, care must be taken to limit releases of FC 3–1–10. To this end, the Agency is also proposing to require (1) that systems not be tested using FC 3–1–10, and (2) that during servicing and maintenance all FC 3–1–10 be recovered from the total flood system and recycled for later use.

(j) [Inert Gas Blend]

[Inert Gas Blend] is approved for use as a 1301 substitute in unoccupied areas. This agent would not be considered a "drop in" replacement in a total flooding system due to its high extinguishing concentration.
Carbon Dioxide

Carbon Dioxide is approved for use as a Halon 1301 substitute in unoccupied areas. CO₂ is currently widely used as a total flooding agent. In the past, CO₂ systems were used in many of the applications now served by halons. As a total flooding agent, CO₂ has an extinguishing concentration ten times that of Halon 1301 and requires 1.4 times the storage volume required by 1301 systems; it is also an asphyxiant in the concentrations required for total flooding. Thus, it is most suited for use in unoccupied areas.

In the review of proposed substitutes, the Agency looks at a variety of health and environmental factors, including whether the agent could potentially contribute to global warming. While carbon dioxide is a greenhouse gas, it is a byproduct of many industrial processes. We realize that carbon dioxide is recaptured and reformulated as a fire fighting agent and thus does not require new production. Therefore, the Agency has determined that its status as a potential global warming is irrelevant to our review.

Water sprinkler systems are also approved for use as a 1301 substitute in unoccupied areas. EPA proposes that such systems should not be used on Class C electrical fires or in instances in which secondary damage is considered unacceptable.

Explosion Inertion

Explosion inertion agents are not currently regulated by OSHA or any other regulatory body. However, design concentrations for systems protecting from explosion of various gases or flammable liquids may expose personnel to cardiotoxic levels of inertion agents. While the Agency is not currently proposing to place conditions for the use of alternatives in occupied areas, it may do so in the final rule subject to public comment as well as further analysis with agencies such as OSHA and OMB. EPA could place a condition for use of alternative agents in occupied areas which would identify the cardiotoxic LOAEL and would prohibit design concentrations that exceed that level.

EPA requests comment on the use of conditions where no regulatory gap, per se, exists, but where the use of an alternative poses risk to the public. By imposing such conditions, EPA would be establishing a new regulatory framework where one did not previously exist.

HFC-22B1

HFC-22B1 is acceptable for use as a Halon 1301 replacement in explosion inertion applications in unoccupied areas. HFC-22B1 is an effective halon substitute for explosion inertion, requiring an inertion concentration of 8 percent. Because this value exceeds the recommended exposure concentrations for short-term exposures to HFBC-22B1, and because it cannot be assumed that occupants would have an opportunity to safely evacuate in the event of an explosion, the Agency considers this substitute safe only for use in unoccupied areas.

HFC-22B1 appears to be a suitable candidate for replacing Halon 1301 in existing explosion inertion applications. The storage volume equivalent for HFBF-22B1 is 1.6, lower than any other halon substitute. Thus, despite the relatively high ODP of HFBF-22B1 compared to other substitute agents, HFBF-22B1 can accelerate the transition away from Halon 1301.

This agent was submitted to the Agency as a Premanufacture Notice (PMN) and is presently subject to requirements contained in a Toxic Substance Control Act (TSCA) section 5(e) Consent Order and associated Significant New Use Rule (40 CFR 721.1296).

HFC-23

HFC-23 is acceptable as an explosion inertion agent only for high value applications such as those involving the protection of public safety or national security; telecommunication or computer equipment related to public safety or national security; or life support functions. While this agent has an ODP of 0, it has a relatively high Global Warming Potential and an atmospheric lifetime of some 300 to 400 years. The Agency is currently restricting its use until further analysis on this issue is complete. Until then, the Agency urges explosion protection specialists to consider alternatives to HFC-23 in unoccupied areas.

HFC-23 is attractive for use as an explosion inertion agent in occupied areas because the draft report on cardiotoxicity indicates that its cardiotoxic NOAEL is over 30% without added oxygen and over 50% with added oxygen. The Agency is awaiting the final report to validate these values, but believes that the draft report adequately represents the likely cardiotoxicity of the agent.

Explosion inertion requires the rapid discharge of agent, often without providing time for evacuation of personnel. Possible exposure of occupants to toxic level of the compound must be carefully controlled and balanced against the risk of explosion. While the Agency is not currently imposing conditions on the use of this agent in occupied areas, employers are advised to evaluate this agent in light of the fact that the required design concentrations vary for different atmospheres. The design concentration should not exceed the cardiotoxic LOAEL for HFC-23 of 50% in an occupied area. The Agency also recommends that employers provide an alarm to alert personnel of system discharge, and to evacuate all personnel as soon as possible after system discharge.

HFC-227ea

HFC-227ea is acceptable for use as an explosion inertion agent in occupied and unoccupied areas. The preliminary report on the cardiotoxicity of HFC-227ea indicates a cardiotoxic LOAEL of at least 10.5%. The Agency is awaiting the final report to validate the data, but believes that the draft report represents a conservative estimate of its likely cardiotoxic value. Because required design concentrations vary for different atmospheres, explosion protection engineers must ensure that this agent is not used in an occupied area when a concentration greater than the estimated cardiotoxic LOAEL of 10.5% is required.

Explosion inertion requires the rapid discharge of agent, often without providing time for evacuation of personnel. Possible exposure of occupants to toxic level of the compound must be carefully controlled and balanced against the risk of explosion. While the Agency is not currently imposing conditions on the use of this agent in occupied areas, employers are advised to evaluate this agent in light of the fact that the required design concentrations vary for different atmospheres. The design concentration should not exceed the cardiotoxic LOAEL for HFC-227ea of 10.5% in an occupied area. The Agency also recommends use of an alarm to alert personnel of system discharge, and
to evacuate all personnel as soon as possible after system discharge.

This agent is also acceptable for unoccupied areas.

(a) FC 3–1–10

FC 3–1–10 is acceptable as an explosion inertion agent only for those limited applications involving the protection of public safety or national security; telecommunication or computer equipment related to public safety or national security; or life support functions. Due to the long atmospheric lifetime of FC 3–1–10 and its potentially large global warming potential, the Agency urges explosion protection specialists to consider alternatives to FC 3–1–10 in unoccupied areas. Explosion inertion studies conducted with methane and propane indicate an inerting concentration of 7.8 percent and 9.5 percent respectively. Additional performance data is being collected for use with other flammable gases. On data has been received by the Agency for explosion suppression applications.

The cardiotoxicity NOAEL of this agent is 40 percent and its LOAEL is greater than 40%, and thus is well suited for use in occupied areas. Explosion inertion requires the rapid discharge of agent, often without providing time for evacuation of personnel. Possible exposure of occupants to toxic level of the compound must be carefully controlled and balanced against the risk of explosion. While the Agency is not currently imposing conditions on the use of this agent in occupied areas, employers are advised to evaluate this agent in light of the fact that the required design concentrations vary for different atmospheres. The design concentration should probably not exceed the cardiotoxic NOAEL for FC 3–1–10 of 40% in an occupied area. The Agency also recommends use of an alarm to alert personnel of system discharge, and to evacuate all personnel as soon as possible after system discharge.

In those limited cases described above in which FC 3–1–10 is determined to be the optimal explosion inertion choice, care must be taken to limit releases of FC 3–1–10. To this end, the Agency is also proposing to require (1) that systems not be tested using FC 3–1–10, and (2) that during servicing and maintenance all FC 3–1–10 be recovered from the inertion system and recycled for later use.

(f) [Inert Gas Blend]

[Inert Gas Blend] is approved for use as a 1301 substitute for explosion inertion in occupied and unoccupied areas. This agent is a non-reactive, non-halocarbon substance, and thus not carcinogenic, mutagenic, or teratogenic; the toxicity and cardiotoxicity tests normally applied to halon substitutes do not apply here. Rather, this agent is a potential asphyxiant as it is designed to decrease the oxygen to a level at which combustion cannot be supported. This blend is designed to increase breathing rates, thus making the oxygen deficient atmosphere breathable for short periods of time. Data submitted by the manufacturer was peer-reviewed by pulmonary, cardiac, and stroke specialists. All have agreed that the blend does not pose significant risk to the working population and may even pose less risk than does exposure to halocarbon agents.

The inerting concentration for this blend is 44 percent for methane/air mixtures and 50 percent for propane/air mixtures. A 50 percent concentration would result in an atmosphere of only 10.5 percent oxygen content, which is the lower limit at which studies show this agent safe for use with healthy, young people. Explosion inertion requires the rapid discharge of agent, often without providing time for evacuation of personnel. Possible exposure of occupants to a hypoxic, or oxygen reduced, atmosphere must be carefully controlled and balanced against the risk of explosion. The Agency therefore requires an alarm to alert personnel of system discharge, and all personnel must evacuate as soon as possible after system discharge.

Concerns have been raised about the decibel level of this system upon discharge. The manufacturer has submitted a report indicating the decibel level to be 117 decibels for 3 seconds followed by a decay in noise level over 5 minutes, compared to 130 decibels for a typical halon system. The Time Weighted Average (TWA) of this system is 57 decibels. These levels are in compliance with the OSHA workplace maximum allowed peak of 140 decibels and a maximum Time Weighted Average (TWA) of 90 decibels.

b. Proposed Unacceptable Substitutes.

(1) Streaming Agents: Commercial/Industrial Use. (a) CFC–11. CFC–11 is proposed unacceptable in its proposed application as a Halon 2402 substitute or for large outdoor uses. This agent has been proposed as a substitute for Halon 2402, as well as for use in a new niche for large outdoor fires, such as for dropping from helicopters. Halon 2402 is not used in the U.S. and thus does not require a substitute agent. As a new use in the large outdoor sector, such as dropping from helicopters, other non-ozone depleting methods are already in use and thus do not warrant introduction of this substitute.

H. Sterilants

1. Overview

CFC–12 is widely used in combination with ethylene oxide (EtO) to sterilize medical equipment and devices. The most prevalent combination consists of 12 percent EtO mixed with 88 percent CFC–12; the mixture is therefore referred to as "12/88". EtO serves as the actual sterilant in this mixture and can be used alone as a sterilant, but by itself, EtO is highly flammable. CFC–12 acts as a stabilizing agent to reduce the overall flammability of the blend.

Sterilants, including 12/88, are used in a variety of applications. These include hospital sterilization, medical equipment sterilization, pharmaceutical production, spice fumigation, commercial research and development, and contract sterilization. Hospitals are by far the most numerous users of sterilants. Within hospitals, 12/88 is the most popular sterilant. Estimates indicate that in 1989, EtO/CFC–12 was used for over 95 percent of all sterilization in hospitals. Pure EtO systems are also used in hospitals, but typically as small, tabletop models. Few hospitals have large pure EtO systems in-house. Other individual users of sterilant such as contract sterilizers and pharmaceutical producers, while less numerous than hospitals, typically consume more sterilant than the average hospital. They are also more likely to use pure EtO sterilization systems to handle large capacity loads.

Despite the varied end uses of sterilants, the Agency did not divide its analysis and regulation of the sterilants sector into distinct end uses. This is because alternatives to 12/88 are consistent across end uses, and the sterilant sector as a whole represents one of the smallest use sectors for Class I substances which is being considered in the SNAP program. On an ODP-weighted basis, US consumption of
CFC–12 for sterilization represented less than 4 percent of the total US consumption of ozone depleting substances in 1990. Several alternatives to 12/88 are currently in widespread use, but each is limited in applicability by material properties of the devices to be sterilized. These currently available alternatives are unlikely to serve as widespread substitutes for 12/88. Steam sterilizers, for example, are used in many applications and are less expensive to purchase and to operate than 12/88 systems. However, steam can only be used to sterilize equipment that can resist high temperatures. Pharmaceutical manufacturers already use steam to the maximum extent possible, but hospitals may be able to shift some of their current 12/88 use to steam by separating heat-resistant devices from heat-sensitive ones. Other alternatives such as radiation, peracetic acid, and glutaraldehyde are also in use, but, like steam, are incompatible with many of the materials now sterilized with 12/88. In fact 30 to 50 percent of new products are initially sterilized with gamma radiation, but it is not possible to re-sterilize hospital surgical equipment with gamma radiation. Instead, 12/88 must be used.

Other alternatives are currently under development. These include chlorine dioxide, gaseous ozone, vapor phase hydrogen peroxide, and ionized gas plasma. Many of these alternatives are also incompatible with materials currently sterilized with 12/88. Those that may be applicable as partial substitutes for 12/88, such as hydrogen peroxide, are not expected to be commercially available in the near term. For these reasons, alternatives such as steam and other currently available technologies should be used wherever applicable, but are not specifically addressed in this proposal. Additional information on such alternatives and on specific uses of 12/88 can be found in the supporting documentation retained in the public docket. The proposed determinations in this section are based on the risk screen described in the background document titled “Characterization of Risk from the Use of Substitutes for Class I Ozone-Depleting Substances: Sterilization.”

2. Substitutes for Sterilization. a. Halocarbons

A number of halocarbon substitutes have been suggested as viable alternatives to CFC–12 in EtO blends for sterilization. These include HCFC–123, HCFC–124, HFC–125, HCFC–141b, and HFC–134a and HFC–227ea. At present, however, only HCFC–124 and HFC–227ea have been proposed as near-term candidates. While HCFC–124 has been fully evaluated by the Agency in this rule, a final determination on HFC–227ea will be completed as soon as exposure data are received. Additional research will be required to determine the suitability of the other agents in EtO blends.

Many of the proposed halocarbons offer good potential as EtO diluents. They demonstrate good flame retardation, low ODPs, low GWP, low toxicity, materials compatibility, acceptable vapor pressures, and good blending properties. Mixtures of halocarbons with EtO would most likely be at ratios similar to 12/88, or with a slightly lower EtO content. HCFC–124 has been tested with 8.8 percent EtO, for example. Such properties would make halocarbon blends virtual drop-in replacements for 12/88 in existing systems. The blends would also be far less damaging to stratospheric ozone than is 12/88.

b. Carbon Dioxide

Carbon dioxide is already in widespread use as a sterilant in blends with EtO. The most common blend contains 10 percent EtO and 90 percent CO₂ and is referred to as “10/90.” While 10/90 is compatible with most of the materials now sterilized with 12/88, it must be used at higher operating pressures than 12/88 systems and hence is not a direct drop-in replacement for 12/88. Use of CO₂ blends requires that the sterilizing unit itself be upgraded to handle higher operating pressures in order to prevent excessive leakages of EtO from the system. However, operating costs for CO₂ systems are typically lower than those for 12/88 systems.

CO₂ and EtO tend to separate while stored in pressurized containers. Thus, initial discharges from the canisters during use may contain excessively high amounts of flammable EtO; final discharges from nearly empty canisters may contain pure CO₂ and may not effectively sterilize equipment. To overcome this problem, “unit dose” canisters have been developed for use in conjunction with CO₂ sterilizers. For safe operation, these canisters must be connected and disconnected from the sterilizing unit before and after each use, thereby increasing the risk of accidental exposure. Improved training procedures will be required with such systems.

c. Pure EtO

Pure EtO systems can also be used in place of current 12/88 sterilizers. By itself, EtO is toxic, carcinogenic, and flammable. Thus, additional precautions must be taken to limit occupational exposures and conflagration. Present OSHA standards and proper engineering controls have demonstrated their ability to provide for safe operation of such systems. Pure EtO systems are currently used by many contract sterilizers, large hospitals, and other large users.

Pure EtO cannot be used in existing 12/88 sterilizing equipment without significant technical changes. Large sterilizers may have to be relocated or rooms modified in order to reduce damage from possible explosions. Both large and small systems require retrofits to provide the capability to properly vent EtO and to prevent explosions. Such conversions are costly, but may produce long-term cost savings. Operating costs for pure EtO systems are lower than those for 12/88 systems.

3. Preliminary Listing Decisions

a. Acceptable. (1) HCFC–124

HCFC–124 is acceptable as a substitute for CFC–12 in EtO blends. Initially testing in hospital, industrial, and laboratory settings indicates that an EtO/HCFC–124 blend can serve as a virtual drop-in replacement for 12/88, enabling users to transition away from CFC–12 while still using their existing equipment.

Use of HCFC–124 in sterilizers will allow significant reductions in skin cancer cases and deaths resulting from ozone depletion. HCFC–124 has an ODP of only 0.02. Modeling results indicate that even if HCFC–124 replaces all current use of CFC–12 in sterilization, resulting skin cancer deaths in the total US population born before 2030 will total only 600 more than if a zero ODP substitute were available. In addition, the low GWP of HCFC–124 ensures that disposal of the chemical in sterilizers will have a negligible effect on global warming.

Under Title III of the Clean Air Act Amendments of 1990, the Agency is required to regulate any of the 189 hazardous air pollutants (HAPs). Ethylene oxide is a HAP, and the user is alerted to follow all upcoming regulations concerning the use of ethylene oxide, whether used alone or in a blend. For example, it is likely in the future that Title III will require a system that prevents venting of EtO into the atmosphere, therefore users installing new HCFC–124/EtO systems may choose to take this into consideration.

(2) Carbon Dioxide

Carbon dioxide is acceptable as a substitute for CFC–12 in EtO blends.
used for sterilization. Carbon dioxide can effectively reduce the flammability of ETO and does not deplete stratospheric ozone. While CO₂ is considered a greenhouse gas, atmospheric modeling indicates that its use in the sterilants sector will have no measurable impact on global warming. Furthermore, most CO₂ currently used in sterilant mixtures is the recaptured by-product of other chemical processes, so its manufacture for use in sterilizers should not increase emissions to the atmosphere. Carbon dioxide is an asphyxiant at high concentrations, but engineering controls designed to limit occupational exposures from the more toxic ETO will also serve to prevent potentially lethal exposures to CO₂.

Blends of CO₂ and ETO are commercially available at present, and proven process cycles already exist. Blends of CO₂ and ETO have been in widespread use for many years and dominated the market before the development of 12/88. Recent flammability tests indicate that the maximum concentration of ETO in CO₂ blends may have to be lowered from its traditional level of 10 per cent to perhaps 8 or 9 per cent to achieve adequate levels of safety. As mentioned above, ethylene oxide is a HAP, and the user is alerted to follow all upcoming regulations concerning the use of ethylene oxide, whether used alone or in a blend.

Carbon dioxide blends will not serve as direct drop-in replacements for 12/88. The higher operating pressures of CO₂/ETO blends will require modifications to existing equipment. The Montreal Protocol's technology assessment report on sterilants estimated that less than one-half of the 12/88 sterilant users for which it was determined that hospitals are certified to operate at the higher pressures necessary for CO₂/ETO blends.

(3) Pure ETO

Pure ETO is acceptable as a substitute for 12/88 in sterilization. By itself, ETO is neither an ozone depleting substance nor a contributor to global warming. However, ETO is toxic, carcinogenic, and flammable. While these factors must be considered in the decision to approve ETO as a substitute for 12/88 and must be considered by users selecting appropriate substitutes for their current use of 12/88, the Agency considers current applicable standards and operating procedures (such as OSHA standards for occupational exposure) sufficient to protect human health and the environment. Thus, pure ETO systems are acceptable substitutes for 12/88. Users are advised to adhere to all existing workplace standards and to train workers in the proper operation of ETO equipment. Historical experience with pure ETO systems indicates that they can be used safely when operated in accordance with such guidelines. Because of the threat posed by vented ETO to the general population, the Agency also recommends that pure ETO systems be used in conjunction with emission control technologies such as catalytic converters or acid water scrubbers to prevent exposures of the general population to dangerous levels of ETO.

As mentioned above, ethylene oxide is a HAP, and the user is alerted to the probability of future regulations concerning the use of ethylene oxide, whether used alone or in a blend. Pure ETO should not be considered a drop-in replacement for 12/88. ETO systems operate at atmospheric pressure or below, allowing some current 12/88 equipment to be retrofitted for pure ETO through the addition of proper ventilation and control technologies. However, the costs associated with such changes, especially with larger equipment, can be prohibitive. Nevertheless, use of pure ETO can reduce operating costs substantially compared to those achieved with equivalent 12/88 systems.

Some CFC aerosol products were specifically exempted from the ban based on a determination of "essentiality." (See reference Essential Use Determinations—Revised, 1978.) The other uses of CFCs in aerosol and pressurized dispenser products (e.g., as an active ingredient, a solvent, or as the sole ingredient) were excluded from the ban because they did not fit the narrow definition of "aerosol propellant". Therefore, prior to the 1990 Clean Air Act Amendments, the only aerosol products that still contained CFCs were products exempted from the 1978 ban on CFC propellants or products excluded from the 1978 ban.

The amended Clean Air Act of 1990 includes statutory authorities relevant to use of HCFCs in several sections of Title VI. Title VI divides controlled ozone-depleting substances into two distinct classes. Class I is comprised of CFCs, halons, carbon tetrachloride and MCF. Class II is comprised solely of HCFCs. In addition to mandating the phase out of Class I and Class II substances, section 610 of Title VI also provides for the prohibition of certain products made with Class I and Class II substances. The product bans for Class I substances and Class II substances are distinct from one another and are addressed in subsections 610(b) and 610(d), respectively. In section 610(b), Congress directed EPA to promulgate regulations that prohibit the sale or distribution of certain “nonessential” products that release Class I substances as of November 15, 1992. Under this subsection, Congress specifies particular products as nonessential and directs EPA to identify other nonessential products. In the Notification of Proposed Rulemaking (57 FR 1992, January 16, 1992), EPA proposed regulations that implement the requirements of section 610(b) and ban certain nonessential products that release Class I substances. Under this rule, EPA proposed to ban, among other products, flexible and packaging foam, and aerosols and other pressurized dispensers using CFCs. The use of methyl chloroform, while a Class I substance, is not restricted under this proposed rule.

As directed by Congress, EPA conducted research into the purpose or intended use of products containing Class I substances, the technological availability of substitutes, safety and health considerations, and other relevant factors including the economic impact of banning selected products. EPA then proposed to ban the use of CFCs as propellants and solvents in all aerosol products with the following
specific exemptions (57 FR 1992, January 16, 1992):

- Contraceptive vaginal foams;
- lubricants for pharmaceutical and tablet manufacture;
- metered dose inhalation devices;
- gauze bandage adhesives and adhesive removers;
- commercial products using CFC-11 or CFC-113 as lubricants, coatings, or cleaning fluids for electrical and electronic equipment;
- commercial products using CFC-11 or CFC-113 as lubricants, coatings, or cleaning fluids for aircraft maintenance; and
- release agents for molds using CFC-11 or CFC-113 in the production of plastic or elastomeric materials.

In addition to the first four products listed above, EPA is likely to exempt additional medical products as directed by the CAA. Medical devices, as defined in section 601, include devices, diagnostic products, drugs, and drug delivery systems that (a) utilize a Class I or Class II substance for which no safe and effective alternative has been developed and (b) have been approved and determined to be essential by the FDA Commissioner in consultation with the EPA Administrator. It is important to note that a product being exempted from the Class I ban does not imply exemption from the phase-out requirements under the CAA, which the Agency is examining separately.

Section 610(d) of the CAA prohibits the sale or distribution of certain products that contain or are manufactured with Class II substances. This ban, which is effective January 1, 1994, extends to certain aerosols and pressurized dispensers which contain Class II substances and plastic foam products which contain or are manufactured with a Class II substance. EPA believes that the ban on certain products containing Class II substances is self-executing. Section 610(d)(1) bans the sale of the specified Class II products on its own terms, without any reference to required regulations. Thus, EPA is not required to determine which products will be banned.

However, section 610(d)(2) allows EPA to grant exceptions and exclusions from the ban on aerosol and pressurized dispenser products containing Class II substances. Specifically, EPA is authorized to grant exceptions from the prohibition where the use of the aerosol product or pressurized dispenser is determined by the Administrator to be essential and where a nonflammable or worker safety, and where the only available alternative to use of a Class II substance is use of a Class I substance which legally could be substituted for such Class II substance (i.e., use of a Class I substance that is still allowed). In addition to these two criteria for exceptions, aerosol products may be excluded from the ban as a result of a third consideration in section 610(d)(2); namely, that the ban on products containing Class II substances shall not apply to any medical device. Reflecting the self-executing nature of the CAA ban, any aerosol product or pressurized dispenser containing a Class II substance is banned as of January 1, 1994, unless EPA grants an exception.

HFCs have current and potential applications as propellants and as solvents in aerosol products. However, until recently, their use has been limited by the aerosol industry because of their high cost relative to traditional options such as CFCs and hydrocarbons. Increased regulation of CFCs, including taxation of these substances and an eventual phase-out, has meant that HFCs are, for an interim period, economically viable in some applications, particularly where concern about flammability limits the use of cheaper alternatives, such as hydrocarbons.

2. Substitutes for Aerosols

The Class I substances that are currently being used in aerosol applications include CFC-11, CFC-12, CFC-113, CFC-114, and methyl chloroform (MCF). Similarly, the Class II substances that are currently being used are HCFC-22, HCFC-142b, and HCFC-141b. The Agency has elected only to discuss alternatives for the CFC-11, CFC-12, MCF, HCFC-22, HCFC-142b, and HCFC-141b.

The uses for CFC-12 and CFC-114 are as propellants in medical applications and will not be discussed here because the substitutes for these applications are currently being developed and will have to undergo FDA approval. Possible substitutes in this application include HFC-134a and HFC-227ea, which both have low toxicity and zero ozone depletion potential. Regulatory approval for these compounds, however, is contingent on FDA approval, which will likely occur over the next several years.

A variety of chemicals are currently being used or are being considered as substitutes for Class I and II controlled substances used in non-inhalation aerosols and pressurized containers. The suitability of alternatives depends upon the product in which they are used. Each of these alternatives has its own physical and chemical characteristics which make it optimal choice for the product in question, in terms of such factors as solvency properties, propellant characteristics, performance, cost, and environmental considerations. However, the Agency believes that a majority of the substitutes considered to replace the Class I and II controlled substances used as propellants or solvents in aerosols and pressurized containers as propellants and solvents are currently available and easily integrated into existing aerosol production facilities.

The primary substitutes for the propellant uses of HCFC-22 and HCFC-142b are as follows:

- Hydrocarbons
- Dimethyl ether
- HFCs
- Compressed Gases
- Alternative Processes

The primary substitutes for the solvent/diluent uses of CFC-11, CFC-113, MCF, and HCFC-141b are as follows:

- Petroleum Distillates
- Ketones, esters, ethers, and alcohols
- HCFC-141b
- Terpenes
- Chlorinated Solvents
- Water-Based Systems

This list of substitutes was compiled with the help of companies that submitted information on substitutes to the Agency in response to the January 16, 1992, Advance Notice of Proposed Rule-Making. Today's decisions on these substitutes are listed in Appendix B. The remainder of the section discusses these substitutes, the decision on each substitute, and the Agency's reasoning behind each determination. Vendors or users of other substitutes not included on the table for the SNAP determinations must provide information on the substitutes so that the Agency can complete the determinations.

a. Substitutes for Propellants.—(1) Hydrocarbons. Hydrocarbons are promising replacements for nonessential uses of HCFC-22 as a propellant in aerosols and pressurized containers. These small chain compounds, such as butane, isobutane, and propane, have low boiling points, making them excellent propellants. They are used separately or in mixtures, are inexpensive compared to HCFC-22 (HCFC-22 is four times more expensive than hydrocarbons), and are readily available from most chemical distributors.

The Agency believes that the major area of concern with the replacement of hydrocarbons for HCFC-22 is the high flammability of hydrocarbons. In areas where a nonflammable propellant is needed, a hydrocarbon could not be used. For example, the use of hydrocarbons around electrical...
equipment could prove hazardous if sparks from the equipment were to ignite the hydrocarbon propellant. Hydrocarbon propellants may substitute propellants where flammability is not a concern. To reduce product flammability, hydrocarbons can be used with water-based formulations in products such as insecticides where product quality would not be adversely impacted. Manufacturers are also hindered from selling hydrocarbon propellants in certain jurisdictions. In California, for example, the use of hydrocarbons is restricted because of their classification as volatile organic compounds which contribute to low level ozone or smog.

(2) Dimethyl Ether. Dimethyl ether (DME) is a medium pressure, flammable, liquefied propellant. Because of its chemical properties, it can be used as a combination propellant/solvent, although it is typically classified together with refrigerants and is used in combination with other propellants. Practices for manufacture and use of aerosol products formulated with DME parallel practices employed with hydrocarbons.

(3) Hydrofluorocarbons. Hydrofluorocarbons (HFCs) such as HFC-134a and HFC-152a are partially fluorinated hydrocarbons, which have recently been developed. These compounds are less dense than HCFC-22, but with minor reformulation adjustments could function equally well as propellants except in products such as noise horns, which require a more dense gas. Because HFCs have only recently been developed, they are only now becoming readily available and are expected to be priced significantly higher than HCFC-22.

Preliminary studies show that HFCs are nonflammable and have low toxicity, which would make them good replacements for HCFC-22 as a propellant. They also may be used in conjunction with flammable chemicals to reduce the flammability of such mixtures. For example, HFCs are being tested for use with dimethyl ether (DME) in safety sprays and animal repellents. Although DME is flammable, the overall product formulation is not. HFCs are also being tested as replacements for CFCs still used in medical applications because of their nonflammable, nontoxic properties.

(4) Compressed Gases. Compressed gases such as carbon dioxide, nitrogen, air, and nitrous oxide are common, low molecular weight gases used as propellants in aerosol products but not as drop-in replacements. First, alternative dispensing mechanisms and stronger containers are needed because these gases are under significantly greater pressure. Containers holding compressed gases are, therefore, larger and bulkier. Second, because these chemicals have low molecular weights, they are inadequate as replacements for HCFC-22 in products requiring a dense gas propellant, such as noise horns, or in products requiring fine dispersion of the product, such as surface lubricants and weld inspection developers. Third, compressed gases dispel material faster because they are under higher pressure, which contributes to wasted product. Compressed gases are readily available from most chemical distributors and are inexpensive. Compressed gases cool upon expansion. This property could be beneficial when they are used as freezing agents and gum removers and could substitute for some nonessential uses of HCFC-22. Compressed gases are also nonflammable and can serve as propellants in applications where a nonflammable propellant is necessary, but not in applications where a fine even dispersion is required.

(5) Alternative Processes. Alternative processes, such as manually operated pumps and sprays, provide an alternative delivery mechanism in place of the aerosol dispenser. Development of alternative process replacements depends on technological feasibility, but successful implementation of these processes depends on consumer or worker preferences. Some products, such as aerosol foams, cannot now be easily formed with alternative processes, making the replacement of the propellant difficult. In other products, the alternative process may not provide proper dispersion or accurate application of the product, limiting its use. Persons using manual pumps or sprays (in applications where alternative processes function adequately as replacements) on a continuous basis may become fatigued with the constant pumping motion, thus reducing consumer satisfaction.

Therefore, alternative processes could not easily replace the use of aerosols in applications where it is not technologically feasible or where the product is used repeatedly. Nonetheless, these substitutes can serve as viable alternatives in certain applications.

b. Substitutes for Solvent/Diluents. (1) Petroleum Distillates. Petroleum distillates are hydrocarbons fractionated from the distillation of petroleum. These compounds are loosely grouped into paraffins (six carbon chains to ten carbon chains—n-hexane, n-heptane, etc.) and light aromatics (toluene and xylene) and come in various grades of purity. These compounds have good solvent properties, are inexpensive (about half the price of MCF), and are readily available from chemical distributors. When a controlled substance is used as a diluent, such as in automotive undercoatings, substitution using petroleum distillates is relatively easy with minor reformulation changes. Many of these products containing petroleum distillates even outperform their chlorinated counterpart.

Petroleum distillates are, however, flammable, and thus cannot be used as replacement solvents in applications where the solvent must be nonflammable such as electronic cleaning applications. In addition, pesticide aerosols formulated with certain petroleum distillates must adhere to requirements imposed under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

(2) Oxygen-Containing Hydrocarbons. Compounds containing oxygen-containing hydrocarbons are compounds are based on hydrocarbons containing appendant oxygen (alcohols and ketones), integral oxygens (ethers), or both (esters). These compounds are relatively inexpensive compared to MCF—about half the cost—and are readily available from chemical distributors. These compounds are also flammable and cannot be used as alternatives to solvents in applications where the solvent must be nonflammable.

These compounds are currently being blended with Class I substances to reduce the amount of Class I substances used in a product formulation. Since the quantity of these compounds is small, the product still remains nonflammable. Some manufacturers, however, are completely reformulating products such as spot removers with ketones, esters, ethers, or alcohols. To continue the use of these convenient products, consumers may have to be educated about the product's increased flammability.

(3) Hydrofluorocarbons (HCFCs). HCFC-141b is a potential substitute to replace CFC-11 and CFC-113 used in solvent/diluent applications in aerosols and pressurized dispensers. HCFC-141b's ODP is similar to MCF, making it unlikely that aerosol manufacturers would reformulate their products away from MCF towards HCFC-141b. HCFC-141b has a number of characteristics which make it a suitable alternative solvent, namely: it is nonconductive, nonflammable, and evaporates quickly. HCFC-141b is expensive compared to the pretax price of CFC-113 (almost three times the cost). However, HCFC-141b is slightly corrosive to plastic parts, and could not
serve as a drop-in replacement for all the uses of CFC–11 and CFC–113 as a solvent.

(4) Terpenes. Terpenes are unsaturated hydrocarbons based on isoprene subunits. They have good solvent properties and could replace ozone-depleting compounds in some solvent cleaning applications. They are flammable, which limits their use in applications that require nonflammable solvents. Some terpenes have a slight citrus scent while others have a more stronger unpleasant odor, thereby making them displeasing to use over a constant period of time.

(5) Chlorinated Solvents. Chlorinated solvents such as perchloroethylene, trichloroethylene, and methylene chloride can be used to replace CFC–11, CFC–113, and MCF in solvent applications in aerosol and pressurized containers. These chlorinated solvents are extremely effective and can dissolve compounds which are difficult to dissolve in other solvents, such as fluorinated polymers used in water and oil repellents. However, due to toxicity concerns associated with these substances, their application is likely to be limited, especially in products sold to the general public or in products that are used frequently by workers. In addition, pesticide aerosols formulated with these chlorinated solvents must adhere to requirements under FIFRA.

Chlorinated solvents, because they are strong solvents and nonflammable, are promising substitutes in cleaning applications for electronic equipment or electric motors where safeguards could be used to protect workers from the potentially toxic fumes. These compounds are readily available from chemical distributors at prices comparable to MCF.

(6) Water-Based Formulations. Water-based formulations provide a replacement for the use of CFC–11, CFC–113, and MCF as solvents in aerosols and pressurized dispensers. These reformulated products usually contain new components/active-ingredients that are water soluble. The overall function of the reformulated product remains the same, but the product’s substitute is changed. Most formulations are nonflammable, yet may be difficult to use around sources of electricity because they may short out electrical equipment. Such products may also have short shelf-lives because the active ingredient may decompose in an aqueous environment. Also, these products when sprayed do not evaporate quickly, resulting in product accumulation. This may be problematic in certain applications such as where the accumulation of a water-based product contributes to rust or corrosion. The possibility of reformulating products is product-specific, depending on the feasibility of finding active ingredients that are water soluble.

(7) Monochlorotoluene/ chlorobenzotrifluorides. Monochlorotoluene and chlorobenzotrifluorides are of commercial interest as solvent substitutes for aerosols. These compounds can be used either in isolation or in various mixtures, depending on desired chemical properties. The Agency recently received information on these formulations, and it will issue a SNAP determination for these substitutes in the next set of listing decisions.

3. Preliminary Listing Decisions

a. Acceptable Substitutes. (1) Propellants (a) Hydrocarbons. Hydrocarbons are acceptable substitutes as propellants in the aerosols sector. Hydrocarbons have several environmental advantages over other substitutes. For example, they have zero ozone-depletion potential, and because of their extremely short atmospheric residence times they are estimated to have insignificant impact on global warming. Yet their reactivity contributes to formation of tropospheric ozone. The Agency has assessed this effect, however, and found that the increase in volatile organic compound emissions (VOCs) from these substitutes will have no significant effect on tropospheric ozone formation.

Hydrocarbons have a long history of use, and the increase due to replacement of CFCs as aerosol propellants represents a fraction of current consumer use. Hydrocarbon propellants acquired industrial importance in the U.S. in the early 1950s. By 1978, when the ban on CFC propellants in the U.S. was promulgated, nearly half of all aerosol units being produced in the U.S were already using hydrocarbon propellants. This percentage grew to nearly 90 percent in 1979. Most of the hydrocarbon propellants are essentially non-toxic. Very high concentrations of hydrocarbons are necessary to alter normal body functions. No temporary or permanent physiological malfunctions are produced by these chemicals. Very high concentrations of hydrocarbons may result in asphyxiation because of lack of oxygen. Hydrocarbon propellants are flammable. Thus, precautions will need to be taken in receiving, unloading, transferring, storing, and filling hydrocarbons aerosol products. The listing of these compounds as acceptable substitutes does not exempt producers or users from other regulatory or industrial standards such as those promulgated by OSHA. However, because of the widespread use of these materials, industry is already familiar with the safety precautions necessary in switching from a CFC filling operation to one using hydrocarbons.

(b) HCFC–22

HCFC–22 is an acceptable substitute as a propellant in the aerosols sector. The principal characteristic of HCFC–22 that has resulted in its increased use is non-flammability. However, the use of HCFC–22, either by itself or blended with other compounds, will be prohibited after January 1, 1994 due to the high ozone-depletion potential of this compound. As noted earlier, section 610(d) of the CAA Amendments of 1990 prohibits the sale and distribution of aerosol products or other pressurized dispensers that contain Class II substances (i.e., HCFCs) by January 1, 1994. Section 610(d)(2) allows EPA to grant exemptions where the use of the aerosol product or pressurized dispenser is determined by the Administrator to be essential as a result of flammability or worker safety, and where the only available alternative to the use of a Class II substance is the legally permitted use of a Class I substance.

The Agency is not restricting substitution of HCFC–22 for Class I propellants at this time. However, the Agency advises companies that, under the SNAP program, the Agency will only allow uses of HCFC–22 consistent with the exemptions provided under section 610(d)(2), once these regulations are promulgated in 1994.

(c) HCFC–142b

HCFC–142b is an acceptable substitute as a propellant in the aerosols sector. Although this compound has a comparatively high ODP, it is one of the few non-toxic, non-flammable substitutes. However, as described in the section on HCFC–22, use of HCFC–142b, either by itself or blended with other compounds, will be prohibited after January 1, 1994 under section 610(d)(2). After that date, the SNAP program will only grant exemptions for use of HCFC–142b for essential applications based on worker safety and flammability as classified under section 610.

(d) HFC–152a and HFC–134a

HFC–152a and HFC–134a are acceptable substitutes as propellants in
the aerosols sector. HFC-152a has both zero ozone-depletion potential and a low global warming potential. However, HFC-152a by itself is flammable, and necessary precautions should be taken when using this chemical. HFC-134a also has zero ozone-depletion potential, yet this compound does have a relatively long atmospheric lifetime and could therefore contribute to global warming. Despite these concerns, the Agency believes that these substitutes do not pose any significant risks, since they rely on mechanical force to replace the propellant.

(2) Solvents

(a) Petroleum Distillates.—Petroleum distillates are acceptable substitutes as solvents in the aerosols sector. Petroleum distillates have a long history of use, and increases due to replacements for aerosol applications represent a fraction of the current consumption across industries. Concerns for risks from these compounds in possible uses as pesticide aerosol solvents have already been addressed under FIFRA authorities.

(b) HCFC-141b

HCFC-141b, either by itself or blended with other compounds, is an acceptable substitute for aerosol solvent applications. Like HCFC-22, the principal problem with HCFC-141b is that it has a comparatively high ODP—0.11. This is the highest ODP of all HCFCs; in fact, the ODP of HCFC-141b is about twice as high as HCFC-22. Yet in certain cases, such as where flammability is a technical impediment to use of other alternatives, HCFC-141b may be the only alternative to replace other ozone-depleting solvents. Several companies have already contacted the Agency indicating that they have tested alternatives, and that in some cases only HCFC-141b meets performance or safety criteria.

Under the SNAP program, the Agency will allow the use of HCFC-141b as a substitute for CFC-11 or CFC-113 use until January 1994, when regulations under section 610(d)(2) will be promulgated. Key features of section 610 are described under the listing decision for HCFC-22.

(c) Other Chlorinated Solvents

Trichloroethylene (TCE), perchloroethylene (PERC) and methylene chloride (MeC1), are acceptable substitutes as solvents in the aerosols sector. These substitutes have the technical capability to meet a large portion of the needs of the aerosols industry. However, the Agency anticipates that, due to toxicity concerns associated with the past use of these alternatives, the market share for these other chlorinated solvents will not increase substantially.

The toxicity of these three solvents has been subject of extensive analysis. Their use has the potential to pose high risks to workers as well as to residents in nearby communities or consumers using products containing such chemicals.

Although risks to workers can be reduced by adhering to OSHA standards, residual risks to residents in nearby communities may remain. The Agency is aware of potential for these risks to occur, and it has the authority necessary to address them under Title III of the CAA. This section of the CAA lists three of these solvents as Hazardous Air Pollutants, and authorizes the Agency to establish controls for their use. In addition, any risks through use of these compounds as pesticide aerosols have already been addressed using FIFRA authorities.

The Agency did not explicitly evaluate risks to consumers, since it received no indication that these chlorinated solvents were of commercial interest for use in consumer aerosols. The Agency strongly encourages manufacturers to formulate consumer products based on other compounds with fewer known adverse effects on human health.

(d) Oxygen-Containing Hydrocarbons

Oxygen-containing hydrocarbons (ketones, esters, ethers, and alcohols) are acceptable substitutes as solvents in the aerosols sector. Most of these compounds have a long history of use, and the increase due to replacement as aerosol substitutes represents a fraction of the current consumption across all industries.

(e) Terpenes

Terpene-based products are acceptable substitutes as solvents in the aerosols sector. Terpene-based chemicals have a long history of use as industrial solvents, and the increase due to replacement of ozone-depleting compounds in aerosol applications represents a fraction of current consumption across all industries. Additionally, many of these chemicals are naturally occurring organic hydrocarbons and exhibit significant biodegradability.

The use history of these chemicals does not negate the inherent toxicity of these compounds to aquatic life. However, the Agency does not believe that in this case significant adverse effects are to be expected, since in aerosol applications the terpenes volatilize during use and would consequently not be discharged to surface or ground water where aquatic species are to be found.
(f) Water-Based Formulations

Water-based formulations are acceptable substitutes for propellants in the aerosols sector. The Agency did not identify any significant environmental concerns associated with use of these products. They can contain small amounts of VOCs, but these amounts are minor in comparison to products formulated solely with organic solvents.

b. Proposed Unacceptable Substitutes.

(1) Propellants.

None

(2) Solvents.

None

J. Tobacco Expansion. 1. Overview

Tobacco expansion is the process of puffing leaves of tobacco to increase the volume of tobacco used in cigarette production. Currently, one of the primary technologies used to expand tobacco in the U.S. uses CFC-11. One and one half million pounds annually are used in the U.S. in this application.

In the CFC-11 process, tobacco is saturated with CFC-11 in a stainless steel vessel maintained at 120 degrees Fahrenheit and pressurized to 20 psi. The tobacco is then permeated with hot air (330°F) which expands the tobacco. The CFC-11 is vaporized and recovered by cooling and compressing. The CFC-11 is continually recovered and recycled.

The Agency received information about three potential substitutes: (1) Carbon dioxide technology, an alternative process substitute, (2) HCFC-123, a drop-in replacement, and (3) HFC-227ea. In this action, the Agency is listing carbon dioxide as an acceptable substitute for CFC-11 in tobacco expansion. The decision on HCFC-123 as a substitute for CFC-11 for tobacco expansion is pending completion of the Agency's review of the data. Similarly, HFC-227ea is pending completion of review of the data.

2. Proposed Acceptable Substitutes. a. Carbon Dioxide

The Agency has determined the use of carbon dioxide as a substitute for CFC-11 in tobacco expansion to be acceptable. Carbon dioxide has been successfully used in the tobacco industry for approximately twenty years. It is non-toxic, non-flammable, and has zero ODP. A permissible exposure level (PEL) has been set at 5,000 ppm, a level that can easily be met during the well contained tobacco expansion process. The carbon dioxide process is similar to the process using CFC-11, though pressure and temperature parameters are different. For this reason carbon dioxide cannot be used as a retrofit for CFC-11 equipment; new equipment must be purchased in order to use carbon dioxide for tobacco expansion.

Although carbon dioxide is a greenhouse gas, increased use of carbon dioxide for tobacco expansion will not increase global warming because the carbon dioxide used in tobacco expansion is a by-product of the production of other gases. The carbon dioxide is captured from a stream of gas that otherwise would be emitted to the ambient air. Additionally, carbon dioxide recycling equipment is available, which will also help limit emissions of carbon dioxide to the atmosphere.

K. Adhesives, Coatings, and Inks. 1. Overview

Methyl chloroform (MCF) is used as a solvent in adhesives, coatings, and inks because of its favorable properties: high solvency, low flammability, low toxicity, relative high stability, and low boiling point. Unlike a number of other solvents classified as volatile organic compounds (VOCs), MCF does not photochemically degrade in the lower atmosphere to lead to ground-level ozone formation. This key property caused many manufacturers to switch from formulations containing VOC solvents to MCF in the mid 1980s as regulatory pressure increased to reduce VOC emissions in nonattainment areas. Companies achieved compliance by altering their solvent-borne formulations, thereby avoiding costly capital investment in new equipment, changes in coating procedures, and employee retraining.

This trend has been reversed as companies have begun to respond to the phase-out of MCF under the stratospheric ozone protection provisions of the Clean Air Act. This section examines substitutes that can be used in place of MCF in this sector and presents the Agency's proposed decisions and supporting analysis on acceptability of these substitutes. These determinations are summarized in Appendix B at the end of the sector discussions.

Of the three uses for MCF in this sector, use of MCF is largest in the adhesives subsector. In 1989, manufacturers of adhesives consumed about 28,000 metric tons (MT) of MCF in their formulations, roughly nine per cent of the total MCF produced in the U.S. (HSIA, 1991). Solvent-based adhesive formulations constitute 15 per cent of all adhesive types. MCF is desirable as a solvent for adhesives because it evaporates rapidly, is nonflammable, performs comparably to or better than VOC-formulated products, and does not photochemically degrade in the lower atmosphere. Current consumption of methyl chloroform as a solvent in the adhesives sector is estimated to be 32,000 MT.

MCF is used in five adhesive types:

- laminate adhesives;
- flexible foam adhesives;
- hardwood floor adhesives;
- metal to rubber adhesives; and
- tire patch adhesives.

MCF is no longer commonly used in the following adhesive applications where its use was once widespread:

- pressure sensitive adhesives (tapes, labels, etc.);
- flexible packaging adhesives;
- aerosol-propelled adhesives; and
- shoe repair glues and other consumer adhesives. In manufacture of coatings and inks, MCF was steadily used throughout the 1980s and began declining in the early 1990s. In 1989, the consumption of MCF used in coatings and inks was 18,480 MT, six percent of the total 310,000 MT of MCF consumed in the U.S. Current consumption in the coatings and inks sector is estimated to be 23,000 MT. MCF is the only ozone-depleting substance currently used in coatings and inks formulations. As with uses in adhesives, MCF has replaced some of the applications in coatings and inks which previously used VOC solvents.

The current use of MCF in coatings and inks applications occurs four use areas:

- flexographic and rotogravure printing inks;
- wood stains;
- metal coatings; and
- aerospace coatings.

2. Substitutes in the Adhesives, Coatings, and Inks Sector

Methyl chloroform-based adhesives, coatings, and inks can be replaced by either substitute solvents or alternative application technologies. In most instances, the alternatives are expected to perform as well as products containing MCF. Factors that determine which particular alternative is best in a given situation include physical and chemical properties, replacement chemical costs, capital investment costs, and product performance.

The primary substitutes to replace methyl chloroform in adhesives, coatings, and inks include:

- petroleum distillates;
- organic solvents (ketones, esters, ethers, alcohols);
- chlorinated solvents;
- terpenes;
- water-based formulations; and
- high-solids formulation, and
substitutes for adhesives, coatings, and chlorobenzotrifluorides are also of minor changes.

Manufacturers could replace MCF in the next set of listing decisions.

Water-based adhesives currently account for about 45 per cent of world adhesive market. Water-based adhesives will likely dominate the market to replace MCF in general consumer uses and in areas where a rigid bond is not needed. Water-based adhesives—especially water-based latexes, which are stable dispersions of solid polymeric material in an essentially aqueous medium—can effectively replace MCF use in the flexible foams sector because of the flexibility of the bond they provide. Water-based latex adhesives have the potential to penetrate 85–90 per cent of the MCF-based adhesive market in flexible foams applications. They still pose a number of problems, however, including:

- long set and dry times;
- deterioration during storage; and
- the production of bacteria-contaminated waste water.

Water-based replacements have not proven effective in binding high density laminates or hardwood flooring. Slow tack, set, and dry times continue to be a problem and trapped moisture enhances the chances of warping. In cases where MCF is used for door assemblies or sealants, water-based urethane adhesives containing polyisocyanates can be used instead.

c. High-Solid Formulations. High-solids coatings resemble conventional coatings in appearance and use, except high-solids coatings contain less solvent and a greater percentage of resin. High-solids coatings are currently used on appliances, metal furniture, and farm and road construction equipment. High-solids coatings are priced 20 to 30 percent higher than methyl chloroform-based coatings, yet the buyer receives more usable paint because the coatings contain less solvent reducing their volume.

High-solids adhesives can reduce the amount of solvent used in adhesives by increasing the percentage of solids in the formulation. Adhesives formerly containing 30–50 percent solids contain about 80 percent solids after reformulation. High-solids adhesives have good performance characteristics, including initial bond strength, and can be applied using existing equipment at normal line speeds with minimal modification. For bonding rubber assemblies, high solid adhesive films are often too thick, resulting in limited versatility and generally poor performance. High-solids formulations, however, are already used widely in the flexible foams, hardwood flooring, and high-pressure laminates industries. The solvent of choice in these industries remains MCF, but with a decreased portion of solvent in the formulations, less solvent is consumed overall. High solids formulations are only a transitional replacement until adequate substitutes are found that do not contain MCF.

d. Alternative Process Substitutes. Powder adhesives, the first category of alternative process substitutes, are composed of one-part epoxies, urethanes, and natural resins. These adhesives are often supplied as powders that require heat to cure. They are generally applied in one of three ways: by sifting the powder onto preheated substrates; by dipping a preheated substrate into the powder; and by melting the powder into a paste or liquid and applying it by conventional means. Since high temperatures are required to activate and thermost set powder adhesives, their ability to replace MCF-based formulations will depend on the characteristics substrates being bonded: if the materials being bonded are heat sensitive, heat-activated powder adhesives can not be used.

Powder coatings have no solvent, containing only resins and pigments in powder form. Typically, the coated object is heated above the powder's melting point, so that the resin fuses into a continuous film. Powder coatings have been used on various types of metal products such as appliances, concrete reinforced bars, automobiles, steel shelving, lawn and farm equipment, and some furniture. The elevated temperatures necessary to melt the coatings, however, restrict the use of powder coatings on plastic and wood products. Powder coatings are priced

- powder formulations
- hot melts
- thermoplastic plasma spray coatings
- radiation cured
- moisture cured
- chemical cured
- reactive liquids.

These substitutes can be grouped into four basic categories: solvent substitutes, water-based formulations, high-solids formulations, and alternative processes.

a. Solvent Substitutes. Petroleum distillates are hydrocarbons fractionated from the distillation of petroleum. These compounds are loosely grouped into paraffins (six carbon chains to ten carbon chains—hexane, heptane, etc.) and light aromatics (toluene and xylene), and come in various levels of purity. These compounds have good solvent properties, cost about half as much as MCF, and are readily available from chemical distributors.

Organic solvents such as alcohols, ketones, ethers, and esters dissolve a wide range of polar and semi-polar substances. These compounds are relatively inexpensive compared to MCF (about half the cost) and are readily available. They function well as solvents and dissolve most resins and binders used in adhesives, coatings, and inks.

Chlorinated solvents such as perchloroethylene and methylene chloride are chlorinated hydrocarbons. These chemicals can be used to replace MCF used in adhesives, coatings and inks. These solvents are commercially available from chemical distributors at prices comparable to those for methyl chloroform.

Chlorinated solvent compounds are chemically similar to MCF and thus are able to substitute directly for MCF with minor changes in the formulation of the product. Product quality is expected to remain unchanged. Manufacturers can use chlorinated solvents in existing equipment with minor changes, resulting in low capital costs.

Terpenes are unsaturated hydrocarbons based on isoprene subunits. They have good solvent properties and could replace MCF in some coating and ink products. Terpenes, such as d-limonene, cost about seven times more than MCF, and are commercially available from chemical distributors. Manufacturers can use terpenes in existing equipment with minor changes.

Monochlorotoluene and chlorobenzotrifluorides are also of commercial interest as solvent substitutes for adhesives, coatings, and inks. These compounds can be used either in isolation or in various mixtures, depending on desired chemical properties. The Agency recently received information on these formulations, and it will issue a SNAP determination for these substitutes in the next set of listing decisions.

b. Water-Based Formulations. Water-based coatings contain water rather than conventional solvents. Primary uses of these coatings include furniture, aluminum siding, hardboard, metal containers, appliances, structural steel, and heavy equipment. Water-based coatings are priced roughly 20 to 30 per cent more than methyl chloroform-based coatings.

Water-based inks use water and other co-solvents such as alcohols and alkyl acetates to dissolve resins, binders, and pigments instead of conventional solvents. Water-based inks accounted for 55 per cent of the flexographic inks and 15 per cent of the gravure inks used in the U.S. in 1987. Water-based inks are priced roughly 10 per cent less than methyl chloroform-based inks.

Water-based adhesives currently account for about 45 per cent of world adhesive market. Water-based adhesives will likely dominate the market to replace MCF in general consumer uses and in areas where a rigid bond is not needed. Water-based adhesives—especially water-based latexes, which are stable dispersions of solid polymeric material in an essentially aqueous medium—can effectively replace MCF use in the flexible foams sector because of the flexibility of the bond they provide. Water-based latex adhesives have the potential to penetrate 85–90 per cent of the MCF-based adhesive market in flexible foams applications. They still pose a number of problems, however, including:

- long set and dry times;
- deterioration during storage; and
- the production of bacteria-contaminated waste water.

Water-based replacements have not proven effective in binding high density laminates or hardwood flooring. Slow tack, set, and dry times continue to be a problem and trapped moisture enhances the chances of warping. In cases where MCF is used for door assemblies or sealants, water-based urethane adhesives containing polyisocyanates can be used instead.

c. High-Solid Formulations. High-solids coatings resemble conventional coatings in appearance and use, except high-solids coatings contain less solvent and a greater percentage of resin. High-solids coatings are currently used on appliances, metal furniture, and farm and road construction equipment.
comparably to methyl chloroform-based coatings.

Hot melt adhesives are 100 percent solid thermoplastic binders that can be used to replace MCF formulations in applications that require a rigid bond. Hot melts currently account for about 20 percent of the adhesives market, and they, along with water-based adhesives, will likely benefit most from the move away from MCF-based adhesive formulations. Hot melts are now used instead of MCF formulations in laminating applications, especially those involving the lamination of flexible foam products. They can also replace MCF-based adhesive formulations in OEM production of high-pressure laminates and possibly in the installation of hardwood flooring.

Thermostatic plasma spray coatings are powder coatings that melt in transit towards the object to be coated propelled by a pressurized inert gas, such as Argon. An electric arc strips electrons from the plastic particles fusing them together as they move through the applicator gun.

Thermostatic plasma spray coatings can be used to coat large and small objects of metal, wood, plastic, or fiberglass.

Radiation curing is a production technique for drying and curing adhesives with radiant energy in the form of ultraviolet (UV) or infrared (IR) light, electron beams (EB), and gamma or x-rays. The binding agents that can be cured with radiant energy are acrylics, epoxies, ureas, and anerobic adhesives, and polyester resins. In many cases, if the materials are either heat sensitive or opaque, radiation curing cannot be employed.

Radiation-dried coatings are applied as either a powder or as a high-solids form and dried using the same radiant energy forms as used in radiation-cured adhesives. The binder systems that can be dried with radiant energy are also similar. In cases where the radiant energy is harmful to a component, such as sensitive electronic equipment, radiation-dried coating cannot be employed.

Moisture-cured, chemical-cured, and reactive liquid adhesives are still not widely used because they are still being developed or because performance or application problems still have to be addressed. They will not be widely commercially available for several years.


(1) Solvent Substitutes. (a) Petroleum Distillates

Petroleum distillates are acceptable substitutes for adhesives, coatings, and inks. The principal concern with these substitutes is over risk to workers during manufacture and use of the alternative solvent. However, the Agency’s analysis of these alternatives indicated that risks from use of petroleum distillates are well understood and, as a consequence, already subject to necessary controls. For instance, although these solvents are flammable, industry has a good record of safe use of these substitutes. Additionally, certain of the petroleum distillates have low Permit Table Exposure Limits (PTLs), for example n-hexane, but the Agency’s survey of exposures in the workplace found that these levels can successfully be attained if adequate ventilation and appropriate work practices are implemented.

The Agency’s analysis of the potential for risks to residents in nearby communities did indicate the potential for adverse effects near a site with industrial use of petroleum distillates if a relatively toxic petroleum distillate is used. However, the Agency does not believe that the risk screen describes the true risk presented by these chemicals.

First, it is unlikely that solvents as toxic as the chemical chosen for the purpose of the risk screen—n-hexane—are in wide-spread use. Second, the screen used as past MCF emissions as a proxy for emissions of n-hexane. This approach does not account for other regulatory controls, such as VOC controls, that limit emissions of petroleum distillates from industrial sites, and would consequently also serve to lower any other health risks to the general population from these chemicals.

For this reason, the Agency believes that petroleum distillates merit use as substitutes, although it encourages manufacturers to formulate products where possible with compounds with lowest inherent toxicity.

(b) Alcohols, Ketones, Ethers and Esters

Alcohols, Ketones, Ethers and Esters are acceptable substitutes for adhesives, coatings, and inks. The concerns for use of these solvents parallel the concerns associated with petroleum distillates. In this case, two of the typical hydrocarbons examined in the Agency’s risk screen, methyl ethyl ketone and methyl isobutyl ketone, also have comparatively low toxicity. For the same reasons described in the section on petroleum distillates, the Agency is approving these compounds as substitutes for MCF. This approval also includes the same guidance to manufacturers—to select chemicals for product formulations with lowest inherent toxicity.

(c) Chlorinated Solvents

Perchloroethylene, methylene chloride and trichloroethylene are acceptable substitutes for adhesives, coatings, and inks. Use of these solvents merits special caution, since they are suspected human carcinogens. However, as with other solvents, the Agency’s risk screen indicates that proper workplace practices significantly reduce risks in occupational settings. The Agency’s examination of risks to the general environment determined the highest potential for adverse effects to be associated with use of trichloroethylene, since it has the greatest cancer potency. The screen pointed to the need for further assessment of the hazards from use of this chemical, and the Agency notes that authorities exist to address any risks determined from such analyses under Title III of the Clean Air Act. Title III lists all three of the chlorinated solvents as Hazardous Air Pollutants, and mandates development of Maximum Achievable Control Technology to control emissions of these chemicals in various industrial settings.

(d) Terpenes

Terpenes are acceptable substitutes for adhesives, coatings, and inks. The principal environmental concern with terpenes is their toxicity to aquatic life. In applications for terpenes in adhesives, coatings, and inks, however, the terpenes are both used and bound in the product formulation, meaning that there are no discharges of wastewater effluent that could present a risk. Other potential environmental hazards associated with these compounds arise from their flammability and unpleasant odors, but these can be controlled by good workplace practices.

(2) Water-Based Formulations/High-Solid Formulations

Water-based formulations and high-solid formulations are acceptable substitutes for adhesives, coatings, and inks. The Agency did not identify any environmental or health concerns associated with use of these products. These formulations do contain small amounts of VOCs, but the increase in VOC loadings from these products is expected to be extremely small in comparison to VOC contributions from other sources.
(3) Alternative Processes

Alternative processes, including powder formulations, hot melt, thermoplastic laminates, spray, radiation-based formulations, and moisture-cured, chemical-cured, and reactive liquid alternatives, are all acceptable substitutes for adhesives, coatings, and inks. The Agency did not identify any health or environmental concerns associated with use of these substitutes. Since this grouping includes such a wide variety of products for which it is difficult to complete an in-depth risk screen, the Agency solicits additional detail on any potential environmental or health effects that merit further investigation.

X. Additional Information

A. Executive Order 12291

Executive Order (EO) 12291 requires the preparation of a regulatory impact analysis for major rules, defined by the order as those likely to result in: (1) An annual effect on the economy of $100 million or more; (2) a major increase in costs or prices for consumers, individual industries, Federal, state or local government agencies; (3) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

EPA has determined that this proposed regulation does not meet the definition of a major rule under EO 12291 and therefore has not prepared a formal regulatory impact analysis. EPA has instead prepared an economic analysis which estimated potential costs of the proposed regulation, using the reductions of production and consumption under the CFC phase-out as a baseline. This analysis showed that the SNAP program was not likely to impose costs of greater than $100 million on industry, and in fact, to the extent the program established by this rule helps spread the word about substitutes for Class I and II ozone-depleting compounds, this rule may well provide benefits to small businesses anxious to examine potential substitutes to any ozone-depleting Class I and II substances they may be using by requiring manufacturers to make information on such substitutes available.

C. Paperwork Reduction Act

The information collection requirements in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB) under the Paperwork Reduction Act, 44 U.S.C. 3501 et seq. An Information Collection Request document has been prepared by EPA (ICR No. 1596.02) and a copy may be obtained from Sandy Farmer, Information Policy Branch, EPA, 401 M St., SW. (PM-223Y), Washington, DC 20460 or by calling (202) 260-2740.

Public reporting burden for this collection of information is estimated to vary from 4 to 168 hours per response with total estimated reporting burden on the industry of 8,772 hours. This estimate includes time for initial contact with the Agency, reviewing instructions, searching existing data sources, gathering and maintaining the data needed, completing the collection and presentation of information, and responding to any additional requests for missing data.

Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Chief, Information Policy Branch, EPA, 401 M St., S.W. (PM-223Y), Washington, DC 20460, and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503, marked "Attention: Desk Officer for EPA." The final rule will respond to any public comments on the information collection requirements contained in this proposal.

XI. References


List of Subjects in 40 CFR Part 82

Administrative practice and procedure, Air pollution control, Reporting and recordkeeping requirements.


Carol M. Browner,
Administrator.

Appendix A to the Preamble—Class I and Class II Ozone-Depleting Substances

Class I and Class II Ozone-Depleting Substances

CLASS I

Group I:

Chlorofluorocarbon-11
CFC-11 (C\textsubscript{3}F\textsubscript{7})

Trichlor﻿luoromethane
Chlorofluorocarbon-12
CFC-12 (C\textsubscript{3}F\textsubscript{8})

Dichlorodifluoromethane
Chlorofluorocarbon-113
CFC-113 (C\textsubscript{3}F\textsubscript{13})

Dichlorotetrafluoroethane
Chlorofluorocarbon-114
CFC-114 (C\textsubscript{3}F\textsubscript{14})

Dichlorotrifluoroethane
Chlorofluorocarbon-115
CFC-115 (C\textsubscript{3}F\textsubscript{15})

Monochloropentafluoroethane

Group II:

Halon—1211
(C\textsubscript{3}F\textsubscript{12}Br)

Bromochlorodifluoromethane
Halon—1301
(C\textsubscript{3}F\textsubscript{14}Br)

Bromotrifluoromethane
Halon—2402
(C\textsubscript{3}F\textsubscript{14}Br\textsubscript{2})

Dibromotetrafluoroethane

Group III:

Chlorofluorocarbon-13
CFC-13 (C\textsubscript{3}F\textsubscript{6})

Chlorotrifluoromethane
Chlorofluorocarbon-111

CFC-111 (C2F5Cl)
Pentachlorodifluoroethane
Chlorofluorocarbon-112
CFC-117 (C3F7Cl)
Tetrachlorodifluoroethane
Chlorofluorocarbon-211
CFC-211 (C3F5Cl)
Heptachlorofluoropropene
Chlorofluorocarbon-212
CFC-212 (C3F5Cl)
Hexachlorodifluoroethane
Chlorofluorocarbon-213
CFC-213 (C3F5Cl)
Pentachlorotrifluoropropene
Chlorofluorocarbon-214
CFC-214 (C3F5Cl)
Tetrachlorotetrafluoroethane
Chlorofluorocarbon-215
CFC-215 (C3F5Cl)
Trichloropentafluoroethane
Chlorofluorocarbon-216
CFC-216 (C3F5Cl)
Dichlorohexafluoroethane
Chlorofluorocarbon-217
CFC-217 (C3F5Cl)
Monochlorobisfluoroethane

Group IV:
Carbon Tetrachloride
(OCl)

Group V:
Methyl Chloroform
(C2H5Cl)
1,1,1 Trifluoroethene

CLASS II
Hydrochlorofluorocarbon-21
HCFC-21 (CHF2Cl)
Dichlorofluoromethane
Hydrochlorofluorocarbon-22
HCFC-22 (C2H3F2Cl)
Monochlorodifluoroethane
Hydrochlorofluorocarbon-31
HCFC-31 (C3H5F2Cl)
Monochlorodifluoroethane
Hydrochlorofluorocarbon-121 HCFC-121
(C2HClF2Cl) Tetrachlorodifluoroethane
Hydrochlorofluorocarbon-122 HCFC-122
(C2HClF2Cl) Tetrachlorodifluoroethane
Hydrochlorofluorocarbon-123 HCFC-123
(C2HClF2Cl) Dichlorodifluoroethane
Hydrochlorofluorocarbon-124 HCFC-124
(C2HClF2Cl) Dichlorodifluoroethane
Hydrochlorofluorocarbon-131 HCFC-131
(C3HClF2Cl) Trichlorotrifluoroethane
Hydrochlorofluorocarbon-133A HCFC-133A
(C3HClF2Cl) Monochloroheptafluoroethane
Hydrochlorofluorocarbon-141B HCFC-141B
(C3HClF2Cl) Dichlorotrifluoroethane
Hydrochlorofluorocarbon-142B HCFC-142B
(C3HClF2Cl) Trichlorotrifluoroethane
Hydrochlorofluorocarbon-211 HCFC-211
(C3HClF2Cl) Hexachloroethane
Hydrochlorofluorocarbon-212 HCFC-212
(C3HClF2Cl) Pentachlorofluoropropene
Hydrochlorofluorocarbon-213 HCFC-213
(C3HClF2Cl) Tetrachlorotetrafluoroethane
Hydrochlorofluorocarbon-215CA HCFC-215CA
(C3HClF2Cl) Dichloropentafluoroethane
Hydrochlorofluorocarbon-215CB HCFC-215CB
(C3HClF2Cl) Dichloropentafluoroethane

REFRIGERANTS—ACCEPTABLE SUBSTITUTES

<table>
<thead>
<tr>
<th>Application</th>
<th>Substitute</th>
<th>Initial decision</th>
<th>Proposed conditions</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>CFC-11 Centrifugal Chillers (Retrofit)</td>
<td>HCFC-123</td>
<td>Acceptable</td>
<td></td>
<td>EPA worker-monitoring studies of 123 show that 8-hour TWA can be kept within 1 ppm (less than the OEL of 10 ppm) when recycling and ASHRAE standards are followed. 123 is the only available retrofit for low-pressure systems; it also has (1) the lowest ODP of all available HFCs and (2) lowest GWP of all available HFCs and HCFCs. EPA worker-monitoring studies of 123 show that 8-hour TWA can be kept within 1 ppm (less than the OEL of 16ppm) when recycling and ASHRAE standards are followed. 123 is the only replacement for low-pressure systems; it also has (1) the lowest ODP of all available HCFCs, and (2) lowest GWP of all available HCFCs and HFCs. Alternative Substance replacement that will allow early transition out of CFCs in some uses. Alternative Substance replacement that may be appropriate in some applications.</td>
</tr>
<tr>
<td>CFC-11 Centrifugal Chillers (New Equipment/ Alternative Substances)</td>
<td>HCFC-123</td>
<td>Acceptable</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>HCFC-22</td>
<td>Acceptable</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>HFC-134a</td>
<td>Acceptable</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Ammonia</td>
<td>Vapor Compression.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Lithium bromide/water absorption.</td>
<td>Acceptable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Application</td>
<td>Substitute</td>
<td>Initial decision / Proposed conditions</td>
<td>Comments</td>
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<td>---------------------------------------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>CFC-12 Centrifugal Chillers (Retrofits)</td>
<td>Ammonia-water absorption</td>
<td>Acceptable</td>
<td>Alternative Substance equipment commercially available for many years.</td>
<td></td>
</tr>
<tr>
<td>CFC-12 Centrifugal Chillers (New Equipment/Alternative Substances)</td>
<td>1HCFC-123</td>
<td>Acceptable</td>
<td>EPA worker-monitoring studies of 123 show that 8-hour TWA can be kept within 1ppm (less than the OEL of 10ppm) when recycling and ASHRAE standards are followed. 123 is the only replacement for low-pressure systems; It also has (1) the lowest ODP of all available HCFCs, and (2) lowest GWP of all available HCFCs and HFCs. Alternative Substance replacement that will allow early transition out of CFCs in some uses.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1HCFC-22</td>
<td>Acceptable</td>
<td>Alternative Substance equipment commercially available.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ammonia Vapor Compression</td>
<td>Acceptable</td>
<td>Alternative Substance equipment commercially available; can be operated using waste heat (e.g. steam); can be source of heated water supply, (heat recovery). Can be retrofitted if system is flushed.</td>
<td></td>
</tr>
<tr>
<td>CFC-12 Reciprocating Chillers (Retrofits)</td>
<td>2HFC-134a</td>
<td>Acceptable</td>
<td>HCFC-22 systems account for majority (&gt;98%) of reciprocating chiller market. Readily available, proven reliability. Extensive research underway to identify zero-ODP, energy-efficient substitutes for HCFC-22—as retrofits and in new systems.</td>
<td></td>
</tr>
<tr>
<td>CFC-12 Reciprocating Chillers (New Equipment/Alternative Substances)</td>
<td>1HCFC-22</td>
<td>Acceptable</td>
<td>To be used as a service refrigerant. Precautions must be taken during recycling of blends to avoid mixing with other refrigerants. Leading candidate as replacement of CFC-12, but testing still underway.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2HFC-134a</td>
<td>Acceptable</td>
<td>Flammability concerns believed to be minor [see ADL/UL reference [64123]; potential for significant energy efficiency. Currently more widely available than 134a, which will allow early transition from CFC-12. Users may experience flammability and/or energy efficiency problems due to potential differential fractionation of this blend in shellside applications. Precautions must be taken during recycling of blends to avoid mixing with other refrigerants. Widely available and practical for some (i.e. very large) applications.</td>
<td></td>
</tr>
<tr>
<td>CFC-12 Household Refrigerators, Single Evaporator (Retrofits)</td>
<td>1HCFC-22/ HFC-152a/ HCFC-124</td>
<td>Acceptable</td>
<td>Expected to be available for higher temperatures near the middle of the decade. Currently, more widely available than HFC-134a, which will allow early transition from CFC-12.</td>
<td></td>
</tr>
<tr>
<td>CFC-12 Household Refrigerators, Single Evaporator (New Equipment/Alternative Substances)</td>
<td>2HFC-152a</td>
<td>Acceptable</td>
<td>Precautions must be taken during recycling of blends to avoid mixing with other refrigerants.</td>
<td></td>
</tr>
<tr>
<td>CFC-12 Cold Storage Warehouses (Retrofits)</td>
<td>1HCFC-22</td>
<td>Acceptable</td>
<td>Expected to be available for higher temperatures near the middle of the decade. Currently, more widely available than HFC-134a, which will allow early transition from CFC-12.</td>
<td></td>
</tr>
<tr>
<td>CFC-12 Cold Storage Warehouses (New Equipment/Alternative Substances)</td>
<td>2HFC-134a</td>
<td>Acceptable</td>
<td>Expected to be available for higher temperatures near the middle of the decade. Currently, more widely available than HFC-134a, which will allow early transition from CFC-12.</td>
<td></td>
</tr>
<tr>
<td>CFC-12 Residential Residential Dehumidifiers (Retrofits)</td>
<td>1HCFC-22/ HFC-152a/ HCFC-124</td>
<td>Acceptable</td>
<td>Precautions must be taken during recycling of blends to avoid mixing with other refrigerants.</td>
<td></td>
</tr>
<tr>
<td>CFC-12 Residential Residential Dehumidifiers (New Equipment/Alternative Substances)</td>
<td>2HFC-134a</td>
<td>Acceptable</td>
<td>Precautions must be taken during recycling of blends to avoid mixing with other refrigerants.</td>
<td></td>
</tr>
<tr>
<td>Application</td>
<td>Substitute</td>
<td>Initial decision</td>
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<td>Comments</td>
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<td>-------------------------------------------------</td>
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<td>--------------------------------------------------------------------------</td>
</tr>
<tr>
<td>CFC-12 Residential Freezers (Retrofits)</td>
<td>1 HFC-22/ HFC-152a/ HCFC-124</td>
<td>Acceptable ......</td>
<td></td>
<td>Precautions must be taken during recycling of blends to avoid mixing with other refrigerants.</td>
</tr>
<tr>
<td>CFC-12 Residential Freezers (New Equipment/Alternative Substances)</td>
<td>1 HFC-22</td>
<td>Acceptable ......</td>
<td></td>
<td>Currently more widely available than HFC-134a, which will allow early transition from CFC-12.</td>
</tr>
<tr>
<td>CFC-12 Commercial Ice Machines (Retrofits)</td>
<td>1 HFC-22</td>
<td>Acceptable ......</td>
<td></td>
<td>Precautions must be taken during recycling of blends to avoid mixing with other refrigerants.</td>
</tr>
<tr>
<td>CFC-12 Commercial Ice Machines (New Equipment/Alternative Substances)</td>
<td>1 HFC-22</td>
<td>Acceptable ......</td>
<td></td>
<td>Currently more widely available than HFC-134a, which will allow early transition from CFC-12.</td>
</tr>
<tr>
<td>CFC-12 Industrial Process Refrigeration (Retrofits)</td>
<td>1 HFC-22</td>
<td>Acceptable ......</td>
<td></td>
<td>Currently more widely available than HFC-134a, which will allow early transition from CFC-12.</td>
</tr>
<tr>
<td>CFC-12 Industrial Process (New Equipment/Alternative Substances)</td>
<td>1 HFC-22</td>
<td>Acceptable ......</td>
<td></td>
<td>Currently more energy efficient and more widely available than HFC-134a, which will allow early transition from CFC-12. Technology is available.</td>
</tr>
<tr>
<td>CFC-12 Refrigerated Transport (Retrofits)</td>
<td>1 HCFC-22/ HFC-152a/ HCFC-124</td>
<td>Acceptable ......</td>
<td></td>
<td>EPA suggests, but does not require, that this substitute only be used at industrial facilities which manufacture or use chlorine in the process stream.</td>
</tr>
<tr>
<td>CFC-12 Refrigerated Transport (New Equipment/Alternative Substances)</td>
<td>1 HCFC-22</td>
<td>Acceptable ......</td>
<td></td>
<td>EPA suggests, but does not require, that this substitute only be used at industrial facilities which manufacture or use hydrocarbons in the process stream.</td>
</tr>
<tr>
<td>CFC-12 Retail Food (Retrofits)</td>
<td>1 HFC-134a</td>
<td>Acceptable ......</td>
<td></td>
<td>EPA suggests, but does not require, that this substitute only be used at industrial facilities which manufacture or use hydrocarbons in the process stream.</td>
</tr>
<tr>
<td>CFC-12 Retail Food (New Equipment/Alternative Substances)</td>
<td>1 HFC-134a</td>
<td>Acceptable ......</td>
<td></td>
<td>EPA suggests, but does not require, that this substitute only be used at industrial facilities which manufacture or use hydrocarbons in the process stream.</td>
</tr>
<tr>
<td>CFC-12 Vending Machines (Retrofits)</td>
<td>1 HCFC-22</td>
<td>Acceptable ......</td>
<td></td>
<td>EPA suggests, but does not require, that this substitute only be used at industrial facilities which manufacture or use hydrocarbons in the process stream.</td>
</tr>
<tr>
<td>CFC-12 Vending Machines (New Equipment/Alternative Substances)</td>
<td>1 HCFC-22</td>
<td>Acceptable ......</td>
<td></td>
<td>EPA suggests, but does not require, that this substitute only be used at industrial facilities which manufacture or use hydrocarbons in the process stream.</td>
</tr>
</tbody>
</table>
### Refrigerants—Acceptable Substitutes—Continued

<table>
<thead>
<tr>
<th>Application</th>
<th>Substitute</th>
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</tr>
</thead>
<tbody>
<tr>
<td>CFC-12 Vending Machines (New Equipment/Alternative Substances)</td>
<td>1HCFC-22/ HFC-152a/ HFC-124.</td>
<td>Acceptable</td>
<td></td>
<td>Users may experience flammability and/or energy efficiency problems due to potential differential fractionation of this blend in shellside applications. Precautions must be taken during recycling of blends to avoid mixing with other refrigerants. Currently more widely available than HFC-134a, which will allow early transition from CFC-12.</td>
</tr>
<tr>
<td>CFC-12 Water Coolers (Retrofits)</td>
<td>1HCFC-22/ HFC-152a/ HFC-124.</td>
<td>Acceptable</td>
<td></td>
<td>Precautions must be taken during recycling of blends to avoid mixing with other refrigerants. Currently more widely available than HFC-134a, which will allow early transition from CFC-12.</td>
</tr>
<tr>
<td>CFC-12 Water Coolers (New Equipment/Alternative Substances)</td>
<td>1HCFC-22/ HFC-152a/ HFC-124.</td>
<td>Acceptable</td>
<td></td>
<td>To be used as a service refrigerant. Precautions must be taken during recycling of blends to avoid mixing with other refrigerants.</td>
</tr>
<tr>
<td>CFC-12 Mobile Air Conditioners (Retrofits)</td>
<td>2HFC-134a/ HFC-134a/ HFC-134a</td>
<td>Acceptable</td>
<td></td>
<td>Users may experience flammability and/or energy efficiency problems due to potential differential fractionation of this blend in shellside applications. Precautions must be taken during recycling of blends to avoid mixing with other refrigerants.</td>
</tr>
<tr>
<td>CFC-12 Mobile Air Conditioners (New Equipment/Alternative Substances)</td>
<td>1HCFC-22/ HFC-152a/ HFC-124.</td>
<td>Acceptable</td>
<td></td>
<td>EPA worker-monitoring studies of 123 show that 8-hour TWA can be kept within 1ppm (less than the OEL of 10ppm) when recycling and ASHRAE standards are followed. 123 is the only replacement for low-pressure systems; it also has (1) the lowest ODP of all available HCFCs, and (2) lowest GWP of all available HCFCs and HFCs.</td>
</tr>
<tr>
<td>CFC-12 Centrifugal Chillers (New Equipment/Alternative Substances)</td>
<td>1HCFC-124</td>
<td>Acceptable</td>
<td></td>
<td>Alternative Substance equipment commercially available; can be operated using waste heat (e.g. steam); can be source of heated water supply (heat recovery). Precautions must be taken during recycling of blends to avoid mixing with other refrigerants. Currently more widely available than HFC-134a, which will allow early transition from CFC-12.</td>
</tr>
<tr>
<td>CFC-500 Centrifugal Chillers (Retrofits)</td>
<td>1HCFC-22/ HFC-152a/ HFC-124.</td>
<td>Acceptable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CFC-500 Centrifugal Chillers (New Equipment/Alternative Substances)</td>
<td>1HCFC-22/ HFC-152a/ HFC-124.</td>
<td>Acceptable</td>
<td></td>
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</tr>
<tr>
<td>CFC-500 Residential Dehumidifiers (Retrofits)</td>
<td>1HCFC-22/ HFC-152a/ HFC-124.</td>
<td>Acceptable</td>
<td></td>
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</tr>
<tr>
<td>CFC-500 Residential Dehumidifiers (New Equipment/Alternative Substances)</td>
<td>1HCFC-22/ HFC-152a/ HFC-124.</td>
<td>Acceptable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CFC-500 Refrigerated Transport (Retrofits)</td>
<td>2HFC-134a/ HFC-134a/ HFC-134a</td>
<td>Acceptable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CFC-500 Refrigerated Transport (New Equipment/Alternative Substances)</td>
<td>1HCFC-22/ HFC-152a/ HFC-124.</td>
<td>Acceptable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ammonia Vapor Compression. Lithium bromide/water absorption.</td>
<td>Acceptable</td>
<td>Acceptable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CFC-600 Residential Dehumidifiers (Retrofits)</td>
<td>1HCFC-22/ HFC-152a/ HFC-124.</td>
<td>Acceptable</td>
<td></td>
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</tr>
<tr>
<td>CFC-600 Refrigerated Transport (Retrofits)</td>
<td>1HCFC-22/ HFC-152a/ HFC-124.</td>
<td>Acceptable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CFC-600 Refrigerated Transport (New Equipment/Alternative Substances)</td>
<td>1HCFC-22/ HFC-152a/ HFC-124.</td>
<td>Acceptable</td>
<td></td>
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</tr>
</tbody>
</table>
### REFRIGERANTS—ACCEPTABLE SUBSTITUTES—Continued

<table>
<thead>
<tr>
<th>Application</th>
<th>Substitute</th>
<th>Initial decision</th>
<th>Proposed conditions</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>CFC-502 Cold Storage Warehouses (Retrofits).</td>
<td>HCFC-22/Propane/HFC-125.</td>
<td>Acceptable</td>
<td></td>
<td>Flammability is a concern. Precautions must be taken during recycling of blends to avoid mixing with other refrigerants.</td>
</tr>
<tr>
<td>CFC-502 Cold Storage Warehouses (New Equipment/Alternative Substances).</td>
<td>HCFC-22/Propane/HFC-125.</td>
<td>Acceptable</td>
<td></td>
<td>Flammability is a concern. Precautions must be taken during recycling of blends to avoid mixing with other refrigerants.</td>
</tr>
<tr>
<td>CFC-502 Refrigerated Transport (Retrofits).</td>
<td>HCFC-22/Propane/HFC-125.</td>
<td>Acceptable</td>
<td></td>
<td>Currently more widely available than 125, which will allow early transition from CFC-12.</td>
</tr>
<tr>
<td>CFC-502 Refrigerated Transport (New Equipment/Alternative Substances).</td>
<td>HCFC-22/Propane/HFC-125.</td>
<td>Acceptable</td>
<td></td>
<td>Flammability is a concern. Precautions must be taken during recycling of blends to avoid mixing with other refrigerants.</td>
</tr>
<tr>
<td>CFC-502 Retail Food (Retrofit)</td>
<td>HCFC-22/Propane/HFC-125.</td>
<td>Acceptable</td>
<td></td>
<td>Currently more widely available than HFC-134a, which will allow early transition from CFC-12.</td>
</tr>
<tr>
<td>CFC-502 Retail Food (New Equipment/Alternative Substances).</td>
<td>HCFC-22/Propane/HFC-125.</td>
<td>Acceptable</td>
<td></td>
<td>Flammability is a concern. Precautions must be taken during recycling of blends to avoid mixing with other refrigerants.</td>
</tr>
</tbody>
</table>

**HCFC-22/Propane/HFC-125.**

Ammonia Vapor Compression. Chlorine

Currently more widely available than HFC-134a, which will allow early transition from CFC-12.

Ammonia Vapor Compression.

EPA suggests, but does not require, that this substitute only be used at industrial facilities which manufacture or use chlorine in the process stream.

Currently more efficient and more widely available than HFC-134a, which will allow early transition from CFC-12.

Currently more widely available than 125, which will allow early transition from CFC-12.
REFRIGERANTS—ACCEPTABLE SUBSTITUTES

<table>
<thead>
<tr>
<th>Application</th>
<th>Substitute</th>
<th>Initial decision</th>
<th>Proposed conditions</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>CFC-12 Centrifugal Chillers (Retrofit).</td>
<td>HCFC-22/HCFC-142b/CFC-12 ...............</td>
<td>Proposed Unacceptable.</td>
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<td></td>
</tr>
<tr>
<td>CFC-12 Reciprocating Chillers (Retrofit).</td>
<td>HCFC-22/HCFC-142b/CFC-12 ...............</td>
<td>Proposed Unacceptable.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CFC-12 Cold Storage Warehouses (Retrofit).</td>
<td>HCFC-22/HCFC-142b/CFC-12 ...............</td>
<td>Proposed Unacceptable.</td>
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<tr>
<td>CFC-12 Retail Food (Retrofit) ..............</td>
<td>HCFC-22/HCFC-142b/CFC-12 ...............</td>
<td>Proposed Unacceptable.</td>
<td></td>
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</tr>
<tr>
<td>CFC-12 Mobile Air Conditioners (Retrofit).</td>
<td>HCFC-22/HCFC-142b/CFC-12 ...............</td>
<td>Proposed Unacceptable.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>All CFC-12 Refrigeration Uses ...</td>
<td>Hydrocarbon Blend A .......................</td>
<td>Proposed Unacceptable.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>All HCFC-22 Refrigeration Uses ..</td>
<td>HCFC-22/HCFC-142b/CFC-12 ...............</td>
<td>Proposed Unacceptable.</td>
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</tr>
</tbody>
</table>

1 Use of HCFCs is subject to (1) no venting during servicing prohibition under section 608, which was effective July 1, 1992, (2) recycling requirements under section 608 once they are promulgated, (3) section 609 motor vehicle air conditioning regulations, (4) the phaseout schedule for all Class II chemicals under section 605, which is currently being revised under EPA’s efforts to accelerate the phaseout of all ozone-depleting chemicals, and (5) mandatory recycling.

2 Use of HFCs is subject to the no venting prohibition under section 608(c)(2), which takes effect November 15, 1995, at the latest.

REFRIGERANTS UNACCEPTABLE SUBSTITUTES

<table>
<thead>
<tr>
<th>Application</th>
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<tbody>
<tr>
<td>CFC-12 Centrifugal Chillers (Retrofit).</td>
<td>HCFC-22/HCFC-142b/CFC-12 ...............</td>
<td>Proposed Unacceptable.</td>
<td></td>
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</tr>
<tr>
<td>CFC-12 Reciprocating Chillers (Retrofit).</td>
<td>HCFC-22/HCFC-142b/CFC-12 ...............</td>
<td>Proposed Unacceptable.</td>
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<tr>
<td>CFC-12 Cold Storage Warehouses (Retrofit).</td>
<td>HCFC-22/HCFC-142b/CFC-12 ...............</td>
<td>Proposed Unacceptable.</td>
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<tr>
<td>CFC-12 Retail Food (Retrofit) ..............</td>
<td>HCFC-22/HCFC-142b/CFC-12 ...............</td>
<td>Proposed Unacceptable.</td>
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</tr>
<tr>
<td>CFC-12 Mobile Air Conditioners (Retrofit).</td>
<td>HCFC-22/HCFC-142b/CFC-12 ...............</td>
<td>Proposed Unacceptable.</td>
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<tr>
<td>All CFC-12 Refrigeration Uses ...</td>
<td>Hydrocarbon Blend A .......................</td>
<td>Proposed Unacceptable.</td>
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<td></td>
</tr>
<tr>
<td>All HCFC-22 Refrigeration Uses ..</td>
<td>HCFC-22/HCFC-142b/CFC-12 ...............</td>
<td>Proposed Unacceptable.</td>
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<td></td>
</tr>
</tbody>
</table>

Flammability may be an issue. Has a high ODP and is not generally available in new equipment.

As a blend of both Class I and Class II chemicals, it poses a higher risk of ozone depletion than use of Class II alone.

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As a blend of both Class I and Class II chemicals, it poses a higher risk of ozone depletion than use of Class II alone.

Flammability may be a serious issue. Data on flammability, fractionation and hose permeability is required for full evaluation.

As a blend of both Class I and Class II chemicals, it poses a higher risk of ozone depletion than use of Class II chemicals alone.

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### REFRIGERANTS—PENDING DECISIONS

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<tr>
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<tbody>
<tr>
<td>CFC-12 Household Refrigerators, Single Evaporator (Retrofit).</td>
<td>HCFC/HFC/fluorokane Blend A</td>
<td>As discussed earlier, EPA is concerned about the potential wide use of perfluorinated compounds, particularly in situations where containment may be difficult to assure. As a result, EPA will be reviewing perfluorinated compound uses to assess the aggregate quantity likely to be used and to determine any necessary emission control.</td>
</tr>
<tr>
<td></td>
<td>HCFC-22/HCFC-142b</td>
<td>EPA has not yet concluded review of the data.</td>
</tr>
<tr>
<td>CFC-12 Household Refrigerators, Single Evaporator (New Equipment/Alternative Substances).</td>
<td>HCFC/HFC/fluorokane Blend A</td>
<td>As discussed earlier, EPA is concerned about the potential wide use of perfluorinated compounds, particularly in situations where containment may be difficult to assure. As a result, EPA will be reviewing perfluorinated compound uses to assess the aggregate quantity likely to be used and to determine any necessary emission control.</td>
</tr>
<tr>
<td></td>
<td>HCFC-22/HCFC-142b</td>
<td>EPA has not yet concluded review of the data.</td>
</tr>
<tr>
<td>CFC-12 Residential Freezers (Retrofit).</td>
<td>HCFC/HFC/fluorokane Blend A</td>
<td>As discussed earlier, EPA is concerned about the potential wide use of perfluorinated compounds, particularly in situations where containment may be difficult to assure. As a result, EPA will be reviewing perfluorinated compound uses to assess the aggregate quantity likely to be used and to determine any necessary emission control.</td>
</tr>
<tr>
<td>CFC-12 Residential Freezers (New Equipment/Alternative Substances).</td>
<td>HCFC/HFC/fluorokane Blend A</td>
<td>EPA has not yet concluded review of the data.</td>
</tr>
<tr>
<td>CFC-12 Commercial Ice Machines (New Equipment/Alternative Substances).</td>
<td>HFC-125/ HFC-143a/ HFC-134a</td>
<td>Final decision pending receipt of data on flammability controls and constituent toxicity of HFC-143a. Precautions must be taken during recycling of blends to avoid mixing with other refrigerants.</td>
</tr>
<tr>
<td>CFC-12 Refrigerated Transport (New Equipment/Alternative Substances).</td>
<td>HFC-125/ HFC-143a/ HFC-134a</td>
<td>EPA has not yet concluded review of the data.</td>
</tr>
<tr>
<td>CFC-12 Cold Storage</td>
<td>R200a</td>
<td>As discussed earlier, EPA is concerned about the potential wide use of perfluorinated compounds, particularly in situations where containment may be difficult to assure. As a result, EPA will be reviewing perfluorinated compound uses to assess the aggregate quantity likely to be used and to determine any necessary emission control.</td>
</tr>
<tr>
<td>CFC-12 Mobile Air Conditioners (Retrofit).</td>
<td>HCFC/HFC/fluorokane Blend A</td>
<td>As discussed earlier, EPA is concerned about the potential wide use of perfluorinated compounds, particularly in situations where containment may be difficult to assure. As a result, EPA will be reviewing perfluorinated compound uses to assess the aggregate quantity likely to be used and to determine any necessary emission control.</td>
</tr>
<tr>
<td>CFC-12 Mobile Air Conditioners (New Equipment/Alternative Substances).</td>
<td>HCFC/HFC/fluorokane Blend A</td>
<td>Final decision pending receipt of data on flammability controls and constituent toxicity of HFC-143a. Precautions must be taken during recycling of blends to avoid mixing with other refrigerants.</td>
</tr>
<tr>
<td>CFC-12 Chillers, Heat Pumps and Commercial Refrigeration Systems.</td>
<td>HFC-227ea</td>
<td>EPA has not yet concluded review of the data.</td>
</tr>
<tr>
<td>CFC-12 Refrigerant</td>
<td>HCFC-142b</td>
<td>EPA has not yet concluded review of the data.</td>
</tr>
<tr>
<td>CFC-13 Refrigerant</td>
<td>HFC-23</td>
<td>EPA requests additional data on the use of this substitute.</td>
</tr>
<tr>
<td>CFC-114 Centrifugal Chillers (New Equipment/Alternative Substances).</td>
<td>R200b</td>
<td>EPA has not yet concluded review of the data.</td>
</tr>
<tr>
<td>CFC-114 Chillers, Heat Pumps and Commercial Refrigeration Systems.</td>
<td>R200c</td>
<td>EPA has not yet concluded review of the data.</td>
</tr>
<tr>
<td>CFC-114 Chillers, Heat Pumps and Commercial Refrigeration Systems.</td>
<td>R200d</td>
<td>EPA has not yet concluded review of the data.</td>
</tr>
<tr>
<td>CFC-502 Air Conditioning, Heat Pumps, and Chillers.</td>
<td>HFC-143a/ HFC-134a</td>
<td>Final decision pending data addressing efficiency concerns. Can be used as a component in mixtures. Not yet widely available.</td>
</tr>
<tr>
<td>CFC-502 Cold Storage</td>
<td>HFC-125</td>
<td>Final decision pending receipt of data on flammability controls and constituent toxicity of HFC-143a. Precautions must be taken during recycling of blends to avoid mixing with other refrigerants.</td>
</tr>
<tr>
<td>CFC-502 Cold Storage</td>
<td>R200a</td>
<td>EPA has not yet concluded review of the data.</td>
</tr>
<tr>
<td>CFC-502 Commercial Ice Machines (New Equipment/Alternative Substances).</td>
<td>HFC-125/ HFC-143a/ HFC-134a</td>
<td>Final decision pending receipt of data on flammability controls and constituent toxicity of HFC-143a. Precautions must be taken during recycling of blends to avoid mixing with other refrigerants.</td>
</tr>
<tr>
<td>CFC-502 Industrial Process Refrigeration (New Equipment/Alternative Substances).</td>
<td>HFC-125/ HFC-143a/ HFC-134a</td>
<td>Pending receipt of data on flammability. Material has high potential GWP.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Final decision pending receipt of data on flammability controls and constituent toxicity of HFC-143a. Precautions must be taken during recycling of blends to avoid mixing with other refrigerants.</td>
</tr>
</tbody>
</table>
### REFRIGERANTS—PENDING DECISIONS—Continued

<table>
<thead>
<tr>
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</tr>
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<tbody>
<tr>
<td></td>
<td>HFC–125</td>
<td>HFC–125 can be used as a component in mixtures. Data on efficiency is needed to fully evaluate.</td>
</tr>
<tr>
<td>CFC–502 Retail Food (New Equipment/Alternative Substances).</td>
<td>HFC–143a</td>
<td>Final decision pending receipt of data on flammability controls and constituent toxicity of HFC–143a. Precautions must be taken during recycling of blends to avoid mixing with other refrigerants.</td>
</tr>
<tr>
<td></td>
<td>HFC–134a</td>
<td>Pending receipt of data on flammability. Material has high potential GWP.</td>
</tr>
<tr>
<td>Heat Pumps</td>
<td>HFC–134a</td>
<td>EPA has not yet concluded review of the data.</td>
</tr>
<tr>
<td></td>
<td>HFC–152a</td>
<td>EPA has not yet concluded review of the data.</td>
</tr>
<tr>
<td></td>
<td>HFC–32</td>
<td>EPA has not yet concluded review of the data.</td>
</tr>
<tr>
<td></td>
<td>HFC–125/ HFC–134a/ HFC–32.</td>
<td>EPA has not yet concluded review of the data.</td>
</tr>
<tr>
<td>Mobile Air Conditioning</td>
<td>R200a</td>
<td>EPA has not yet concluded review of the data.</td>
</tr>
<tr>
<td>Commercial and Residential Air Conditioners, Cold Storage Warehouses, Industrial Cooling, Mobile Air Conditioning. Conventional Air Conditioning</td>
<td>CO2</td>
<td>EPA has not yet concluded review of the data.</td>
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</tbody>
</table>

### FOAMS—ACCEPTABLE SUBSTITUTES

<table>
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<tr>
<th>Application</th>
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<tbody>
<tr>
<td>CFC–11 Polyurethane, Rigid Laminated Boardstock</td>
<td>HCFC–123</td>
<td>Acceptable</td>
<td></td>
<td>Recent worker monitoring studies indicate OEL for 123 (10 ppm) can be achieved with increased ventilation, where needed. Only chemical alternative that is or soon will be available in sufficient quantities to meet demand of industry. Has highest ODP of HCFCs. Will allow virtually immediate transition out of CFC–11. Fairly good energy efficiency properties.</td>
</tr>
<tr>
<td></td>
<td>HCFC–141b</td>
<td>Acceptable</td>
<td></td>
<td>Technology not yet available in most applications to allow near-term use. Increases in thermal conductivity may reduce energy efficiency.</td>
</tr>
<tr>
<td></td>
<td>HCFC–142b</td>
<td>Acceptable</td>
<td></td>
<td>Technology under development.</td>
</tr>
<tr>
<td></td>
<td>HCFC–22</td>
<td>Acceptable</td>
<td></td>
<td>Technology under development. HCFC–141b is only chemical alternative that is currently available in sufficient quantities to meet demand of industry and has fairly good energy efficiency properties.</td>
</tr>
<tr>
<td></td>
<td>HCFC–22/ HCFC–141b.</td>
<td>Acceptable</td>
<td></td>
<td>Recent worker monitoring studies indicate OEL for 123 (10 ppm) can be achieved with increased ventilation, where needed. Fairly good energy efficiency properties.</td>
</tr>
<tr>
<td></td>
<td>HCFC–141b/ HCFC–123.</td>
<td>Acceptable</td>
<td></td>
<td>Technology not yet available in most applications to allow near-term use. Increases in thermal conductivity may reduce energy efficiency.</td>
</tr>
<tr>
<td></td>
<td>HCFC–22/ HCFC–142b.</td>
<td>Acceptable</td>
<td></td>
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<th>Proposed conditions</th>
<th>Comments</th>
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<tbody>
<tr>
<td>HFC-134a</td>
<td>Acceptable</td>
<td></td>
<td></td>
<td>Technology not yet available in most applications to allow near-term use. Potentially large increases in thermal conductivity which will reduce energy efficiency.</td>
</tr>
<tr>
<td>HFC-152a</td>
<td>Acceptable</td>
<td></td>
<td></td>
<td>Technology not yet available in most applications to allow near-term use. Potentially large increases in thermal conductivity which will reduce energy efficiency. Flammability may be an issue for workers and consumers.</td>
</tr>
<tr>
<td>Hydrocarbons (Pentane etc.)</td>
<td>Acceptable</td>
<td></td>
<td></td>
<td>Technology not yet available in most applications to allow near-term use. Potentially large increases in thermal conductivity which will reduce energy efficiency. Flammability may be an issue for workers and consumers. Major sources of VOC emissions are subject to the New Source Review (NSR) program.</td>
</tr>
<tr>
<td>Carbon Dioxide</td>
<td>Acceptable</td>
<td></td>
<td></td>
<td>Technology under development. Flammability may be an issue for workers and consumers.</td>
</tr>
<tr>
<td>CFC-11 Polyurethane, Rigid Appliance</td>
<td>HCFC-22</td>
<td>Acceptable</td>
<td></td>
<td>Technology under development. Increases in thermal conductivity may reduce energy efficiency. Recent worker monitoring studies indicate OEL for 123 (10 ppm) can be achieved with increased ventilation, where needed. Easy to use as a retrofit; energy efficiency close to CFC-11. Current availability is limited. Only chemical alternative that is or will soon be available in sufficient quantities to meet demand of industry. Has highest ODP of HCFCs. Will allow virtually immediate transition out of CFC-11. Fairly good energy efficiency properties.</td>
</tr>
<tr>
<td>HCFC-123</td>
<td>Acceptable</td>
<td></td>
<td></td>
<td>Technology under development. Increases in thermal conductivity may reduce energy efficiency.</td>
</tr>
<tr>
<td>HCFC-141b</td>
<td>Acceptable</td>
<td></td>
<td></td>
<td>Technology under development. HCFC-141b is only chemical alternative that is currently available in sufficient quantities to meet demand of industry and has fairly good energy efficiency properties.</td>
</tr>
<tr>
<td>HCFC-142b</td>
<td>Acceptable</td>
<td></td>
<td></td>
<td>Technology under development. Increases in thermal conductivity may reduce energy efficiency. Recent worker monitoring studies indicate OEL for 123 (10 ppm) can be achieved with increased ventilation, where needed. Fairly good energy efficiency properties.</td>
</tr>
<tr>
<td>HCFC-22/HCFC-141b</td>
<td>Acceptable</td>
<td></td>
<td></td>
<td>Technology not yet available in most applications to allow near-term use. Potential increases in thermal conductivity which will reduce energy efficiency.</td>
</tr>
<tr>
<td>Hydrocarbons (Pentane, Isopentane, Hexane etc.)</td>
<td>Acceptable</td>
<td></td>
<td></td>
<td>Technology not yet available in most applications to allow near-term use. Potential increases in thermal conductivity which will reduce energy efficiency. Flammability may be an issue for workers and consumers. Major sources of VOC emissions are subject to the New Source Review (NSR) program.</td>
</tr>
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<th>Comments</th>
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<tbody>
<tr>
<td>CFC-11 Polyurethane, Rigid Commercial Refrigeration Foams, Spray Foams and Sandwich Panel Foams.</td>
<td>HCFC-22</td>
<td>Acceptable</td>
<td></td>
<td>Technology under development. Increases in thermal conductivity may reduce energy efficiency.</td>
</tr>
<tr>
<td></td>
<td>HCFC-123</td>
<td>Acceptable</td>
<td></td>
<td>Recent worker monitoring studies indicate OEL for 123 (10 ppm) can be achieved with use of increased ventilation, where needed. Easy to use as a retrofit; energy efficiency close to CFC-11. Current availability is limited.</td>
</tr>
<tr>
<td></td>
<td>HCFC-141b</td>
<td>Acceptable</td>
<td></td>
<td>Only chemical alternative currently or soon to be available in sufficient quantities to meet demand of industry. Has highest ODP of the HCFCs. Will allow virtually immediate transition out of CFC-11. Fairly good energy efficiency properties.</td>
</tr>
<tr>
<td>CFC-11 Polyurethane, Rigid Commercial Refrigeration Foams, etc. (continued).</td>
<td>HCFC-142b</td>
<td>Acceptable</td>
<td></td>
<td>Technology under development. Potential increases in thermal conductivity which will reduce energy efficiency.</td>
</tr>
<tr>
<td></td>
<td>HCFC-22/142b</td>
<td>Acceptable</td>
<td></td>
<td>Technology under development. Potential increases in thermal conductivity which will reduce energy efficiency.</td>
</tr>
<tr>
<td></td>
<td>HFC-134a</td>
<td>Acceptable</td>
<td></td>
<td>Technology under development. Potential increases in thermal conductivity which will reduce energy efficiency.</td>
</tr>
<tr>
<td></td>
<td>HFC-152a</td>
<td>Acceptable</td>
<td></td>
<td>Technology under development. Potential increases in thermal conductivity which will reduce energy efficiency.</td>
</tr>
<tr>
<td>Hydrocarbons: Pentane, isopentane, Hexane etc.</td>
<td>Acceptable</td>
<td></td>
<td>Technology under development. Potential increases in thermal conductivity which will reduce energy efficiency. Flammability may be an issue for workers and consumers. Major sources of VOC emissions are subject to the New Source Review (NSR) program.</td>
<td></td>
</tr>
<tr>
<td>Carbon Dioxide</td>
<td>HCFC-22</td>
<td>Acceptable</td>
<td></td>
<td>Technology under development. Increases in thermal conductivity may reduce energy efficiency.</td>
</tr>
<tr>
<td></td>
<td>HCFC-141b</td>
<td>Acceptable for use in insulating and flotation foams only.</td>
<td>Only chemical alternative that is or soon will be available in sufficient quantities to meet demand of industry. Will allow virtually immediate transition out of CFC-11. Fairly good energy efficiency properties. HCFC-141b has an ODP of 0.11, almost equivalent to that of methyl chloroform, a Class I substance. The Agency believes that, with the exception of flotation applications, there are other non-ODP alternatives, or alternatives with lower ODPs, available for use in packaging, decorative, and other noninsulating applications. Use of HCFC-141b for flotation foams may be restricted further under section 610 Non-Essential Use Ban. See HCFC discussion in Preamble for detail.</td>
<td></td>
</tr>
<tr>
<td>Application</td>
<td>Substitute</td>
<td>Initial decision</td>
<td>Proposed conditions</td>
<td>Comments</td>
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<td>---------------------------------------------------------</td>
<td>--------------------------------------------------------------------------</td>
</tr>
<tr>
<td>CFC-12 Poly-styrene, Extruded Boardstock</td>
<td>HCFC-123</td>
<td>Acceptable</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Hydrocarbons (Pentane, Isopentane, Butane, Isobutane etc.)</td>
<td>Acceptable</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Carbon Dioxide</td>
<td>Acceptable</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>HCFC-22</td>
<td>Acceptable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CFC-11, CFC-113 Phenolic Insulation Board</td>
<td>HCFC-142b</td>
<td>Acceptable</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>HCFC-22/142b</td>
<td>Acceptable</td>
<td></td>
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<tr>
<td></td>
<td>HFC-134a</td>
<td>Acceptable</td>
<td></td>
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<td>HFC-152a</td>
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<tr>
<td></td>
<td>Hydrocarbons (Pentane, Isopentane, Butane, Isobutane etc.)</td>
<td>Acceptable</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>HCFC-22/Hydrocarbons (Isopentane etc.)</td>
<td>Acceptable</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Carbon Dioxide</td>
<td>Acceptable</td>
<td></td>
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<tr>
<td></td>
<td>HCFC-141b</td>
<td>Acceptable</td>
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<tr>
<td></td>
<td>HCFC-142b</td>
<td>Acceptable</td>
<td></td>
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<tr>
<td></td>
<td>HCFC-22</td>
<td>Acceptable</td>
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<tr>
<td></td>
<td>HCFC-22/142b</td>
<td>Acceptable</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>HCFC-22/Hydrocarbons (Isopentane etc.)</td>
<td>Acceptable</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Hydrocarbons (Pentane, Isopentane etc.)</td>
<td>Acceptable</td>
<td></td>
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</tr>
</tbody>
</table>

Recent worker monitoring studies indicate OEL for 123 (10 ppm) can be achieved increased ventilation, where needed. Easy to use as a retrofit; energy efficiency close to CFC-11. Current availability is limited. Technology under development. Potential increases in thermal conductivity which will reduce energy efficiency. Flammability may be an issue for workers and consumers. Major sources of VOC emissions are subject to the New Source Review (NSR) program.

Technology under development. Increases in thermal conductivity may reduce energy efficiency.

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Technology under development. Potential increases in thermal conductivity which will reduce energy efficiency. Flammability may be an issue for workers and consumers.

Only chemical alternative that is or soon will be available in sufficient quantities to meet demand of industry. Has highest OPD of HCFCs. Will allow virtually immediate transition out of CFC-11. Fairly good energy efficiency properties.

Technology under development. Increases in thermal conductivity may reduce energy efficiency.

Technology under development. Increases in thermal conductivity may reduce energy efficiency.

Technology under development. Increases in thermal conductivity may reduce energy efficiency.

Technology under development. Potential increases in thermal conductivity which will reduce energy efficiency. Flammability may be an issue for workers and consumers.

Technology under development. Potential increases in thermal conductivity which will reduce energy efficiency. Major sources of VOC emissions are subject to the New Source Review (NSR) program. Flammability may be an issue for workers and consumers.
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<tr>
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<th>Initial decision</th>
<th>Proposed conditions</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>CFC-11 Polyurethane, Flexible.</td>
<td>2-Chloropropane</td>
<td>Acceptable</td>
<td></td>
<td>Proprietary technology. Flammability may be an issue for workers and consumers.</td>
</tr>
<tr>
<td></td>
<td>Carbon Dioxide</td>
<td>Acceptable</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>HCFC-123</td>
<td>Acceptable</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>HFC-134a</td>
<td>Acceptable</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>HFC-152a</td>
<td>Acceptable</td>
<td></td>
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<tr>
<td></td>
<td>Methylene Chloride.</td>
<td>Acceptable</td>
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<td></td>
<td>Acetone</td>
<td>Acceptable</td>
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<td></td>
<td>AB Technology</td>
<td>Acceptable</td>
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<tr>
<td></td>
<td>Carbon Dioxide</td>
<td>Acceptable</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>HCFC-22/HCFC-141b.</td>
<td>Acceptable only for uses which provide for motor vehicle safety in accordance with Federal Motor Vehicle Safety Standards.</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>HCFC-141b</td>
<td>Acceptable</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>HCFC-123</td>
<td>Acceptable</td>
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<tr>
<td></td>
<td>HFC-134a</td>
<td>Acceptable</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>HFC-152a</td>
<td>Acceptable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CFC-11 Polyurethane, Integral Skin.</td>
<td>HCFC-141b</td>
<td>Acceptable only for uses which provide for motor vehicle safety in accordance with Federal Motor Vehicle Safety Standards.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>HCFC-22/HCFC-141b.</td>
<td>Acceptable only for uses which provide for motor vehicle safety in accordance with Federal Motor Vehicle Safety Standards.</td>
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</tr>
<tr>
<td></td>
<td>HCFC-141b</td>
<td>Acceptable</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>HCFC-123</td>
<td>Acceptable</td>
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<td></td>
<td>HFC-134a</td>
<td>Acceptable</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>HFC-152a</td>
<td>Acceptable</td>
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</table>

Current availability is extremely limited. Recent worker monitoring studies indicate OEL for 123 (10 ppm) can be achieved with increased ventilation, where needed. Subject to section 610 Non-essential Use Ban.

Technology under development. Flammability may be an issue for workers and consumers.

Revised OSHA PELs have been proposed at 25 ppm (TWA) for methylene chloride (Nov. 7, 1991). Subject to meeting all future ambient air controls for hazardous air pollutants under Title III of the 1990 CAAA.

Regulated as a VOC under Title I of the Clean Air Act. Major sources of VOC emissions are subject to the New Source Review (NSR) program. Flammability may be an issue for workers and consumers.

AB generates more carbon monoxide (CO) than other blowing agents. OSHA has yet a PEL for CO at 35 ppm TWA with a ceiling of 200 ppm.

Technology not yet available in most applications to allow near-team use. Subject to section 610 Non-essential Use Ban.

Recent worker monitoring studies indicates OEL for HCFC-123 (10 ppm) can be achieved with increased ventilation, where needed. Very easy to use as a retrofit; energy efficiency close to CFC-11. Current availability is extremely limited. Subject to section 610 Non-essential Use Ban.

Only chemical alternative that is currently available in sufficient quantities to meet demand of industry. Will allow virtual immediate transition out of CFC-11. HCFC-141b has an ODP of 0.11, almost equivalent to that of methyl chloroform, a Class I substance. The Agency believes that, with the exception of motor vehicle safety foams, there are other non-ODP alternatives, or alternatives with lower ODPs, available for use in integral skin foams. See HCFC discussion in Preamble for detail on section 610 Non-Essential Use Ban and motor vehicle safety foams exemption.

HCFC-141b has an ODP of 0.11, almost equivalent to that of methyl chloroform, a Class I substance. The Agency believes that, with the exception of motor vehicle safety foams, there are other non-ODP alternatives, or alternatives with lower ODPs, available for use in integral skin foams. See HCFC discussion in Preamble for detail on section 610 Non-Essential Use Ban and motor vehicle safety foams exemption.

Technology under development. Flammability may be an issue for workers and consumers.
**FOAMS—ACCEPTABLE SUBSTITUTES—Continued**

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<th>Initial decision</th>
<th>Proposed conditions</th>
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</tr>
</thead>
<tbody>
<tr>
<td>CFC-12 Polyurethane, rigid slabstock and other.</td>
<td>Hydrocarbons (Pentane, isopentane, butane etc.).</td>
<td>Acceptable</td>
<td>Technology under development. Major sources of VOC emissions are subject to the New Source Review (NSR) program. Flammability may be an issue for workers and consumers.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Methylen Chloride.</td>
<td>Acceptable</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Carbon Dioxide.</td>
<td>Acceptable</td>
<td>Technology not yet available in most applications to allow near-term use.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>HFC-134a</td>
<td>Acceptable</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>HFC-152a</td>
<td>Acceptable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CFC-12, CFC-114, CFC-11 Polyolefin.</td>
<td>Hydrocarbons (Pentane, isopentane, butane, isobutane etc.).</td>
<td>Acceptable</td>
<td>Major sources of VOC emissions are subject to the New Source Review (NSR) program. Flammability may be an issue for workers and consumers.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>HCFC-22</td>
<td>Acceptable</td>
<td>Technology not yet available in most applications to allow near-term use.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>HCFC-142b</td>
<td>Acceptable</td>
<td>Technology not yet available in most applications to allow near-term use.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>HCFC-22/HCFC-142b.</td>
<td>Acceptable</td>
<td>Technology not yet available in most applications to allow near-term use.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>HCFC-22/HCFC-142b. Hydrocarbons (isopentane etc.).</td>
<td>Acceptable</td>
<td>Technology under development. Major sources of VOC emissions are subject to the New Source Review (NSR) program. Flammability may be an issue for workers and consumers.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>HFC-134a</td>
<td>Acceptable</td>
<td>Technology not yet available in most applications to allow near-term use.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>HFC-152a</td>
<td>Acceptable</td>
<td>Technology not yet available in most applications to allow near-term use.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Hydrocarbons (butane, isopentane etc.).</td>
<td>Acceptable</td>
<td>Technology under development. Major sources of VOC emissions are subject to the New Source Review (NSR) program. Flammability may be an issue for workers and consumers.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Carbon Dioxide.</td>
<td>Acceptable</td>
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</tr>
</tbody>
</table>

**FOAMS—UNACCEPTABLE SUBSTITUTES**

<table>
<thead>
<tr>
<th>Application</th>
<th>Substitute</th>
<th>Initial decisions</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>CFC-11 polyurethane, rigid slabstock and other.</td>
<td>HCFC-141b (or blends thereof).</td>
<td>Proposed unacceptable</td>
<td>HCFC-141b has an ODP of 0.11, almost equivalent to that of methyl chloroform, a Class I substance. The Agency believes that, with the exception of flotation applications, there are other non-ODP alternatives, or alternatives with lower ODPs, available for use in packaging, decorative, and other non-insulating applications. Use of HCFC-141b may be restricted further under section 610 Non-Essential Use Ban. See HCFC discussion in Preamble for details.</td>
</tr>
<tr>
<td>CFC-11 polyurethane, flexible.</td>
<td>HCFC-141b (or blends thereof).</td>
<td>Proposed unacceptable.</td>
<td>HCFC-141b has an ODP of 0.11, almost equivalent to that of methyl chloroform, a Class I substance. The Agency believes that non-ODP alternatives are sufficiently available to render the use of HCFC-141b unnecessary in flexible polyurethane foams.</td>
</tr>
</tbody>
</table>
FOAMS.—UNACCEPTABLE SUBSTITUTES—Continued

<table>
<thead>
<tr>
<th>Application</th>
<th>Substitute</th>
<th>Initial decisions</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>CFC-11 polyurethane, integral skin.</td>
<td>HCFC-141b (or blends thereof).</td>
<td>Proposed unacceptable except for use in motor vehicle safety foams.</td>
<td>HCFC-141b has an ODP of 0.11, almost equivalent to that of methyl chloroform, a Class I substance. The Agency believes that, with the exception of motor vehicle safety foams, there are other non-ODP alternatives, or alternatives with lower ODPs, available for use in integral skin foams. See HCFC discussion in Preamble for details on section 610 Non-Essential Use Ban and motor vehicle safety foams.</td>
</tr>
<tr>
<td>CFC-114, CFC-12, CFC-11 polyolefin.</td>
<td>HCFC-141b (or blends thereof).</td>
<td>Proposed unacceptable.</td>
<td>HCFC-141b has an ODP of 0.11, almost equivalent to that of methyl chloroform, a Class I substance. The Agency believes that non-ODP alternatives, or alternatives with lower ODPs, are sufficiently available to render the use of HCFC-141b unnecessary in polyolefin foams. See HCFC discussion in Preamble for details on section 610 Non-Essential Use Ban and motor vehicle safety foams.</td>
</tr>
</tbody>
</table>

FOAMS.—PENDING SUBSTITUTES

<table>
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<tr>
<th>Application</th>
<th>Substitute</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>CFC-11, CFC-113 polyurethane, rigid laminated boardstock. CFC-11, CFC-113 rigid polyurethane, appliance foams. CFC-11 polyurethane, rigid slabstock and other. CFC-11 polyurethane, rigid spray and commercial refrigeration foams, and sandwich panels CFC-11, CFC-113 phenolic CFC-11 polyurethane, flexible Foams, alternative process CFC-12, CFC-114 polystyrene, extruded.</td>
<td>Alternative products: expanded polystyrene, fiberboard, fiberglass. Alternative products: fiberglass, vacuum panels. Alternative products: fiberglass, expanded polystyrene. Alternative products: fiberglass, expanded polystyrene. Alternative technologies: new polyol technologies. Enviro-Cure Process Alternative products: fiberfill, natural latex foams, polyester batting. Electroset process HCFC-142/isopentane blend HFC-124 HFC-125 HFC-143a</td>
<td>Agency has not completed review of data. Agency has not completed review of data. Agency has not completed review of data. Agency has not completed review of data. Pending receipt of additional data. Agency has not completed review of data. Insufficient data. Also need information on proposed end-use. Agency has not completed review of data. Also need more data on proposed end use: sheet and/or boardstock. Insufficient data. Also need information on proposed end-use: sheet and/or boardstock. Insufficient data. Also need information on proposed end-use: sheet and/or boardstock. Insufficient data. Also need information on proposed end-use: sheet and/or boardstock. Agency has not completed review of data.</td>
</tr>
<tr>
<td>CFC-12, CFC-114 polystyrene, extruded boardstock. CFC-12, CFC-114 polyolefin Polyurethane, rigid/frothing process Polyurethane, rigid Blowing Agent.</td>
<td>Alternative products: expanded polystyrene, fiberboard. Alternative products: paper, cardboard, expanded polystyrene. HFC-143a HFC-356 HFC-227ea/pentane HFC-227ea/2-methylpropane Nitrogen gas</td>
<td>Agency has not completed review of data. Agency has not completed review of data. Insufficient data. Also need information on proposed end-use. Insufficient data. Also need information on proposed end-uses. Insufficient data. Also need information on proposed end-uses. Insufficient data. Also need information on proposed end-uses.</td>
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SOLVENT CLEANING—ACCEPTABLE SUBSTITUTES

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<tr>
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<th>Initial decision</th>
<th>Proposed condition</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Metals cleaning w/ CFC-113, MCF.</td>
<td>Aqueous cleaners</td>
<td>Acceptable</td>
<td></td>
<td>EPA expects to issue effluent guidelines for this industry under the Clean Water Act by 1994. Constituents should be drawn from the Agency's list of cleaner components, available from the SNAP Coordinator.</td>
</tr>
<tr>
<td>Application</td>
<td>Substitute</td>
<td>Initial decision</td>
<td>Proposed condition</td>
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<tr>
<td><strong>Precision cleaning</strong> w/CFC-113, MCF.</td>
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</tr>
<tr>
<td>Semi-aqueous cleaners (terpenes/surfactants).</td>
<td>Acceptable</td>
<td></td>
<td>EPA expects to issue effluent guidelines for this industry under the Clean Water Act by 1994. Constituents should be drawn from the Agency's list of cleaner components, available from the SNAP Coordinator.</td>
<td></td>
</tr>
<tr>
<td>Semi-aqueous cleaners (alcohols).</td>
<td>Acceptable</td>
<td></td>
<td>EPA expects to issue effluent guidelines for this industry under the Clean Water Act by 1994. Constituents should be drawn from the Agency's list of cleaner components, available from the SNAP Coordinator.</td>
<td></td>
</tr>
<tr>
<td>Semi-aqueous cleaners (petroleum-based).</td>
<td>Acceptable</td>
<td></td>
<td>EPA expects to issue effluent guidelines for this industry under the Clean Water Act by 1994. Constituents should be drawn from the Agency's list of cleaner components, available from the SNAP Coordinator.</td>
<td></td>
</tr>
<tr>
<td>Organic solvents (esters, ketones, ethers, etc.).</td>
<td>Acceptable</td>
<td></td>
<td>OSHA standards must be met, if applicable. EPA investigating workplace exposures where no OSHA standards exist.</td>
<td></td>
</tr>
<tr>
<td>Trichloro-ethylene, perchloro-ethylene, methylene chloride.</td>
<td>Acceptable</td>
<td></td>
<td>OSHA standards must be met. EPA expects to issue Maximum Achievable Control Technology requirements under the Clean Air Act for this application by 1994.</td>
<td></td>
</tr>
<tr>
<td>Supercritical fluids, plasma cleaning, UV/Ozone cleaning.</td>
<td>Acceptable</td>
<td></td>
<td>OSHA standards for ozone must be met.</td>
<td></td>
</tr>
<tr>
<td><strong>Electronics cleaning</strong> w/CFC-113, MCF.</td>
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</tr>
<tr>
<td>Aqueous cleaners</td>
<td>Acceptable</td>
<td></td>
<td>EPA expects to issue effluent guidelines for this industry under the Clean Water Act by 1994. Constituents should be drawn from the Agency's list of cleaner components, available from the SNAP Coordinator.</td>
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<tr>
<td>Semi-aqueous cleaners (terpenes/surfactants).</td>
<td>Acceptable</td>
<td></td>
<td>EPA expects to issue effluent guidelines for this industry under the Clean Water Act by 1994. Constituents should be drawn from the Agency's list of cleaner components, available from the SNAP Coordinator.</td>
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<td>Semi-aqueous cleaners (petroleum-based).</td>
<td>Acceptable</td>
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<td>EPA expects to issue effluent guidelines for this industry under the Clean Water Act by 1994. Constituents should be drawn from the Agency's list of cleaner components, available from the SNAP Coordinator.</td>
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<td></td>
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<td></td>
</tr>
<tr>
<td>No-clean alternatives</td>
<td>Acceptable</td>
<td></td>
<td>Approval covers low solids fluxes and inert gas soldering.</td>
<td></td>
</tr>
<tr>
<td>Supercritical fluids, plasma cleaning, UV/Ozone cleaning.</td>
<td>Acceptable</td>
<td></td>
<td>OSHA standards for ozone must be met.</td>
<td></td>
</tr>
<tr>
<td>Perfluoro-carbons</td>
<td>Acceptable for spot-free cleaning and drying of high-performance computer components where no other alternative exists.</td>
<td></td>
<td>Under SNAP, EPA has reviewed and found acceptable only certain narrowly defined uses of perfluorinated compounds. Wider use of perfluorinated compounds (e.g., basic metal cleaning or circuit board defluxing) is of concern due to long atmospheric lifetimes, and potential to contribute to global warming.</td>
<td></td>
</tr>
<tr>
<td><strong>Precision cleaning</strong> w/CFC-113, MCF.</td>
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<tr>
<td>Aqueous cleaners</td>
<td>Acceptable</td>
<td></td>
<td>EPA expects to issue effluent guidelines for this industry under the Clean Water Act by 1994. Constituents should be drawn from the Agency's list of cleaner components, available from the SNAP Coordinator.</td>
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<td></td>
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<tr>
<td>Semi-aqueous cleaners (alcohols).</td>
<td>Acceptable</td>
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<td>EPA expects to issue effluent guidelines for this industry under the Clean Water Act by 1994. Constituents should be drawn from the Agency's list of cleaner components, available from the SNAP Coordinator.</td>
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## Solvent Cleaning—Acceptable Substitutes—Continued

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<td>Semi-aqueous cleaners</td>
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<td></td>
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<tr>
<td>(petroleum-based).</td>
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<tr>
<td>Organic solvents (esters,</td>
<td>Acceptable</td>
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<td></td>
<td>OSHA standards must be met, if applicable. EPA investigating workplace exposures where no OSHA standards exist.</td>
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<td>ketones, ethers, etc.)</td>
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</tr>
<tr>
<td>Trichloro-ethylene,</td>
<td>Acceptable</td>
<td></td>
<td></td>
<td>OSHA standards must be met. EPA expects to issue Maximum Achievable Control Technology requirements for this application by 1994.</td>
</tr>
<tr>
<td>perchloro-ethylene, methyl-</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>ylene chloride.</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Supercritical fluids,</td>
<td>Acceptable for spot-free cleaning</td>
<td></td>
<td></td>
<td>OSHA standards for ozone must be met.</td>
</tr>
<tr>
<td>plasma cleaning, UV/Ozone</td>
<td>and drying of high-performance</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>cleaning.</td>
<td>computer components where no other alternative exists.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Perfluoro-carbons</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

## Solvent Cleaning—Unacceptable Substitutes

<table>
<thead>
<tr>
<th>Application</th>
<th>Substitute</th>
<th>Initial decision</th>
<th>Proposed condition</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Metals cleaning w/</td>
<td>HCFC 141b and blends with alcohols</td>
<td>Proposed</td>
<td>Proposed unacceptable with limited critical use exemptions.</td>
<td>High ODP; other alternatives exist. Effective date: As of 30 days after final rule for new equipment; as of January 1, 1996 for existing equipment. EPA will grant limited critical use exemptions where all other substitutes fail to meet safety or performance standards.</td>
</tr>
<tr>
<td>CFC-113.</td>
<td></td>
<td>unacceptable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Metals cleaning w/ MCF.</td>
<td>HCFC 141b blends with alcohols</td>
<td>Proposed</td>
<td>Proposed unacceptable with limited critical use exemptions.</td>
<td>High ODP; other alternatives exist. Effective date: As of 30 days after final rule for new equipment; as of January 1, 1996 for existing equipment. EPA will grant limited critical use exemptions where all other substitutes fail to meet safety or performance standards.</td>
</tr>
<tr>
<td>Electronics cleaning w/CFC-113.</td>
<td>HCFC 141b and blends with alcohols</td>
<td>Proposed</td>
<td>Proposed unacceptable with limited critical use exemptions.</td>
<td>High ODP; other alternatives exist. Effective date: As of 30 days after final rule for new equipment; as of January 1, 1996 for existing equipment. EPA will grant limited critical use exemptions where all other substitutes fail to meet safety or performance standards.</td>
</tr>
<tr>
<td>Electronics cleaning w/MCF.</td>
<td>HCFC 141b blends with alcohols</td>
<td>Proposed</td>
<td>Proposed unacceptable with limited critical use exemptions.</td>
<td>High ODP; other alternatives exist. Effective date: As of 30 days after final rule for new equipment; as of January 1, 1996 for existing equipment. EPA will grant limited critical use exemptions where all other substitutes fail to meet safety or performance standards.</td>
</tr>
<tr>
<td>Precision cleaning w/CFC-113.</td>
<td>HCFC 141b and blends with alcohols</td>
<td>Proposed</td>
<td>Proposed unacceptable with limited critical use exemptions.</td>
<td>High ODP; other alternatives exist. Effective date: As of 30 days after final rule for new equipment; as of January 1, 1996 for existing equipment. EPA will grant limited critical use exemptions where all other substitutes fail to meet safety or performance standards.</td>
</tr>
<tr>
<td>Precision cleaning w/MCF.</td>
<td>HCFC 141b blends with alcohols</td>
<td>Proposed</td>
<td>Proposed unacceptable with limited critical use exemptions.</td>
<td>High ODP; other alternatives exist. Effective date: As of 30 days after final rule for new equipment; as of January 1, 1996 for existing equipment. EPA will grant limited critical use exemptions where all other substitutes fail to meet safety or performance standards.</td>
</tr>
</tbody>
</table>

## Solvent Cleaning—Pending Decisions

<table>
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<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>Metals cleaning w/</td>
<td>Monochloro-toluene/benzo-trifluorides</td>
<td>Agency has not completed review of data.</td>
</tr>
<tr>
<td>CFC-113, MCF.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Electronics Cleaning w/</td>
<td>Brominated hydrocarbons</td>
<td>Agency has not completed review of data.</td>
</tr>
<tr>
<td>CFC-113, MCF.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Precision cleaning w/</td>
<td>Brominated hydrocarbons</td>
<td>Agency has not completed review of data.</td>
</tr>
<tr>
<td>CFC-113, MCF.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

## Notes

- Under SNAP, EPA has reviewed and found acceptable only certain narrowly defined uses of perfluorinated compounds. Wider use of perfluorinated compounds (e.g., circuit board defluxing or basic metal cleaning) is of concern due to long atmospheric lifetimes, and potential to contribute to global warming.
SOLVENT CLEANING—PENDING DECISIONS—Continued

<table>
<thead>
<tr>
<th>Application</th>
<th>Substitute</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>HCFC-123</td>
<td></td>
<td>More information needed on feasibility of achieving OEL. EPA investigating toxicity concerns.</td>
</tr>
<tr>
<td>HCFC-225</td>
<td></td>
<td>Toxicity data yet to be completed. HCFC-225cb isomer is of commercial interest, but toxicity concerns may limit interest in the isomer.</td>
</tr>
</tbody>
</table>

HALONS—ACCEPTABLE SUBSTITUTES

<table>
<thead>
<tr>
<th>Application</th>
<th>Substitute</th>
<th>Initial decision</th>
<th>Proposed conditions</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Halon 1211 Stream-</td>
<td>HBFC-22B1</td>
<td>Acceptable in non-residential uses only.</td>
<td></td>
<td>ODP of compound (.74) precludes acceptability of widespread use in consumer applications. Will be phased out (except for essential uses) January 1, 1996. Anticipated exposure levels in consumer applications exceed toxic levels. This agent was submitted to the Agency as a Premanufacture Notice (PMN) and is presently subject to requirements contained in a Toxic Substance Control Act (TSCA) Consent Order.</td>
</tr>
<tr>
<td>ing Agents—Consumer Applications</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>HCFC-123</td>
<td>Acceptable</td>
<td></td>
<td>Contains small percentage of PFC which has an unusually long atmospheric lifetime, and could potentially contribute to global climate change. EPA suggests but does not require that users minimize emissions by minimizing use during training, and by recovery and recycling during maintenance and servicing.</td>
</tr>
<tr>
<td></td>
<td>[HCFC Blend] B</td>
<td>Acceptable</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>[CFC Blend]</td>
<td>Acceptable in non-residential uses only.</td>
<td></td>
<td>[CFC Blend] can help transition away from halon 1211 in applications requiring a highly effective fire extinguishant with low toxicity. Because CFCs are a Class I substance, production will be phased out by January 1, 1996. The manufacturer notes that this agent is not suitable for Class B fires involving escaping gases. Not rated for use against Class A fires. Can result in temporary loss of visibility if discharged in confined areas. Not suitable for use against electrical fires (Class C). Effective against flammable liquids. Can also be used against Class A fires. Not suitable for discharge onto live electrical equipment. Proper procedures regarding the operation of the extinguisher and ventilation following dispensing the extinguishant is recommended. Worker exposure may be a concern in small office areas. Acceptability in commercial applications will accelerate the transition away from Halon 1211 which has a significantly higher ODP.</td>
</tr>
<tr>
<td>Carbon Dioxide</td>
<td>Acceptable</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dry Chemical</td>
<td>Acceptable</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Water</td>
<td>Acceptable</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Foam</td>
<td>Acceptable</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Halon 1211 Stream-</td>
<td>HBFC-22B1</td>
<td>Acceptable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ing Agents—Commercial/Industrial Applications</td>
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<tr>
<td>Application</td>
<td>Substitute</td>
<td>Initial decision</td>
<td>Proposed conditions</td>
<td>Comments</td>
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<td>-------------------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>HCFC-123</td>
<td>Acceptable</td>
<td>Acceptable</td>
<td>Contains small percentage of PFC which has an unusually long atmospheric lifetime,</td>
<td>Contains small percentage of PFC which has an unusually long atmospheric lifetime, and could potentially contribute to global climate change. EPA suggests but does not require that users minimize emissions by minimizing use during training, and by recovery and recycling during maintenance and servicing.</td>
</tr>
<tr>
<td>[HCFC Blend] B</td>
<td></td>
<td></td>
<td></td>
<td>[HCFC Blend] can help transition away from halon 1211 in applications requiring a highly effective fire extinguishing agent with low toxicity. Because CFCs are a Class I substance, production will be phased out by January 1, 1996. The manufacturer notes that this agent is not suitable for Class B fires involving escaping gases.</td>
</tr>
<tr>
<td>[CFC Blend]</td>
<td>Acceptable</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dry Chemical</td>
<td>Acceptable</td>
<td></td>
<td>Can result in temporary loss of visibility if discharged in confined areas.</td>
<td></td>
</tr>
<tr>
<td>Carbon Dioxide</td>
<td>Acceptable</td>
<td></td>
<td>Not rated for use against Class A fires.</td>
<td></td>
</tr>
<tr>
<td>Water</td>
<td>Acceptable</td>
<td></td>
<td>Not suitable for use against electrical fires (Class C).</td>
<td></td>
</tr>
<tr>
<td>Foam</td>
<td>Acceptable</td>
<td></td>
<td>Effective against flammable liquids. Can also be used against Class A fires.</td>
<td>Not suitable for discharge onto live electrical equipment. Acceptability in commercial applications will accelerate the transition away from Halon 1211 which has a significantly higher ODP. HBFC-22B1 is considered an interim substitute for Halon 1211. Because the HBFC-22B1 has an ODP of .74, production will be phased out on January 1, 1996. This agent was submitted to the Agency as a Premanufacture Notice (PMN) and is presently subject to requirements contained in a Toxic Substance Control Act (TSCA) Consent Order.</td>
</tr>
<tr>
<td>HBFC-22B1</td>
<td>Acceptable</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Halon 1211</td>
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<tr>
<td>Halon 1211 Stream-</td>
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<tr>
<td>ing Agents—Military</td>
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<tr>
<td>Applications</td>
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</tr>
<tr>
<td>[HCFC Blend] B</td>
<td>Acceptable</td>
<td></td>
<td>Contains small percentage of PFC which has an unusually long atmospheric lifetime,</td>
<td>Contains small percentage of PFC which has an unusually long atmospheric lifetime, and could potentially contribute to global climate change. EPA suggests but does not require that users minimize emissions by minimizing use during training, and by recovery and recycling during maintenance and servicing.</td>
</tr>
<tr>
<td>FC 5–1–14</td>
<td>Acceptable</td>
<td></td>
<td>FC 5–1–14 shall not be used during training exercises.</td>
<td>Under SNAP, EPA has reviewed and found acceptable only certain narrowly defined uses of perfluorinated compounds. Wider use of perfluorinated compounds is of concern due to long atmospheric lifetimes and potential to contribute to global warming.</td>
</tr>
<tr>
<td>[CFC Blend]</td>
<td>Acceptable</td>
<td></td>
<td></td>
<td>[CFC Blend] can help transition away from halon 1211 in applications requiring a highly effective fire extinguishing agent with low toxicity. Because CFCs are a Class I substance, production will be phased out by January 1, 1996. The manufacturer notes that this agent is not suitable for Class B fires involving escaping gases. Does not penetrate well behind obstacles. Not rated for use against Class A fires.</td>
</tr>
<tr>
<td>Dry Chemical</td>
<td>Acceptable</td>
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<td></td>
</tr>
<tr>
<td>Carbon Dioxide</td>
<td>Acceptable</td>
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</table>
### HALONS—ACCEPTABLE SUBSTITUTES—Continued

<table>
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<tr>
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<tbody>
<tr>
<td><strong>Water</strong></td>
<td></td>
<td>Acceptable</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Foam</strong></td>
<td></td>
<td>Acceptable</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>HBFC-22B1</strong></td>
<td></td>
<td>Acceptable</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>HCFC-22</strong></td>
<td></td>
<td>Acceptable</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Halon 1301 Total Flooding—Occupied Areas**

- **Water**
  - Acceptable
  - Not suitable for use against electrical fires (Class C).
  - Effective against flammable liquids. Can also be used against Class A fires.
  - Not suitable for discharge onto live electrical equipment.
  - HBFC-22B1 can be utilized in existing equipment with only minor modifications and can thus facilitate a more rapid transition away from Halon 1301.
  - The design concentration is approximately 5.3% while its cardiotoxic LOAEL is 1%.
  - Evacuation must be complete before 1% concentration is reached.
  - Must conform with OSHA 29 CFR 1910 Subpart L Section 1910.160 of the U.S. Code. This section requires that employees be alerted to impending system discharge by suitable alarms and provided with sufficient time to safely exit the area prior to system discharge.
  - Per OSHA requirements, protective gear (SCBA) must be available in the event personnel must reenter the area.
  - HBFC-22B1 can be considered only an interim substitute for Halon 1301. HBFC-22B1 has an ODP of .74; thus, production will be phased out on January 1, 1996.
  - This agent was submitted to the Agency as a Premanufacture Notice (PMN) and is presently subject to requirements contained in a Toxic Substances Control Act (TSCA) Consent Order.
  - The design concentration is approximately 13.9% while its cardiotoxic NOAEL is 2.5% and the LOAEL is 5%.
  - Must conform with OSHA 29 CFR 1910 Subpart L Section 1910.160 of the U.S. Code. This section requires that employees be alerted to impending system discharge by suitable alarms and provided with sufficient time to safely exit the area prior to system discharge.
  - Per OSHA requirements, protective gear (SCBA) must be available in the event personnel must reenter the area.

**Foam**

- Acceptable
- For occupied areas from which personnel cannot be evacuated in one minute, use is permitted only up to concentrations not exceeding the cardiotoxic NOAEL.
- For occupied areas from which personnel can be evacuated or egress can occur between 30 and 60 seconds, use is permitted up to a concentration not exceeding the LOAEL.
- All personnel must be evacuated before concentration of HBFC-22B1 exceeds 1%.

**HCFC-22**

- Acceptable
- For occupied areas from which personnel cannot be evacuated in one minute, use is permitted only up to concentrations not exceeding the cardiotoxic NOAEL.
- For occupied areas from which personnel can be evacuated or egress can occur between 30 and 60 seconds, use is permitted up to a concentration not exceeding the LOAEL.
- All personnel must be evacuated before concentration of HCFC-22 exceeds 5%.
**HALONS—ACCEPTABLE SUBSTITUTES—Continued**

<table>
<thead>
<tr>
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<th>Initial decision</th>
<th>Proposed conditions</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>HCFC-124</td>
<td>Acceptable</td>
<td>For occupied areas from which personnel cannot be evacuated in one minute, use is permitted only up to concentrations not exceeding the cardiotoxic NOAEL. For occupied areas from which personnel can be evaluated or egress can occur between 30 and 60 seconds, use is permitted up to a concentration not exceeding the LOAEL. All personnel must be evacuated before concentration of HCFC-124 exceeds 2.5%</td>
<td>The design concentration is approximately 9.8% while its cardiotoxic NOAEL is 1.0% and its LOAEL is 2.5%. Must conform with OSHA 29 CFR 1910 Subpart L Section 1910.160 of the U.S. Code. This section requires that employees be alerted to impending system discharge by suitable alarms and provided with sufficient time to safely exit the area prior to system discharge. Per OSHA requirements, protective gear (SCBA) must be available in the event personnel must reenter the area.</td>
<td></td>
</tr>
<tr>
<td>[HCFC BLEND] A</td>
<td>Acceptable</td>
<td>For occupied areas from which personnel cannot be evacuated in one minute, use is permitted only up to concentrations not exceeding the cardiotoxic NOAEL. For occupied areas from which personnel can be evaluated or egress can occur between 30 and 60 seconds, use is permitted up to a concentration not exceeding the LOAEL. All personnel must be evacuated before concentration of [HCFC BLEND] A exceeds the design concentration of 10.3%</td>
<td>The design concentration is approximately 10.3%. Preliminary data indicates that the NOAEL is at least 10.0%, and therefore the LOAEL is likely to be higher. Until the Agency receives the LOAEL data, this agent is approved to the design concentration of 10.3%. Evacuation must be complete before 10.3% concentration is exceeded. EPA awaits the final report on cardiotoxicity test data. Must conform with OSHA 29 CFR 1910 Subpart L Section 1910.160 of the U.S. Code. This section requires that employees be alerted to impending system discharge by suitable alarms and provided with sufficient time to safely exit the area prior to system discharge. Per OSHA requirements, protective gear (SCBA) must be available in the event personnel must reenter the area.</td>
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</tbody>
</table>
## HALONS—ACCEPTABLE SUBSTITUTES—Continued

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<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>HFC-23</td>
<td>Acceptable</td>
<td>For occupied areas from which personnel cannot be evacuated in one minute, use is permitted only up to concentrations not exceeding the cardiotoxic NOAEL.</td>
<td>The design concentration is approximately 14.9% while preliminary data indicates that its cardiotoxic NOAEL is 30% without added oxygen and 50% with added oxygen. Evacuation must be complete before 30% concentration is reached. EPA awaits the final report on cardiotoxicity test data. Must conform with OSHA 29 CFR 1910 Subpart L Section 1910.160 of the U.S. Code. This section requires that employees be alerted to impending system discharge by suitable alarms and provided with sufficient time to safely exit the area prior to system discharge.</td>
<td>Per OSHA requirements, protective gear (SCBA) must be available in the event personnel must reenter the area. Due to concerns about this agent's Global Warming Potential, the agency is currently restricting its use until further analysis is complete. Required extinguishing concentration and storage volume ratio are the highest of all potential candidates, but weight ratio is only 2.0.</td>
</tr>
<tr>
<td>HFC-134a</td>
<td>Acceptable</td>
<td>For occupied areas from which personnel cannot be evacuated in one minute, use is permitted only up to concentrations not exceeding the cardiotoxic NOAEL. For occupied areas from which personnel can be evacuated or egress can occur between 30 and 60 seconds, use is permitted up to a concentration not exceeding the LOAEL. All personnel must be evacuated before concentration of HFC-23 exceeds 30%</td>
<td>The design concentration is approximately 12.6% while its cardiotoxic LOAEL is approximately 8.0% Evacuation must be complete before 8.0% concentration is reached. Must conform with OSHA 29 CFR 1910 Subpart L Section 1910.160 of the U.S. Code. This section requires that employees be alerted to impending system discharge by suitable alarms and provided with sufficient time to safely exit the area prior to system discharge.</td>
<td>Per OSHA requirements, protective gear (SCBA) must be available in the event personnel must reenter the area.</td>
</tr>
<tr>
<td>HFC-227ea</td>
<td>Acceptable</td>
<td>For occupied areas from which personnel cannot be evacuated in one minute, use is permitted only up to concentrations not exceeding the cardiotoxic NOAEL.</td>
<td>The design concentration is approximately 7.1% while preliminary data indicates that its cardiotoxic NOAEL is 8.1% and its LOAEL is greater than 10.5%. Evacuation must be complete before a concentration of 10.5% is exceeded. EPA awaits the final report on cardiotoxicity test data.</td>
<td>Per OSHA requirements, protective gear (SCBA) must be available in the event personnel must reenter the area.</td>
</tr>
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<tbody>
<tr>
<td>FC 3-1-10</td>
<td>Acceptable for applications involving the protection of public safety or national security; telecommunication or computer equipment related to public safety or national security; or life support functions.</td>
<td>For occupied areas from which personnel can be evacuated or egress can occur between 30 and 60 seconds, use is permitted up to a concentration not exceeding the LOAEL. All personnel must be evacuated before concentration of HFC-227ea exceeds 10.5%.</td>
<td>Must conform with OSHA 29 CFR 1910 Subpart L Section 1910.160 of the U.S. Code. This section requires that employees be alerted to impending system discharge by suitable alarms and provided with sufficient time to safely exit the area prior to system discharge. Per OSHA requirements, protective gear (SCBA) must be available in the event personnel must reenter the area.</td>
<td></td>
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</tbody>
</table>

This agent was submitted to the Agency as a Premanufacture Notice (PMN) agent and is presently subject to requirements contained in a Toxic Substances Control Act (TSCA) Significant New Use Rule (SNUR). The design concentration is approximately 6.6% while its cardioxic NOAEL is 40% and its LOAEL is over 40%. Must conform with OSHA 29 CFR 1910 Subpart L Section 1910.160 of the U.S. Code. This section requires that employees be alerted to impending system discharge by suitable alarms and provided with sufficient time to safely exit the area prior to system discharge. Per OSHA requirements, protective gear (SCBA) must be available in the event personnel must reenter the area. |

Under SNAP, EPA has reviewed and found acceptable only certain narrowly defined uses of perfluorinated compounds. Wider use of perfluorinated compounds is of concern due to long atmospheric lifetimes, and potential to contribute to global warming.
### HALONS—ACCEPTABLE SUBSTITUTES—Continued

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<tbody>
<tr>
<td>[Inert Gas Blend]</td>
<td>Acceptable</td>
<td>The design concentration must result in at least 14% oxygen and 4% CO₂. If the oxygen concentration of the atmosphere falls below 12%, personnel must be evacuated and egress must occur within 30 seconds.</td>
<td></td>
<td>Studies have shown that healthy, young individuals can remain in a 12% to 14% oxygen atmosphere for 30 to 40 minutes without impairment. However, in a fire emergency, the oxygen level may be reduced below safe levels, and the decomposition products formed by the fire are likely to cause harm. Thus, the Agency does not contemplate personnel remaining in the space after system discharge during a fire without Self-Contained Breathing Apparatus (SCBA) as required by OSHA. System design must adhere to OSHA 1910.162(b)(5) and NFPA Standard 12.</td>
</tr>
<tr>
<td>CO₂</td>
<td>Acceptable</td>
<td></td>
<td></td>
<td>HBFC-22B1 can be considered only as an interim substitute for Halon 1301. HBFC-22B1 has an ODP of .74; thus, production will be phased out January 1, 1996. This agent was submitted to the Agency as a Premanufacture Notice (PMN) and is presently subject to requirements contained in a Toxic Substance Control Act (TSCA) Consent Order. OSHA requires that protective gear (SCBA) be worn by personnel entering the space until oxygen levels return to 19.5% and relevant decomposition products decrease to OSHA limits.</td>
</tr>
<tr>
<td>Water</td>
<td>Acceptable</td>
<td></td>
<td></td>
<td>OSHA requires that protective gear (SCBA) be worn by personnel entering the space until oxygen levels return to 19.5% and relevant decomposition products decrease to OSHA limits.</td>
</tr>
<tr>
<td>HBFC-22</td>
<td>Acceptable</td>
<td></td>
<td></td>
<td>OSHA requires that protective gear (SCBA) be worn by personnel entering the space until oxygen levels return to 19.5% and relevant decomposition products decrease to OSHA limits.</td>
</tr>
<tr>
<td>HCFC-124</td>
<td>Acceptable</td>
<td></td>
<td></td>
<td>OSHA requires that protective gear (SCBA) be worn by personnel entering the space until oxygen levels return to 19.5% and relevant decomposition products decrease to OSHA limits.</td>
</tr>
<tr>
<td>[HCFC BLEND] A</td>
<td>Acceptable</td>
<td></td>
<td></td>
<td>OSHA requires that protective gear (SCBA) be worn by personnel entering the space until oxygen levels return to 19.5% and relevant decomposition products decrease to OSHA limits. Due to concerns about this agent’s Global Warming Potential, its use is restricted pending further review by the Agency. Required extinguishing concentration and storage volume ratio are the highest of all potential candidates, but weight ratio is only 2.0.</td>
</tr>
<tr>
<td>HFC-23</td>
<td>Acceptable for high value applications such as those involving the protection of public safety or national security; telecommunication or computer equipment related to public safety or national security; Life support functions such as Armored Personnel Vehicles and related vehicles; and for explosion Inertion suppression with flammable liquids and gasas.</td>
<td></td>
<td></td>
<td>OSHA requires that protective gear (SCBA) be worn by personnel entering the space until oxygen levels return to 19.5% and relevant decomposition products decrease to OSHA limits.</td>
</tr>
<tr>
<td>HFC-125</td>
<td>Acceptable</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### HALONS—ACCEPTABLE SUBSTITUTES—Continued

<table>
<thead>
<tr>
<th>Application</th>
<th>Substitute</th>
<th>Initial decision</th>
<th>Proposed conditions</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Halon 1301</td>
<td>HFC-134a</td>
<td>Acceptable</td>
<td></td>
<td>OSHA requires that protective gear (SCBA) be worn by personnel entering the space until oxygen levels return to 19.5% and relevant decomposition products decrease to OSHA limits.</td>
</tr>
<tr>
<td></td>
<td>HFC-227ea</td>
<td>Acceptable</td>
<td></td>
<td>OSHA requires that protective gear (SCBA) be worn by personnel entering the space until oxygen levels return to 19.5% and relevant decomposition products decrease to OSHA limits.</td>
</tr>
<tr>
<td></td>
<td>FC 3–1–10</td>
<td>Acceptable</td>
<td>FC 3–1–10 may not be used for training exercises. Detection should be cross-zoned to avoid unnecessary discharge and maintained to high reliability. Recycling/recovery equipment must be used during servicing of fire protection system.</td>
<td>Under SNAP, EPA has reviewed and found acceptable only certain narrowly defined uses of perfluorinated compounds. Wider use of perfluorinated compounds is of concern due to long atmospheric lifetimes, and potential to contribute to global warming. OSHA requires that protective gear (SCBA) be worn by personnel entering the space until oxygen levels return to 19.5% and relevant decomposition products decrease to OSHA limits.</td>
</tr>
<tr>
<td></td>
<td>[Inert Gas Blend]</td>
<td>Acceptable</td>
<td></td>
<td>OSHA requires that protective gear (SCBA) be worn by personnel entering the space until oxygen levels return to 19.5% and relevant decomposition products decrease to OSHA limits.</td>
</tr>
<tr>
<td></td>
<td>Carbon Dioxide</td>
<td>Acceptable</td>
<td></td>
<td>OSHA requires that protective gear (SCBA) be worn by personnel entering the space until oxygen levels return to 19.5% and relevant decomposition products decrease to OSHA limits.</td>
</tr>
<tr>
<td></td>
<td>Water</td>
<td>Acceptable</td>
<td></td>
<td>OSHA requires that protective gear (SCBA) be worn by personnel entering the space until oxygen levels return to 19.5% and relevant decomposition products decrease to OSHA limits.</td>
</tr>
<tr>
<td></td>
<td>HBFC-22B1</td>
<td>Acceptable</td>
<td></td>
<td>OSHA requires that protective gear (SCBA) be worn by personnel entering the space until oxygen levels return to 19.5% and relevant decomposition products decrease to OSHA limits.</td>
</tr>
</tbody>
</table>

**NBFC-22B1**: Can be considered only an interim substitute for Halon 1301. NBFC-22B1 has an ODP of .74; thus, production will be phased out on January 1, 1996. This agent was submitted to the Agency as a Premanufacture Notice (PMN) and is presently subject to requirements contained in a Toxic Substance Control Act (TSCA) Consent Order. OSHA requires that protective gear (SCBA) be worn by personnel entering the space until oxygen levels return to 19.5% and relevant decomposition products decrease to OSHA limits.
## HALONS—ACCEPTABLE SUBSTITUTES—Continued

<table>
<thead>
<tr>
<th>Application</th>
<th>Substitute</th>
<th>Initial decision</th>
<th>Proposed conditions</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>HFC-23</td>
<td>HFC-23</td>
<td>Acceptable for high value applications such as those involving the protection of public safety or national security; telecommunication or computer equipment related to public safety or national security; life support functions; and for explosion inertion/suppression with flammable liquids and gases.</td>
<td></td>
<td>Preliminary analysis of cardiotoxicity tests indicates that the no effect level for cardiac sensitization exceeds 50%. Design concentrations vary for different atmospheres. The design concentration should not exceed the cardiotoxic LOAEL of 50% in an occupied area. Due to concerns about this agent's Global Warming Potential, its use is restricted pending further Agency review. Required extinguishing concentration and storage volume ratio are the highest of all potential candidates, but weight ratio is only 2.0.</td>
</tr>
<tr>
<td>HFC-125</td>
<td>HFC-125</td>
<td>Acceptable only in normally unoccupied areas.</td>
<td></td>
<td>OSHA requires that protective gear (SCBA) be worn by personnel entering the space until oxygen levels return to 19.5% and relevant decomposition products decrease to OSHA limits. Design concentrations vary for different atmospheres. The design concentration must not exceed the cardiotoxic LOAEL of 10.5% in an occupied area. OSHA requires that protective gear (SCBA) be worn by personnel entering the space until oxygen levels return to 19.5% and relevant decomposition products decrease to OSHA limits. This agent was submitted to the Agency as a Premanufacture Notice (PMN) and is subject to requirements contained in a Toxic Substance Control Act (TSCA) Significant New Use Rule (SNUR).</td>
</tr>
<tr>
<td>HFC-227ea</td>
<td>HFC-227ea</td>
<td>Acceptable</td>
<td></td>
<td>Design concentrations vary for different atmospheres. The design concentration must not exceed the cardiotoxic LOAEL of 10.5% in an occupied area. OSHA requires that protective gear (SCBA) be worn by personnel entering the space until oxygen levels return to 19.5% and relevant decomposition products decrease to OSHA limits. This agent was submitted to the Agency as a Premanufacture Notice (PMN) and is subject to requirements contained in a Toxic Substance Control Act (TSCA) Significant New Use Rule (SNUR).</td>
</tr>
<tr>
<td>FC 3-1-10</td>
<td>FC 3-1-10</td>
<td>Acceptable for applications involving the protection of public safety or national security; telecommunication or computer equipment related to public safety or national security; life support functions; and for explosion inertion/suppression with flammable liquids and gases.</td>
<td>FC 3-1-10 shall not be used to test explosion inertion systems unless captured and recycled or destroyed.</td>
<td>Design concentrations vary for different atmospheres. The design concentration must not exceed the cardiotoxic LOAEL of 40% in an occupied area.</td>
</tr>
<tr>
<td>[Inert Gas Blend]</td>
<td>Acceptable</td>
<td></td>
<td></td>
<td>Under SNAP, EPA has reviewed and found acceptable only certain narrowly defined uses of perfluorinated compounds. Wider use of perfluorinated compounds is of concern due to long atmospheric lifetimes, and potential to contribute to global warming. OSHA requires that protective gear (SCBA) be worn by personnel entering the space until oxygen levels return to 19.5% and relevant decomposition products decrease to OSHA limits. Efficacy data required for acceptance in normally occupied areas. OSHA requires that protective gear (SCBA) be worn by personnel entering the space until oxygen levels return to 19.5% and relevant decomposition products decrease to OSHA limits.</td>
</tr>
</tbody>
</table>
### HALONS—UNACCEPTABLE SUBSTITUTES

<table>
<thead>
<tr>
<th>Application</th>
<th>Substitute</th>
<th>Initial decision</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Halon 1211</td>
<td>[CFC-11]</td>
<td>Proposed Un-acceptable.</td>
<td>This agent has been proposed for large outdoor fires for which non-ozone depleting alternatives are currently used.</td>
</tr>
<tr>
<td>Streaming Agents—Commercial/Industrial Applications</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### HALONS—PENDING DECISIONS

<table>
<thead>
<tr>
<th>Application</th>
<th>Substitute</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Halon 1211</td>
<td>HFC-227ea</td>
<td>Cardiotoxicity and personnel monitoring data required.</td>
</tr>
<tr>
<td>Streaming Agents—Consumer Applications</td>
<td>HFC-227ea</td>
<td>Cardiotoxicity and personnel monitoring data required.</td>
</tr>
<tr>
<td>Streaming Agents—Commercial/Industrial Applications</td>
<td>HFC-227ea</td>
<td>Cardiotoxicity and personnel monitoring data required.</td>
</tr>
<tr>
<td>Total Flooding—Occupied Areas</td>
<td>HFC-32</td>
<td>HBFC-22B1 is considered an interim substitute for Halon 1211. Because the HBFC-22B1 has an ODP of .74, production will be phased out (except for essential uses) on January 1, 1996.</td>
</tr>
<tr>
<td>Water Mist/Fog</td>
<td>HFC-125</td>
<td>Need additional information on potential flammability. Cardiotoxicity data is required.</td>
</tr>
<tr>
<td>Water Mist/Fog</td>
<td>SF6</td>
<td>No company has proposed commercialization of this agent as a halon substitute. Due to its potential flammability, this agent may require blending with another agent.</td>
</tr>
<tr>
<td>Halon 1301</td>
<td>[HCFC BLEND]</td>
<td>This newly developing technology for use on Class A, B, and C fires is of high interest. The Agency has not yet received a formal submission in order to complete its evaluation.</td>
</tr>
<tr>
<td>Total Flooding—Unoccupied Areas</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Halon 1301</td>
<td>[HCFC BLEND]</td>
<td>Explosion Inertion test data on blend required.</td>
</tr>
<tr>
<td>Explosion Inertion</td>
<td>SF6</td>
<td>This agent has been proposed as an alternative for discharge testing of halon systems.</td>
</tr>
</tbody>
</table>

### STERILANTS—ACCEPTABLE SUBSTITUTES

<table>
<thead>
<tr>
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<th>Initial decision</th>
<th>Proposed conditions</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>12/88 Blend of EtO/CFC-12. Sterilant</td>
<td>CO₂/EtO</td>
<td>Acceptable</td>
<td>CO₂/EtO blends can serve as drop-in replacements to 12/88 in some but not in all existing equipment because they require a higher operating pressure. Maximum EtO concentration in a CO₂/EtO blend may have to be reduced to 8–9 percent to reduce flammability.</td>
<td></td>
</tr>
<tr>
<td>Sterilant</td>
<td>HCFC-124/EtO</td>
<td>Acceptable</td>
<td>In a blend with EtO, HCFC-124 is the only available drop-in replacement for about half of the equipment now using 12/88. However, HCFC-124 is an ozone depleting substance; it should be use to sterilize only that equipment that cannot be sterilized using other alternatives such as steam or CO₂/EtO blends. Because HCFC-124 is a Class II substance, its use may be subject to future regulation promulgated under Section 608 of the Clean Air Act Amendments of 1990. As a HAP, use of EtO must comply with Title Ill of the CAA.</td>
<td></td>
</tr>
</tbody>
</table>
### Sterilants—Acceptable Substitutes—Continued

<table>
<thead>
<tr>
<th>Application</th>
<th>Substitute</th>
<th>Initial Decision</th>
<th>Proposed Conditions</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>12/88 Blend of ETO/CFC-12</td>
<td>Pure ETO</td>
<td>Acceptable</td>
<td></td>
<td>ETO is a toxic, carcinogenic substance and is considered a hazardous air pollutant. Potential exposures of the general population to ETO releases can be limited either through the use of catalytic converters which convert waste ETO into CO2 and water, or through the use of acid water scrubbers which convert waste ETO into ethylene glycol. Must be used in accordance with manufacturer recommendations to address flammability concerns. Must be used in accordance with OSHA standards to limit occupational exposures. Applicable only to devices resistant to heat and moisture.</td>
</tr>
</tbody>
</table>

### Sterilants—Pending Decisions

<table>
<thead>
<tr>
<th>Application</th>
<th>Substitute</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>12/88 blend of ETO/CFC-12 sterilant</td>
<td>[HCFC Blend] A</td>
<td>Agency has not completed review of data.</td>
</tr>
<tr>
<td></td>
<td>HFC-125/ETO</td>
<td>Agency has not completed review of data.</td>
</tr>
<tr>
<td></td>
<td>HFC-227ea/ETO</td>
<td>Need exposure data.</td>
</tr>
</tbody>
</table>

### Aerosols—Acceptable Substitutes

<table>
<thead>
<tr>
<th>Application</th>
<th>Substitute</th>
<th>Initial Decision</th>
<th>Proposed Conditions</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>CFC-11, HCFC-22, HCFC-142b as aerosol propellants.</td>
<td>Hydrocarbons (Propane, isobutane, n-butane), Dimethyl ether, HFC-152a, HFC-134a, Alternative processes (pumps, mechanical pressure dispensers, non-spray dispensers), Compressed Gases (Carbon dioxide, air, nitrogen, nitrous oxide).</td>
<td>Acceptable</td>
<td>Hydrocarbons are flammable materials and must be used with the necessary precautions. DME is flammable and must be used with the necessary precautions. Blends of DME with HCFCs would be subject to section 610 restrictions. Expense of these compounds is likely to limit widespread use.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>CFC-11 as aerosol propellant.</td>
<td>HCFC-142b</td>
<td>Acceptable</td>
<td>Use of HCFC-142b, either by itself or blended with other compounds will be prohibited January 1, 1994 under section 610 (d).</td>
</tr>
<tr>
<td></td>
<td>HCFC-22</td>
<td>Acceptable</td>
<td>Use of HCFC-22, either by itself or blended with other compounds will be prohibited January 1, 1994 under section 610 (d).</td>
<td></td>
</tr>
<tr>
<td></td>
<td>CFC-11, CFC-113, MCF, HCFC-141b as aerosol solvents.</td>
<td>Petroleum Distillates (C-6 to C-10 paraffins and light aromatics), Chlorinated solvents (trichloroethylene, perchloroethylene, methylene chloride), Organic solvents (e.g., methanol, ethanol, isopropanol, acetone), Terpenes</td>
<td>Acceptable</td>
<td>Petroleum distillates are flammable materials and must be used with the necessary precautions. Pesticide aerosols must adhere to FIFRA standards. EPA expects to issue control technology requirements under Title III of the Clean Air Act. Pesticide aerosols must adhere to FIFRA standards. Not suitable for use in consumer products. These substitutes are flammable materials and must be used with the necessary precautions. These substitutes are flammable materials and must be used with the necessary precautions.</td>
</tr>
</tbody>
</table>
### AEROSOLS—ACCEPTABLE SUBSTITUTES—Continued

<table>
<thead>
<tr>
<th>Application</th>
<th>Substitute</th>
<th>Initial Decision</th>
<th>Proposed Conditions</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>CFC-11, CFC-113, MCF as aerosol solvents.</td>
<td>Water-Based Formulations, HCFC-141b</td>
<td>Acceptable</td>
<td></td>
<td>Use of HCFC-141b, either by itself or blended with other compounds will be prohibited January 1, 1994 under Section 610 (d).</td>
</tr>
</tbody>
</table>

### AEROSOLS—PENDING DECISIONS

<table>
<thead>
<tr>
<th>Application</th>
<th>Substitute</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>CFC-12 as aerosol propellant</td>
<td>HFC-227</td>
<td>FDA approval still required in metered dose inhalers. Likely to have low environmental impacts.</td>
</tr>
<tr>
<td>CFC-11, CFC-113, MCF, HCFC-141b as aerosol solvents.</td>
<td>Monochloro/toluene/benzo-trifluorides.</td>
<td></td>
</tr>
</tbody>
</table>

### TOBACCO EXPANSION—ACCEPTABLE SUBSTITUTES

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<tr>
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<th>Initial decision</th>
<th>Proposed conditions</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>CFC-11 Tobacco expansion</td>
<td>Carbon dioxide</td>
<td>Acceptable</td>
<td></td>
<td>Carbon dioxide cannot be used as a drop-in or retrofit, but requires new equipment.</td>
</tr>
</tbody>
</table>

### TOBACCO EXPANSION—PENDING SUBSTITUTES

<table>
<thead>
<tr>
<th>Application</th>
<th>Substitute</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>CFC-11 Tobacco expansion</td>
<td>HCFC-123</td>
<td>Agency has not completed review of data. Potential drop-in replacement.</td>
</tr>
<tr>
<td></td>
<td>HFC-227ea</td>
<td>Agency has not completed review of data.</td>
</tr>
</tbody>
</table>

### ADHESIVES, COATINGS, AND INKS—ACCEPTABLE SUBSTITUTES

<table>
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<tr>
<th>Application</th>
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<th>Initial decision</th>
<th>Proposed conditions</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methyl Chloroform, Adhesives, Coatings, and Inks.</td>
<td>Petroleum distillates</td>
<td>Acceptable</td>
<td></td>
<td>OSHA standards exist for many of these chemicals. Formulators should use chemicals with lowest toxicity, where possible.</td>
</tr>
<tr>
<td></td>
<td>Organic solvents (Alcohols, Ketones, Ethers, and Esters).</td>
<td>Acceptable</td>
<td></td>
<td>OSHA standards exist for many of these chemicals. Formulators should use chemicals with lowest toxicity, where possible.</td>
</tr>
<tr>
<td></td>
<td>Chlorinated solvents (methylene chloride, trichloro-ethylene, perchloro-ethylene).</td>
<td>Acceptable</td>
<td></td>
<td>High inherent toxicity. Use only when necessary.</td>
</tr>
<tr>
<td></td>
<td>Terpenes</td>
<td>Acceptable.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Water-based formulations</td>
<td>Acceptable.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>High-solid formulations</td>
<td>Acceptable.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Alternative technologies (e.g., powder, hot melt, thermoplastic plasma spray, radiation-cured, moisture-cured, chemical-cured, and reactive liquid).</td>
<td>Acceptable.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### ADHESIVES, COATING, AND INKS—PENDING DECISIONS

<table>
<thead>
<tr>
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<th>Substitute</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methyl Chloroform Adhesives, Coatings and Inks.</td>
<td>Monochloro/toluene/benzo-trifluorides</td>
<td>Agency has not completed review of data.</td>
</tr>
</tbody>
</table>
For the reasons set out in the preamble, EPA is hereby proposing to amend 40 CFR Part 82 as follows:

**PART 82—PROTECTION OF STRATOSPHERIC OZONE**

1. Authority: The authority citation for part 82 continues to read as follows: 42 U.S.C. 7414, 7601, 7671—7671q.

2. Part 82 is proposed to be amended by adding Subpart G to read as follows:

**Subpart G—Significant New Alternatives Policy Program**

Sec.
82.170 Purpose and scope.
82.172 Definitions.
82.174 Prohibitions.
82.176 Applicability.
82.178 Information required to be submitted.
82.180 Agency review of SNAP submissions.
82.182 Confidentiality of data.
82.184 Petitions.

§82.170 Purpose and scope.

(a) The purpose of the regulations in this subpart is to implement section 612 of the Clean Air Act, as amended, regarding the safe alternatives policy on acceptability of substitutes for ozone-depleting compounds. This program will henceforth be referred to as the "Significant New Alternatives Policy" (SNAP) program. The objective of this program is to identify substitutes for ozone-depleting compounds, to evaluate the acceptability of those substitutes, and to promote the use of those substitutes believed to present lower overall risks to human health and the environment.

(b) The regulations in this subpart describe persons and substitutes subject to reporting requirements under the SNAP program and explain preparation and submission of notices and petitions on substitutes. The regulations also establish Agency procedures for reviewing, processing, and for making public EPA’s notices and petitions on substitutes. Finally, the regulations prohibit the use of alternatives which EPA has determined may have adverse effects on human health or the environment where EPA has identified alternatives that on an overall basis; reduce risk to human health and the environment and are currently or potentially available.

§82.172 Definitions.

(a) Act means the Clean Air Act, as amended, 42 U.S.C. 7401 et seq.

EPA means the U.S. Environmental Protection Agency.

Class I or II means the specific ozone-depleting compounds described in section 602 of the Act.

**Commerce means trade, traffic, transportation, or other commerce that could potentially occur between a place in a state of the United States and any place outside of such state.**

Critical use means uses of a substitute where no other substitute exists that meets existing performance or technical standards.

Decision means any final determination made by the Agency under section 612 of the Act on the acceptability or unacceptability of a substitute for a Class I or II compound.

EPA means the U.S. Environmental Protection Agency.

Formulator means any person engaged in the preparation or formulation of a substitute, after chemical manufacture of the substitute or its components, for distribution or use in commerce.

Health and safety study or study means any study of any effect of a substitute or its components on health or the environment or on both, including underlying data and epidemiological studies, studies of occupational, ambient, and consumer exposure to a substitute, toxicological, clinical, and ecological, or other studies of a substitute and its components, and any other pertinent test. Chemical identity is always part of a health and safety study.

(1) Information which arises as a result of a formal, disciplined study is included in the definition. Also included is information relating to the effects of a substitute or its components on health or the environment. Any available data that bear on the effects of a substitute or its components on health or the environment would be included.

(2) Examples include:

(i) Long- and short-term tests of mutagenicity, carcinogenicity, or teratogenicity; data on behavioral disorders; dermotoxicity; pharmacological effects; mammalian absorption, distribution, metabolism, and excretion; cumulative, additive, and synergistic effects; acute, subchronic, and chronic effects; and structure/activity analyses;

(ii) Tests for ecological or other environmental effects on invertebrates, fish, or other animals, and plants, including: acute toxicity tests, chronic toxicity tests, critical life stage tests, behavioral tests, algal growth tests, seed germination tests, microbial function tests, bioconcentration or bioaccumulation tests, and model ecosystem (microcosm) studies;

(iii) Assessments of human and environmental exposure, including workplace exposure, and effects of a particular substitute on the...
environment, including surveys, tests, and studies of: biological, photochemical, and chemical degradation; air, water and soil transport; biomagnification and bioconcentration; and chemical and physical properties, e.g., boiling point, vapor pressure, evaporation rates from soil and water, octanol/water partition coefficient, and water solubility; (iv) Monitoring data, when they have been aggregated and analyzed to measure the exposure of humans or the environment to a substitute; (v) Any assessments of risk to health or the environment resulting from the manufacture, processing, distribution in commerce, use, or disposal of the substitute or its components. **Importer** means any person who imports a chemical substitute into the United States. "Importer" includes the person primarily liable for the payment of any duties on the merchandise or an authorized agent acting on his or her behalf. The term also includes, as appropriate: (1) The consignee; (2) The importer of record; (3) The actual owner if an actual owner's declaration and superseding bond has been filed; or (4) The transferee, if the right to draw merchandise in a bonded warehouse has been transferred. **Major industrial use sector** means a sector which EPA has reviewed under the SNAP program with consumption patterns of ozone-depleting substances comparable to those for refrigeration, foam-blowing, fire extinguishing, solvent cleaning, aerosols, sterilants, tobacco puffing, pesticides, or adhesives, coatings and inks. **Manufacturer** means any person engaged in the direct chemical manufacture of a substitute. **Mixture** means any mixture or blend of two or more individual chemical compounds. **Person** means any natural person, firm, company, corporation, joint-venture, partnership, sole proprietorship, association, or any other business entity, any state or political subdivision thereof, any municipality, any interstate body, and any department, agency or instrumentality of the Federal government. **Pesticide** has the meaning contained in the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. Section 136 et seq. and the regulations issued under it. **Premanufacture Notice Program** has the meaning described in 40 CFR part 720 subpart A under the Toxic Substances Control Act, 15 U.S.C. Section 2601 et seq. **Producer** means any person who manufactures or formulates a substitute for distribution or use in commerce. **Research and development** means quantities of a substitute manufactured, imported, or processed or proposed to be manufactured, imported, or processed solely for research and development. **Significant new use** means use of a substitute in a major industrial use sector as a result of the phase-out of ozone-depleting compounds. **Small uses** means uses of a substitute outside of a major industrial use sector (see definition of major industrial use sector in this section) or uses of a substitute of less than 10,000 lbs per year within a major industrial use sector or any other sector. **Substitute** means any chemical product substitute, or alternative manufacturing process, whether existing or new, that could replace a Class I or II compound. **Test marketing** means the distribution in commerce of a substitute to no more than a defined number of potential customers to explore market capability in a competitive situation during a limited testing period prior to the broader distribution of that substitute in commerce. **Use** means any application of a substitute, whether for use in a manufacturing process or product, consumption by the end-user, or in intermediate uses such as formulation or packaging for other subsequent uses. **§ 82.174 Prohibitions.** (a) No person may use a substitute before the expiration of 90 days after a notice is submitted to EPA under § 82.176(a). (b) No person may use a substitute which a person knew or has reason to know was manufactured, processed, or imported in violation of the regulations in this subpart or in violation of any condition in the acceptability determination. (c) No person may use a substitute without adhering to the conditions set by the acceptability decision. (d) No person may use a substitute after the effective date of any rulemaking adding such substitute to the list of unacceptable substitutes. **§ 82.176 Applicability.** (a) Any producer of a substitute must submit a notice of intent to introduce a substitute into commerce 90 days prior to such introduction. Any producer or formulator of a substitute already in commerce must submit a notice as of 90 days after [THE EFFECTIVE DATE OF THE FINAL RULE], if such substitute has not already been reviewed and approved by the Agency. (b) Substitutes exempt from reporting requirements under the SNAP program are listed in paragraph (c) of this section. (c) The following substitutes are exempt from notification requirements: (1) **Substitutes already listed as acceptable.** Producers of substitutes need not resubmit notices of a substitute if the substitute has already been listed under existing Agency decisions as acceptable. (2) **Small use.** Substitutes covered by the Agency's definition of small uses in § 82.172 are exempt from notification requirements. However, the Agency may evaluate a substitute classified as a small use if it has reason to believe the substitute could present a risk of significant adverse effects on human health and the environment, and require submissions to support such evaluations. EPA will announce the obligation to make such submissions through the quarterly Federal Register notifications or to individual affected parties. (3) **Test marketing.** Production of substitutes for the sole purpose of test marketing is exempt from reporting requirements. Persons taking advantage of this exemption are, however, required to notify the Agency in writing. (4) **Research and development.** Production of substitutes for the sole purpose of research and development is exempt from reporting requirements. Persons taking advantage of this exemption are, however, required to notify the Agency in writing. (5) **Second-generation substitutes.** Substitutes that replace first-generation substitutes that are not ozone-depleting chemicals are exempt from reporting. However, if the second generation substitute is replacing a compound that contributes to stratospheric ozone depletion, information must be submitted to EPA for review under SNAP. (6) **Formulation changes.** In cases where substitution of Class I or II compounds causes formulators to change other components in a product, these auxiliary formulation changes are exempt from reporting. (7) **Substitutes for export only.** Substitutes entirely produced for export only are not subject to reporting. (8) **Substitutes used as feedstocks.** Substitutes used as feedstocks which are largely or entirely consumed, transformed or destroyed in the manufacturing or use process are exempt from reporting.
§82.176 Information required to be submitted.

(a) Persons whose substitutes are subject to reporting requirements pursuant to § 82.176 must provide the following information:

(1) Name and description of the substitute. The substitute should be identified by its (i) Commercial name; (ii) Chemical name; (iii) Trade name(s); (iv) identification numbers (e.g., Chemical Abstract Service (CAS) registry, National Institutes of Occupational Safety and Health Registry of Toxic Effects of Chemical Substances (NIOSH RTECS), EPA hazardous waste identification number, OHM—TADS, DOT/UN/NA/IMCO shipping, HSDB, NCI); (v) Chemical formula; and (vi) Chemical structure.

(2) Physical and chemical information. Key properties to EPA will use to characterize the substitute include: molecular weight; physical state; melting point; boiling point; density; taste and/or odor threshold; solubility; partition coefficients (Log Kow, Log Koc); vapor pressure; and Henry’s Law Constant.

(b) Substitute applications. Identification of the applications in which the substitutes are likely to be used.

(c) Process description. For each application identified, descriptive data on processing, including in-place pollution controls.

(d) Ozone depletion potential. The predicted ozone depletion potential (ODP) of substitute chemicals. The submitter must also provide supporting documentation.

(e) Global warming potential. Submitters must provide data on the total global warming potential of the substitute, including information on direct and indirect contributions to global warming caused by the production or use of the substitute (e.g., energy changes).

(f) Toxicity date. Health and safety studies on the effects of a substitute, its components, its impurities, and its degradation products on any organism (e.g., humans, mammals, fish, wildlife, and plants). For tests on mammals, the Agency requires a minimum submission of the following tests to characterize substitute risks: A range-finding study that considers the appropriate exposure pathway for the specific use (e.g., oral ingestion, inhalation, etc.), and a 90-day subchronic repeated dose study in an appropriate rodent species. For substitutes being evaluated as fire suppressants, a cardiotoxicity study is also required. Additional mammalian toxicity tests may be identified based on the substitute and application in question. To sufficiently characterize aquatic toxicity concerns, both acute and chronic toxicity data for a variety of species are required. For this purpose, the Agency requires a minimum data set as described in “Guidelines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and their Uses,” which is available through the National Technical Information Service (#PB—85–227049).

Other relevant information and data summaries, such as the Material Safety Data Sheets, should also be submitted. To assist in locating any studies referred to but not included in a submission, the submitter must provide citations for the date and type of submission to ensure that these studies can be located quickly.

(g) Environmental fate and transport. Where available, EPA requests information on the environmental fate and transport of substitutes. Such data shall include information on bioaccumulation, biodegradation, adsorption, volatility, transformation, and other data necessary to characterize movement and reaction of substitutes in the environment.

(h) Flammability. Data on the flammability of a substitute chemical or mixture. Specifically, data on flash point and flammability limits must be submitted, as well as information on the procedures used for determining the flammability limits. For substitutes that will be used in consumer applications, documentation of testing results conducted by independent laboratories should be submitted where appropriate. Detail on any suggested abatement techniques to minimize the risks associated with the use of flammable substances or blends should also be provided.

(i) Exposure data. Modeling or monitoring data on exposures associated with the manufacture, formulation, transport, and use of a substitute. Descriptive process information for each substitute application, as described in this section, will be used to develop exposure estimates where exposure data are not readily available. Depending on the application, exposure profiles will be needed for workers, consumers, and the general population.

(j) Environmental release data. Data on emissions from the substitute application and equipment, as well as pollutant releases or discharge to all environmental media (ambient air, surface and groundwater, hazardous/solid waste). Submitters should provide information on release locations. Any information on any pollution controls used or that could be used in association with the substitute (e.g., emissions reduction technologies, wastewater treatment, treatment of hazardous waste) and the costs of such technology is also requested.

(k) Replacement ratio for a chemical substitute. The Agency must receive information on the replacement ratio for a chemical substitute versus the Class I or II substances being replaced. The term “replacement ratio” means how much of a substitute must be used to replace a given quantity of Class I or II substance being replaced.

(l) Required changes in use technology. Detail on the changes in technology needed to use the alternative is required. Such information should include a description of whether the substitute can be used in existing equipment—with or without some retrofit—or only in new equipment. Data on the cost (capital and operating expenditures) and estimated life of the technology modifications should also be submitted.

(m) Cost of substitute. Data on the expected average cost of the alternative. In addition, information is needed on the expected equipment lifetime for an alternative technology. Other critical cost considerations should be identified, as appropriate.

(n) Availability of substitute. If the substitute is not currently available, the timing of availability of a substitute.

(o) Anticipated market share. Data on the anticipated near-term and long-term nationwide substitute sales.

(p) Applicable regulations under other environmental statutes. Information on whether the substitute(s) is (are) regulated under other statutory authorities, in particular the Clean Water Act, Safe Drinking Water Act, the Resource Conservation and Recovery Act, the Federal Insecticide, Fungicide, and Rodenticide Act, the Toxic Substances Control Act, the Comprehensive Environmental Response, Compensation and Liability Act, the Emergency Planning and Community Right-to-Know Act, or other titles under the Clean Air Act (CAA).

(q) Information already submitted to the Agency. Information requested in the SNAP program notice that has been previously submitted to the Agency as part of past regulatory and information-gathering activities may be referenced. Submitters that cannot provide references to data sent previously to the Agency should include all requested information in the SNAP notice.

(r) Information already available in the literature. If any of the data needed to complete the SNAP program notice are available in the literature, complete...
references for such information should be provided.

(b) The Significant New Alternatives Policy (SNAP) form is designed to provide the Agency with the information necessary to reach a decision on the acceptability of a substitute.

(1) Submitters requesting review under the SNAP program only should send the SNAP form to the address for the SNAP coordinator provided on the form.

(2) Submitters filing jointly under SNAP and PMN should send the SNAP addendum along with the PMN form to the PMN coordinator identified on the SNAP form. Submitters must also send both documents to the SNAP coordinator, with a reference to indicate the notice has been furnished to the Agency under the PMN program.

Submitters providing information on new chemicals for joint review under the Premanufacture Notice program and SNAP must adhere to the TSCA minimum testing requirements described in TSCA section 4.

(3) Submitters filing jointly under SNAP and under the Federal Insecticide, Fungicide, and Rodenticide Act should send the SNAP form to the Office of Pesticide Programs, Registration Division, as well as to the SNAP coordinator.

§82.180 Agency review of SNAP submissions.

(a) Processing of SNAP Notices.

(1) 90-day review process. The 90-day review process will begin once EPA receives a submission and determines that such submission includes data on the substitute that are complete and adequate, as described in §82.178. The Agency may suspend or extend the review period to allow for submission of additional data needed to complete the review of the notice.

(2) Letter of receipt. The SNAP coordinator will send a letter of receipt to the submitter once the Agency receives the SNAP notice. The SNAP coordinator will also assign the SNAP notice a tracking number, which will be identified in the letter of receipt.

(3) Initial review of notice. The SNAP coordinator will review the notice to ensure that basic information necessary to process the submission is present (i.e., name of company, identification of substitute, etc.). The SNAP coordinator will also review substantiation of any claim of confidentiality.

(4) Determination of data adequacy. Upon receipt of the SNAP submission, the Agency will review the completeness of the information supporting the application. If additional data are needed, the submitter will be contacted following completion of this review. The 90-day review period will not commence until EPA has received data it judges adequate to support analysis of the submission.

(5) Availability of new information during review period. If critical new information becomes available during the review period that may influence the Agency's evaluation of a substitute, the submitter must notify the Agency about the existence of such information within 10 days of learning of such data. The submitter must also inform the Agency of new studies underway, even if the results will not be available within the 90-day review period. The Agency may contact the submitter to explore extending or suspending the review period depending on the type of information received and the stage of review.

(6) Completion of detailed review. Once the preliminary data review steps have been completed, the Agency will complete a detailed evaluation of the notice. If during any time the Agency perceives a lack of information necessary to reach a SNAP determination, it will contact the submitter and request the missing data.

(7) Criteria for review. To determine whether a substitute is acceptable or unacceptable as a replacement for Class I or II compounds, the Agency will evaluate:

(i) Atmospheric effects and related health impacts;
(ii) General population risks from ambient exposure to compounds with direct toxicity and to increased ground-level ozone;
(iii) Ecosystem risks;
(iv) Occupational risks;
(v) Consumer risks; and
(vi) Cost and availability of the substitute.

(8) Communication of decision. (i) Communication of decision to the submitter. Once the SNAP program notice review has been completed, the Agency will notify the submitter in writing of the decision. Sale or manufacture may continue if the Agency lacks the power to reach a decision within 90 days or fails to communicate that decision or the need for additional data to the submitter.

(ii) Communication of decision to the public. The Agency will publish in the Federal Register every three months a complete list of the acceptable and unacceptable alternatives that have been reviewed to date. In the case of substitutes proposed for placement on the unacceptable list or for removal from either list, a formal rule-making process will ensue.

(b) Types of listing decisions. When reviewing and listing substitutes, the Agency will place substitutes in one of 5 categories:

(1) General acceptance. Where the Agency has reviewed a substitute and found no reason to prohibit its use, it will list the alternative as acceptable for the applications listed in the notice.

(2) Approval subject to use limitations. After reviewing a notice, the Agency may make a determination that a substitute is acceptable if certain conditions are met to minimize risks to human health and the environment.

(3) General prohibition. This designation will apply to substitutes where the Agency's review indicates that the substitute poses risk of adverse effects to human health and the environment and that alternatives exist that reduce overall risk.

(4) Prohibition with limited exemptions for critical use. Even though the Agency can restrict the use of a substitute based on the potential for adverse effects, it may be necessary to grant a limited number of exemptions because of the lack of alternatives for specialized uses within the application. The Agency will refer to such exemptions as "critical use exemptions." Critical use exemptions will be granted only for the time period necessary to develop and implement alternatives not yet available. These exemptions are discussed further in §82.194.

(5) Substitutes pending completion of review. Submissions for which the Agency has not reached a determination will be described as pending. For all substitutes in this category, the Agency will work with the submitter to obtain any missing information and to determine a schedule for providing the missing information if the Agency wishes to extend the 90-day review period. EPA will use the authority under section 114 of the Clean Air Act to gather this information, if necessary. In some instances, the Agency may also explore using additional statutory provisions (e.g., section 4 of TSCA) to collect the needed data.

(c) Outreach. The Agency will publish the SNAP determinations and any revisions four times a year in the Federal Register. In addition to the quarterly publications, the Agency will communicate decisions through a clearinghouse and its outreach program. The outreach program includes a hotline and presentations at conferences and in trade journals. The Agency will maintain a list of vendors that sell substitutes that EPA has determined present lower environmental risks than the Class I and II compounds.
(d) Joint processing under SNAP and FIFRA. The Agency will coordinate reviews of substitutes submitted for evaluation under both FIFRA and the CAA.

(a) Joint processing under SNAP and TSCA. The Agency will coordinate reviews of substitutes submitted for evaluation under both the TSCA PMN program and the CAA.

§ 82.184 Petitions.
(a) Who may petition. Any person may petition the Agency to amend existing listing decisions under the SNAP program, or to add a new substance to the SNAP lists.
(b) Types of petitions. Four types of petitions exist:
(1) Petitions to add a substitute not previously reviewed under the SNAP program to the approved list.
(2) Petitions to add a substitute not previously reviewed under the SNAP program to the prohibited list.
(3) Petitions to delete a substitute from the approved list and add it to the prohibited list.
(4) Petitions to delete a substitute from the prohibited list and add it to the approved list.

§ 82.182 Confidentiality of data.
(a) Clean Air Act provisions. Anyone submitting information must assert a claim of confidentiality at the time of submission for any data they wish to have treated as confidential. Business information (CBI) under 40 CFR part 2, subpart B. Failure to assert a claim of confidentiality at the time of submission may result in disclosure of the information by the Agency without further notice. The submitter should also be aware that under section 114(c) of the Clean Air Act, emissions data may not be claimed as confidential.
(b) Substantiation of confidentiality claims. At the time of submission, EPA requires a substantiation of any confidentiality claims made. Moreover, any confidentiality claims may later be reviewed even when confidentiality claims are received. The submitter will also be contacted as part of this evaluation process.
(c) Confidential provisions for toxicity data. In the event that toxicity or health and safety studies are listed as confidential, this information cannot be maintained as confidential where such data is also submitted under TSCA or FIFRA because of specific disclosure provisions in those statutes. However, information contained in the toxicity study that is not relevant to the effects of a substance on human health and the environment (e.g., discussion of process information, proprietary blends) can be maintained as confidential subject to 40 CFR part 2, subpart B.
(d) Joint submissions under other statutes. Information submitted as part of a joint submission to either SNAP/TSCA or SNAP/FIFRA must adhere to CBI practices under those statutes. For such submissions, the SNAP handling of such notices will follow CBI requirements under those statutes.
Part III

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 352 et al.
Sunscreen Drug Products for Over-the-Counter Human Use; Tentative Final Monograph; Proposed Rule
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 352, 700, and 740

[Docket No. 78N-0038]

RIN 0905-AA06

Sunscreen Drug Products for Over-the-Counter Human Use; Tentative Final Monograph

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is issuing a notice of proposed rulemaking in the form of a tentative final monograph that would establish conditions under which over-the-counter (OTC) sunscreen drug products are generally recognized as safe and effective and not misbranded. FDA is issuing this notice of proposed rulemaking after considering the report and recommendations of the Advisory Review Panel on OTC Topical Analgesic, Antirheumatic, Otic, Burn, and Sunburn Prevention and Treatment Drug Products (Topical Analgesic Panel), which was the advisory review panel responsible for evaluating data on the active ingredients in this drug class. Interested persons were invited to submit comments by November 24, 1978. In a notice published in the Federal Register of December 1, 1978 (43 FR 56249), FDA extended the period for comments to December 15, 1978, to allow more time for the collection and assessment of data to provide for more meaningful comments on the advance notice of proposed rulemaking. Reply comments in response to comments filed in the initial comment period could be submitted by December 26, 1978.

In a notice published in the Federal Register of March 21, 1980 (52 FR 18403), the agency advised that it had reopened the administrative record for OTC sunscreen drug products to allow for consideration of data and information that had been filed in the Dockets Management Branch after the date the administrative record previously had officially closed. The agency concluded that any new data and information filed prior to March 21, 1980, should be available to the agency in developing a proposed regulation in the form of a tentative final monograph. In a notice of public meeting and reopening of the administrative record published in the Federal Register of September 4, 1987 (52 FR 33598), the agency announced that a public meeting would be held to discuss recommendations of the Topical Analgesic Panel regarding final product testing and related claims of OTC sunscreen drug products. The meeting was held on January 26, 1988, and minutes of the meeting are on public display in the Dockets Management Branch (Ref. 1). Interested persons were given until April 26, 1988, to submit comments in response to the meeting. In a notice published in the Federal Register of May 4, 1988 (53 FR 15853), FDA extended the period for submission of comments on the testing procedures and related claims for OTC sunscreen drug products to May 26, 1988, to allow full opportunity for informed comments on the testing procedures.

The agency has received four petitions and one comment requesting that it reopen the administrative record for sunscreen drug products to admit several OTC sunscreen ingredients that have been marketed in Europe but not in the United States. Although no decision has been reached regarding these petitions, they are discussed in this tentative final monograph. All data and information on other subjects that have been submitted to the agency while the rulemaking was closed will be considered after the tentative final monograph is published.

In accordance with §330.10(a)(10), the data and information considered by the Panel were put on public display in the Dockets Management Branch (address above), after deletion of a small amount of trade secret information. Data and information received after the administrative record was reopened have also been put on display in the Dockets Management Branch.

In response to the advance notice of proposed rulemaking, 27 manufacturers, 2 manufacturers' associations, 31 consumers, 6 universities, 1 health care professional, and 1 health care professional society submitted comments. Two manufacturers, one manufacturer's association, and one university submitted reply comments. In response to the notice of public meeting and the public meeting, 13 manufacturers, 2 manufacturers' associations, 1 foreign manufacturer's association, 1 foreign professional association, 2 universities, 1 foreign government, 2 testing laboratories, 1 health care research institute, and 5 health care professionals submitted comments. Copies of the comments received are on public display in the Dockets Management Branch.

The advance notice of proposed rulemaking, which was published in the Federal Register on August 25, 1978 (43 FR 38206), was designated as a “proposed monograph” in order to conform to terminology used in the OTC drug review regulations (21 CFR §330.10). Similarly, the present document is designated in the OTC drug review regulations as a “tentative final monograph.” Its legal status, however, is that of a proposed rule. In this tentative final monograph (proposed rule) to establish part 352 (21 CFR part 352), FDA states for the first time its position on the establishment of a monograph for OTC sunscreen drug products. Finally, agency action on this matter will occur with the publication at a future date of a final monograph, which will be a final rule establishing a monograph for OTC sunscreen drug products. This proposal constitutes FDA’s tentative adoption of the Panel’s conclusions and recommendations on OTC sunscreen drug products as modified on the basis of the comments.
The OTC drug procedural regulations (21 CFR 330.10) now provide that any testing necessary to resolve the safety or effectiveness issues that formerly resulted in a Category III classification, and submission to FDA of the results of that testing or any other data, must be done during the OTC drug rulemaking process before the establishment of a final monograph. Accordingly, FDA will no longer use the terms "Category I" (generally recognized as safe and effective and not misbranded), "Category II" (not generally recognized as safe and effective or misbranded), and "Category III" (available data are insufficient to classify as safe and effective, and further testing is required) at the final monograph stage, but will use instead the terms “monograph conditions” (old Category II) and “nonmonograph conditions” (old Categories II and III). This document retains the concepts of Categories I, II, and III at the tentative final monograph stage.

The agency advises that the conditions under which the drug products that are subject to this monograph would be generally recognized as safe and effective and not misbranded (monograph conditions) will be effective 12 months after the date of publication of the final monograph in the Federal Register. On or after that date, no OTC drug product that is subject to the monograph and that contains a nonmonograph condition, i.e., a condition that would cause the drug to be not generally recognized as safe and effective or to be misbranded, may be initially introduced or initially delivered for introduction into interstate commerce unless it is the subject of an approved application. Further, any OTC drug product subject to this monograph that is repackaged or relabeled after the effective date of the monograph must be in compliance with the monograph regardless of the date the product was initially introduced or initially delivered for introduction into interstate commerce. Manufacturers are encouraged to comply voluntarily with the monograph at the earliest possible date.

In the advance notice of proposed rulemaking for OTC sunscreen drug products (43 FR 38208), the agency suggested that the conditions included in the monograph (Category I) be effective 30 days after the date of publication of the final monograph in the Federal Register and that the conditions excluded from the monograph (Category II) be eliminated from OTC drug products effective 6 months after the date of publication of the final monograph, regardless of whether further testing was undertaken to justify their future use. Experience has shown that relabeling of products covered by the monograph is necessary in order for manufacturers to comply with the monograph. New labels containing the monograph labeling have to be written, ordered, received, and incorporated into the manufacturing process. The agency has determined that it is impractical to expect new labeling to be in effect 30 days after the date of publication of the final monograph. Experience has shown also that if the deadline for relabeling is too short, the agency is burdened with extension requests and related paperwork.

In addition, some products may have to be reformulated to comply with the monograph. Reformulation often involves the need to do stability testing on the new product. An accelerated aging process may be used to test a new formulation; however, if the stability testing is not successful, and if further reformulation is required, there could be a further delay in having a new product available for manufacture.

The agency wishes to establish a reasonable period of time for relabeling and reformulation in order to avoid an unnecessary disruption of the marketplace that could not only result in economic loss, but also interfere with consumers’ access to these drug products. Therefore, the agency is proposing that the final monograph be effective 12 months after the date of its publication in the Federal Register. The agency believes that within 12 months after the date of publication most manufacturers can order new labeling and reformulate their products and have them in compliance in the marketplace.

If the agency determines that any labeling for a condition included in the final monograph should be implemented sooner than the 12-month effective date, a shorter deadline may be established. Similarly, if a safety problem is identified for a particular nonmonograph condition, a shorter deadline may be set for removal of that condition from OTC drug products.

All "OTC Volumes" cited throughout this document refer to the submissions made by interested persons pursuant to the call-for-data notice published in the Federal Register of December 12, 1972 (37 FR 26156) or to additional information that has come to the agency’s attention since publication of the advance notice of proposed rulemaking. The volumes are on public display in the Dockets Management Branch (address above).

Reference
(1) Comment No. TR1, Docket No. 78N0038, Dockets Management Branch.

I. Introduction

In section 201(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(g)(1)), a “drug” is defined as (A) articles recognized in the official United States Pharmacopeia, official Homeopathic Pharmacopeia of the United States, or official National Formulary, or any supplement to any of them, (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals, (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals, and (D) articles intended for use as a component of any articles specified in (A), (B), or (C) above.

Sunscreen products are marketed with various intended uses, such as (1) beach products for occasional use to protect consumers from extreme sunlight conditions, (2) tanning products to aid consumers in acquiring a tan, and (3) non-beach products for daily use to protect consumers from chronic exposure to sunlight (e.g., make-up preparations and lipsticks). Although these intended uses are different, the agency considers each one a drug use.

Beach products are considered drugs because they prevent sunburn, protect the skin against harm from the sun, and prevent skin damage through overexposure to the sun. In addition, consumers equate these products with mitigating harmful effects of the sun. For these reasons, sunscreen beach products are drugs under section 201(g)(1)(B). Such products are also drugs under section 201(g)(1)(C) because they affect the body’s physiological response to solar radiation (i.e., they lessen the erythema reaction). Tanning products that contain sunscreens are drugs because they prevent a sunburn (section 201(g)(1)(B)) and affect melanogenesis (section 201(g)(1)(C)).

Non-beach sunscreen products are drugs because they prevent lip or skin damage (section 201(g)(1)(B)) as well as freckling and uneven skin coloration (section 201(g)(1)(C)). The drug/cosmetic distinction of products containing sunscreens is discussed further in comment 27.
Throughout this tentative final monograph, the agency makes extensive use of acronyms. For the reader's convenience, the agency is including in one easily accessible place a chart containing the most commonly used acronyms in this document.

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<tr>
<th>Acronym</th>
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<tr>
<td>AAD</td>
<td>American Academy of Dermatology</td>
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<td>CIE</td>
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**II. The Agency’s Tentative Conclusions on the Comments**

**A. General Comments on Sunscreen Drug Products**

1. One comment urged the agency to recognize explicitly the legal status of the monographs issued under the OTC drug review as being interpretive, as distinguished from substantive, regulations. The comment incorporated by reference previous comments dated March 4, 1972 on the proposed procedural regulations governing the OTC drug review and comments dated June 4, 1973 on the proposed antacid monograph.

The agency addressed this issue in paragraphs 85 through 91 of the preamble to the procedures for classification of OTC drug products, published in the Federal Register of May 11, 1972 (37 FR 9464 at 9471 to 9472) and in paragraph 3 of the preamble to the tentative final monograph for OTC antacid drug products, published in the Federal Register of November 12, 1973 (38 FR 31260).

2. One comment recommended that the term "ultraviolet light" be replaced throughout the Panel’s report by the term "ultraviolet radiation." The comment stated that light is the part of the electromagnetic spectrum that can be seen by the eye, and because UV radiation is by definition invisible, the use of the word "light" is inappropriate.

The agency agrees with the comment that the use of the term "ultraviolet light" is inappropriate. Because the term "light" refers to the waveband detectable by the human eye (i.e., visible light of approximately 400 to 760 nanometers (nm)), the term "ultraviolet radiation" is preferred when speaking of the wavelength region of approximately 100 to 400 nm (Refs. 1 and 2). Therefore, the agency is using the term "ultraviolet radiation" throughout this tentative final monograph. The agency is also using the following terminology for wavelength ranges in the UV radiation portion of the spectrum: UVA for the range from 320 to 400 nm, UVB for the range from 290 to 320 nm, and UVC for the range from 200 to 290 nm.

**References**


3. Referring to the Panel’s discussion of the types of solar radiation (43 FR 38206 at 38209), one comment stated that the reference cited for the statement that the solar spectrum at the earth’s surface consists of wavelengths between 295 and 1,800 nm is not authoritative. The comment stated that Bener (Ref. 1), Johnson (Ref. 2), and Schulze and Grafe (Ref. 3) should be credited for that statement.


The agency agrees with the comment and is including the above information in the administrative record for this rulemaking.

References


5. One comment asserted that the Panel’s statement, "The sun’s rays..."
associated with diseases are related to the light sensitivity range from 290 to 800 nm, " at 43 FR 38208 at 38209 is inconsistent with statements made at 43 FR 38210 to 38212 about the harmful effects of sunlight on the skin. The comment stated that the Panel's discussion from exposure to the sun's rays referred only to effects caused by rays in the range of 290 to 400 nm. Therefore, according to the comment, it was inappropriate to generalize and refer to the effects of solar radiation from 290 to 800 nm.

The Panel's reference to solar radiation in the range of 290 to 800 nm was background information to identify the range of wavelengths associated with diseases related to light sensitivity, i.e., photosensitivity reactions (Ref. 1). The Panel's discussion of photosensitization appears at 43 FR 38219. The Panel's discussion at 43 FR 38210 to 38212 describes in detail the more serious and common harmful effects, i.e., skin cancer and premature skin aging, that may be induced by the UV radiation from the sun. It was not intended to be a discussion of all light sensitivity diseases. Therefore, the agency finds no inconsistency in the statements referred to by the comment.

Reference


6. Referring to the Panel's statement that "UV-C is not effective in stimulating pigmentation (tanning)" (43 FR 38206 at 38209 and 38210), one comment contended that this statement is incorrect and should have read "UV-C is much less effective in producing pigmentation than UV-B."

The agency has reviewed the scientific literature regarding the types of solar radiation involved in tanning and agrees with the Panel's statement. As the Panel pointed out, UVC radiation from sunlight does not reach the earth's surface (43 FR 38208). Tanning involves two distinct photobiological processes: immediate tanning and delayed tanning (Refs. 1 and 2). Immediate tanning can be induced by UVA radiation (320 to 400 nm) and visible light (400 to 700 nm). It is an immediate darkening reaction that occurs 1 to 2 hours after exposure to sunlight. It does not involve melanogenesis but is due to the darkening of preformed pigment in the skin. Delayed tanning is a process that occurs 48 to 72 hours after exposure to UVB radiation (290 to 320 nm) and involves the synthesis of new melanin pigment. The agency is unaware of any data showing that solar UVC radiation (200 to 290 nm) stimulates pigmentation through either of the two tanning processes.

References


7. One comment argued that the Panel's statement that the maximum UVB effect is reached at 296.7 nm (43 FR 38208 at 38209) is incorrect and that the maximum effectiveness of the UVB erythema action spectrum is between 292 and 295 nm.

For many years, 296.7 or 297 nm was accepted as the most erythrogenic UVB wavelength in the standard erythema curve. At the time the Panel conducted its review, various sources reported different wavelengths of UVB radiation as producing the maximum erythrogenic skin response: 296 nm (Ref. 1), 296.7 nm (Ref. 2), and 297 nm (Ref. 3). However, other sources have reported slightly lower wavelengths as producing this response. For example, the results of a study on the maximum erythrogenic response of the skin of the abdomen using a high pressure xenon arc grating monochromator showed 292 nm as the most erythrogenic UVB wavelength (Ref. 4). Another investigation of the effect of UVB radiation on the skin on the back of the trunk utilizing a high intensity prism grating monochromator resulted in values of 292.5 nm for the maximum erythrogenic response (Refs. 5 and 6). Such discrepancies may be the result of improvements in the skin of the abdomen using a high pressure xenon arc grating monochromator showed 292 nm as the most erythrogenic UVB wavelength (Ref. 4). Another investigation of the effect of UVB radiation on the skin on the back of the trunk utilizing a high intensity prism grating monochromator resulted in values of 292.5 and 294 nm for the maximum erythrogenic response (Refs. 5 and 6). Such discrepancies may be the result of improvements in the skin of the abdomen using a high pressure xenon arc grating monochromator showed 292 nm as the most erythrogenic UVB wavelength (Ref. 4).

8. One comment disagreed with the Panel's statement, "At 307.4 nm the maximal amount of energy to cause sunburn is delivered by the sun to the skin" (43 FR 38208 at 38209). The comment contended that "the maximal amount of sunburn causing energy" is not delivered at 307.4 nm, but rather that the "maximal effectiveness" of noon sunlight at UVB wavelength 306 nm rather than 295 nm.

The agency has reviewed the study by Schulze et al. (Ref. 1), which the Panel cited as the basis for its statement that the maximal amount of energy to cause sunburn is delivered at 307.4 nm. The agency agrees with the comment that the statement is incorrect. Schulze combined data from a 1935 study by the CIE, which determined the relative erythema efficiency of various wavelengths of UVB radiation, with data from a study by Bener conducted in Davos, Switzerland, which determined the irradiation intensity of sunlight (see Table 1 and Fig. 2 in Ref. 1). Schulze combined the data from the two studies to obtain an efficiency curve for global radiation, i.e., the relative erythema efficiency of various wavelengths of UV radiation multiplied by the intensity of the irradiation of those wavelengths. This produced an action spectrum curve for natural sunlight with a peak at 307.4 nm. Because 307.4 nm is the peak of the curve resulting from the combination of
the erythema action spectrum (CIE values) and the solar spectrum, the value actually represents an erythema effectiveness maximum. (See comment 84 for a discussion of the erythema effectiveness spectrum.) Therefore, the Panel's statement should have read, "The maximal effectiveness of ultraviolet radiation from noon sunlight occurs at about 307 nm."

Reference


9. Three comments disagreed with the Panel's statement that the erythema reaction is maximal in intensity at 6 to 20 hours after exposure to UVB radiation (43 FR 38206 at 38209). Two of the comments stated that the postexposure time for the maximum intensity of the erythema reaction to UBV radiation is 12 to 24 hours, and the third comment reported it as 18 to 24 hours. One comment added that if postexposure redness is maximum in 6 to 8 hours, the radiation source contained significant UVC radiation (wavelengths less than 280 nm), and provided a reference for this statement (Ref. 1). One of the comments also disagreed with the Panel's statement that the erythema reaction to UVA radiation is maximal in intensity about 72 hours after exposure (43 FR 38209). The comment maintained that the erythema reaction to UVA radiation is maximal in intensity at 12 to 24 hours following exposure and is only maximum at 72 hours when photosensitizing agents such as methoxypсорalen (8-MOP) are applied topically or given orally.

The information on solar energy provided by the Panel at 43 FR 38209 was intended as background information and is not included in the tentative final monograph. Because UVC radiation from the sun is strongly absorbed by the earth's ozone layer and, thus, largely prevented from reaching the earth's surface (Ref. 2), the agency believes that it is not necessary to consider UVC radiation in the tentative final monograph on OTC sunscreen drug products.

The Panel recommended postexposure time limits of 16 to 24 hours for the evaluation of an erythema reaction to the radiation under the testing procedures described in §§ 352.42(b), 352.43, and 352.46. Although the comments differed on the lower time limit for the occurrence of the maximum intensity of an erythema reaction following UBV radiation-exposure, there appears to be general agreement on 24 hours as the upper time limit. Investigators assessing the effects of UVA and UBV radiations generally use 24 hours postexposure as the time period to determine the skin's erythema reaction to these radiations. The agency believes that the disagreement concerning the lower postexposure time limit is due to the maximum intensity of the erythemogenic response is a result of differences in methodology between laboratories, i.e., differences in light source, skin types, area and location of skin exposed, and variations in the judgment of the maximum response. Moreover, the agency believes that immediate pigmentation may interfere with an investigator's perception of the MED if the evaluation is done at 16 hours' postexposure. The agency believes that sunscreen testing results will more accurately if the MED is determined at 22 to 24 hours post irradiation rather than 16 to 24 hours post irradiation. Therefore, the agency is proposing those time frames in §§ 352.72(h) and 352.73 of this tentative final monograph. (See comment 95.)

References


11. Two comments disagreed with the Panel's statement "In the long run, suntanning is not good for the skin," (43 FR 38209). One comment felt that the term "suntanning" is not accurate in this context and that the term "prolonged sunbathing" would be preferred. The other comment stated that the term "suntanning" is erroneous and anachronistic and that the resulting sun is protective against subsequent actinic damage. This comment stated that the term "prolonged sunbathing" or "excessive sun exposure" should have been used.

The Panel felt that overexposure to sunlight damages the skin and can lead to various skin lesions, and that the cumulative exposure to sunlight from childhood into adulthood can lead to skin cancer (43 FR 38209). When the Panel stated that "suntanning is not good for the skin," it was expressing a general opinion on the cumulative effects of exposure to sunlight. The use of the term "suntanning," as opposed to "excessive sun exposure" or "prolonged sunbathing," was the Panel's choice of words. The use of any of these terms
would be acceptable; however, changing the Panel's statement would not affect the substance of the Panel's report or the tentative final monograph. Therefore, the agency sees no basis for revising the Panel's statement.

12. One comment stated that the investigators (Refs. 1 and 2) who were cited in the text for discussion of the types of solar radiation (43 FR 38206 at 38210) did not evaluate the energy requirements for the induction of an erythema reaction by UVA, UVB, or UVC radiation. The comment stated that the Panel should have referred to investigators who reported the energy required to produce the MED reaction (i.e., UVA radiation requires about 20 to 50 J/cm², UVB radiation requires approximately 20 to 50 mJ/cm², and UVC radiation requires about 5 to 20 mJ/cm²) (43 FR 38209 to 38210). The comment argued that a literature citation of this important information is essential.

The agency is not aware of the specific source used by the Panel for the data on energy requirements for the induction of an erythema reaction as a result of UVA, UVB, or UVC radiation. The agency notes, however, that the figures used at 43 FR 38209 are comparable to those appearing generally in the literature (Refs. 3 and 4).

References


13. Referring to the Panel's discussion of factors affecting the amount of sunlight exposure (43 FR 38206 at 38210), one comment stated that the UV energy of sunlight is greatest between 10 a.m. and 2 p.m. at all times of the year, rather than (just) in midsummer as stated by the Panel. The comment added that while the amount of radiation received varies with the seasons, relative intensity does not. The comment said that in the Panel's discussion of morning and late afternoon sun angle, the phrase "reducing the ultraviolet radiation component of sunlight by as much as 75 percent" is an appropriate statement, rather than the phrase "reducing the sunlight's intensity by 75 percent."

The agency agrees with the comment. On any day of the year, the intensity of the UV energy of sunlight is greatest between 10 a.m. and 2 p.m. (Ref. 1); the intensity of the UV sunburning component of sunlight is reduced 75 percent when the sun is at an angle of about 45 degrees (e.g., in the late afternoon) (Ref. 2). The amount or intensity of UVB radiation received at the earth's surface is reduced in proportion to the angle of incidence of the radiation. At lower angles of incidence UVB radiation is attenuated by a longer passage through the ozone layer, which absorbs UVB radiation.

References


14. One comment contended that the table "Guide for Fair-Skinned People" (43 FR 38206 at 38210) is confusing. The comment stated that it is not apparent why 4 times the MED should produce a painful sunburn in New Jersey, but 5 times the MED should do so in Florida, or why 8 times the MED should produce a blistering sunburn in New Jersey and 12 times the MED should do so in Florida. The comment argued that these data are incompatible with each other and should be verified with the authors (Ref. 1).

The agency has determined that the cited reference (Ref. 1) in the Panel's report is not the source of the information that appears in the "Guide for Fair-Skinned People" (43 FR 38210). Further, the agency is not aware of the source of this information. Because the information in the "Guide" has no bearing on the content of the tentative final monograph, it will not be discussed further.

Reference


15. Referring to the Panel's discussion of the harmful effects of sunlight on the skin (43 FR 38206 at 38210), one comment stated that "light is only one of the parameters inducing skin cancer." The comment added that "other environmental parameters are responsible for a less resistant cell, e.g., nutrition, lack of exercise, alcohol, drugs, smoking."

The agency recognizes that UV radiation is not the only parameter believed to be responsible for inducing skin cancer. However, parameters such as those named by the comment are unrelated to the use of OTC sunscreen drug products and are beyond the scope of this rulemaking.

16. One comment stated that the word "would" appearing at 43 FR 38206 at 38210, third column, line 6 should be replaced by "could," and that at 43 FR 38211, second column, line 23, the words "lower wavelength limit of cancer-producing radiation" should be replaced by "upper wavelength limit."

The agency notes, however, that the comment is part of a comment (Ref. 1). The agency has reviewed this reference and finds that it is correctly quoted. Therefore, the agency recognizes that the sentence in the Panel's report could have been clearer if it had stated "* * * because the wavelengths that cause cancer of the skin of experimental animals are those 320 nm and shorter, i.e., the same spectral range that produces sunburn in human skin * * * ." This wording would be more consistent with the statement made by Blum.

References


17. Referring to the Panel's definition of "sunscreen sunburn preventive agent" (43 FR 38206 at 38213), one comment recommended that the Panel make a statement that "the sunscreen may remove the sunburning rays, but it may or may not transmit long-wavelength ultraviolet radiation of 320-400 nm." The comment mentioned that FABA may absorb radiation from 290 to 320 nm but will transmit radiation greater than 320 nm, whereas a benzophenone derivative may absorb UV radiation from 290 to 380 nm.

In discussing the types of solar radiation, the Panel noted that
"sunburn" radiation has a wavelength in the 300 to 320 nm region and not the 320 to 400 nm region (43 FR 38206). Therefore, the Panel defined a sunscreen sunburn preventive agent as an active ingredient that absorbs 95 percent or more of the light in the UV range at wavelengths from 290 to 320 nm and thereby removes the sunburning rays (43 FR 38213). The Panel did not include this definition for a "sunscreen sunburn preventive agent" in its recommended monograph, but included a definition for a "sunscreen active ingredient" (in § 352.3(b)) as follows: "An active ingredient that absorbs at least 85 percent of the light in the UV range at wavelengths from 290 to 320 nanometers, but transmits UV light at wavelengths longer than 320 nanometers. Such agents permit tanning in the average individual and also permit some reddening (erythema) without pain." This definition contains part of the statement requested by the comment concerning the transmittance of the longer wavelengths of UV radiation, i.e., "transmits UV light at wavelengths longer than 320 nm." However, the definition would not apply to ingredients which absorb UV radiation longer than 320 nm, e.g., dioxybenzone, a benzophenone derivative. Therefore, the agency is replacing the word "transmits" with the phrase "may or may not transmit" in the definition and is including the revised definition in § 352.3(c) of this tentative final monograph. The definition will be applicable to sunscreen active ingredients that absorb and transmit UV radiation in the 320 to 400 nm range. The agency is also proposing to replace the term "UV light" with "UV radiation." (See comment 2.) Regarding the last sentence in the Panel's recommended definition, the agency does not believe that this sentence is necessary to define a sunscreen active ingredient. Therefore, the last sentence in the Panel's recommended definition is not being retained. The proposed definition in § 352.3(c) for a sunscreen active ingredient now reads as follows: "An active ingredient that absorbs at least 85 percent of the radiation in the UV range at wavelengths from 290 to 320 nanometers, but may or may not transmit radiation at wavelengths longer than 320 nanometers."

18. Referring to the Panel's definitions of a sunscreen sunburn preventive agent and a sunscreen suntanning agent (43 FR 38206 at 38213), one comment suggested that these definitions should mention the measuring conditions because of the correlation between layer thickness and transmission."

The Panel realized that its definitions are based on the UV-absorbing properties of a single active ingredient of a sunscreen product, not on how the ingredient might perform in a final formulation or in combination with other active ingredients (48 FR 38213). Therefore, the Panel included final formulation testing, with specific measuring conditions, in its recommended monograph. The Panel, however, did not include definitions of a sunscreen sunburn preventive agent or a sunscreen suntanning agent in its recommended monograph. The agency also does not propose to include definitions in the tentative final monograph. Thus, it is not necessary to revise the Panel's definitions.

19. One comment noted that the Panel stated that sunscreen active ingredients may be combined with other active ingredients such as skin protectants (43 FR 38206 at 38217). The comment added that the Panel did not define the term "skin protectant" and asked the meaning of the term.

The term "skin protectant" was defined in proposed § 347.3(a) of the tentative final monograph for OTC skin protectant drug products, published in the Federal Register of February 15, 1983 (48 FR 6832), as follows: "A drug which on exposure skin or mucous membrane surface from harmful or annoying stimuli." A final definition will appear in the final monograph for OTC skin protectant drug products in a future issue of the Federal Register.

20. Referring to the Panel's general discussion on sunscreens (43 FR 38206 at 38218), one comment questioned the source of the Panel's description of an ideal vehicle. The comment stated that every person has his or her own ideas about an ideal vehicle, depending on skin constitution and the environment, and added that certain content of emollients is important, especially in a dry climate and in water.

The Panel described the characteristics of an ideal sunscreen vehicle at 43 FR 38218 as follows: "An ideal sunscreen vehicle would be stable, neutral, nongreasy, nondegreasing, nonirritant, nondehydrazing, nonoydrying, odorless, efficient on all kinds of human skin, hold at least 50 percent water, be easily compounded of known chemicals, and have infinite stability during storage." The Panel pointed out that there is no ideal vehicle and that the vehicles in common use represent a compromise of advantages against disadvantages. Vehicles for topical delivery of active ingredients are complex mixtures of substances involved in physical and chemical interactions with the outer layer of human skin. The effects of abrasion, sweating, and washing on the physical and chemical properties of the active ingredients often depend upon the vehicle.

The agency believes that the Panel based its description of an ideal sunscreen vehicle on the experience of its members with various dermatological preparations and on information found in standard references, textbooks, and the scientific literature concerning the anatomy and physiology of the skin (43 FR 38217). The Panel did not make any recommendations concerning sunscreen vehicles for inclusion in the monograph. However, it did state in its definition of SPF value in § 352.3(d) that this determination is to be made on the "final formulation of the sunscreen product," which includes the vehicle. Also, the water resistant tests proposed by the Panel in § 352.46 are to be conducted with the final-formulated sunscreen product. (The agency is not proposing the Panel's recommended sweat resistance test. See comment 100.)

The agency acknowledges that there are different ideas about what constitutes an ideal vehicle for a sunscreen drug product. The Panel's general discussion on vehicles provides useful guidance to manufacturers of these products.

21. Referring to the Panel's general discussion on sunscreens (43 FR 38206 at 38219), one comment stated that the Panel's definition of the term phototoxicity is inaccurate and incomplete. The comment recommended careful wording and revision of the definition. The comment argued that (1) phototoxicity is a dose-related response ("usually an exaggerated sunburn reaction of all individuals to adequate simultaneous exposure to a photoreactive chemical and radiation of appropriate wavelengths"), (2) the exposure of skin to radiation alone may not produce any reaction in skin or may produce a minimal reaction which is not pathologic, (3) the topical application of the product or the chemical ingredient of the product may not produce any reaction, (4) in phototoxic reactions, simultaneous exposure of the skin to the chemical and the radiation of appropriate wavelength will result in an abnormal pathologic reaction manifested by erythema, edema, and even a blistering response, (5) the fluorescence property of a molecule has nothing to do with phototoxicity because there are hundreds of molecules that are fluorescent and yet are not photosensitizing, and (6) skin
photosensitization can occur when the absorbed energy by the chemical leads to the formation of either free radicals, singlet oxygen, covalent conjugation with DNA, ribonucleic acid, and protein, or damage of the cell membrane and lysosomes.

The Panel's report was not intended to be an in-depth discussion of phototoxicity. Rather, the Panel defined phototoxicity as it relates to the general discussion of sunscreens and the effects of exposure to sunlight. The agency is not including a definition of phototoxicity in this tentative final monograph. However, the agency discusses its position on sunscreen protection from phototoxi

22. One comment recommended that FDA "advertise" the most effective sunscreen products and the recommended percentage of the ingredients in sunscreen preparations.

The agency is proposing in this tentative final monograph explicit and detailed labeling that what manufacturers may use for all Category I sunscreen drug products. This includes SPF values, which are required in sunscreen labeling as a guide as to how a product will act on a consumer's skin, and five optional labeling claims (under "Product Category Designation") that are related to the SPF values of sunscreen ingredients (e.g., minimal (SPF 2 to under 4), moderate (SPF 4 to under 8), high (SPF 8 to under 12), very high (SPF 12 to under 20), and ultra high (SPF 20 to 30)). (See comment 45 for a discussion of new terminology for PCD's.) In addition, the monograph will provide the effective dosage limits (on a percentage basis) for each Category I sunscreen ingredient. (See comment 37.)

23. One comment suggested that the agency formulate specific guidelines for providing safe, effective sunscreen lotions, creams, and gels for use on children. The comment stated that the AAD and the Skin Cancer Foundation are committed to educating parents on the importance of protecting their children against the potential harmful effects of solar radiation. The comment contended that, although the skin of children is more sensitive to the effects of sunlight than is the skin of adults, specific sunscreens for children have not been marketed. Also, specific guidelines for evaluating the safety and effectiveness of sunscreens for children are not available. However, the comment also stated that children are more sensitive to contact irritation reactions and delayed hypersensitivity reactions to chemicals that may be present in a sunscreen product. The comment added that recently some manufacturers are claiming the effectiveness of their product for children's skin, but that tests performed to support such a claim were unsatisfactory.

A second comment disagreed with the comment above regarding the need for special guidelines on SPF values of sunscreens designed especially for children. This comment stated that, as with all sunscreen sunscreens, a proper safety and effectiveness testing should be conducted prior to marketing. This comment cited the transcript of the January 26, 1988 FDA meeting on OTC sunscreen drug products at page 37 (Ref. 1) where one participant contended that "** there is a great need for high SPF sunscreens in children. They are the ones who get the most sunlight." In another comment, a participant stated that "** two-thirds of all the radiation you are going to get is before age 15 or 20 and it is there that the greatest protection has to be given."

The Topical Analgesic Panel discussed "adult skin" and "infant skin" in its report on OTC external analgesic drug products, published in the Federal Register of December 4, 1972 (44 FR 69768 at 69773), and in its report on OTC sunscreen drug products (43 FR 38206 at 38217). The Panel was concerned with possible differences in percutaneous absorption between infant skin and adult skin. The Panel thoroughly discussed the absorptive characteristics of infant and adult skin and defined adult human skin to be that of individuals older than 6 months of age. The Panel stated that the skin of infants under 6 months may have different absorptive characteristics. In order to provide an added margin of safety, the Panel stated that sunscreen ingredients which it reviewed are not to be used on children under the age of 6 months (44 FR 69773). The Panel considered this margin of safety important because biologic systems which metabolize and excrete drugs absorbed through the skin may not be fully developed in children under the age of 6 months (43 FR 38217). The Panel recommended, and the agency agrees, that only sunscreen drug products providing a minimum SPF value of 4 should be used on children between 6 months and 2 years of age. All sunscreen products, regardless of their SPF value, may be used on children 2 years of age and older. The agency is proposing to include these requirements in the directions for use. (See comments 61 and 66.)

In addition, the agency notes that the first comment did not submit data to support its contention that the skin of children is more sensitive than is the skin of adults to sunlight, contact dermatitis, or delayed sensitivity reactions; nor did the comment submit results to substantiate its claim that "tests performed ** were unsatisfactory."

The agency agrees that the use of sunscreens with high SPF values may be advantageous to adults and children. (See comment 46.) The agency believes, however, that the need for special guidelines for the use of sunscreen drug products designed especially for children, as suggested by the first comment, has not been established.

Reference

(1) Transcript of meeting between the public and FDA to discuss appropriate testing procedures for OTC sunscreen drug products, January 26, 1988, Rockville, MD, page 37, comment no. TR, Docket No. 38217.

B. Comments on Drug/Cosmetic Status of Sunscreen Drug Products

24. Four comments maintained cosmetic companies were not afforded the opportunity to participate in the sunscreen products rulemaking process because they were not given adequate notice. One comment stated that the fact that a cosmetic trade association and certain cosmetic manufacturers participated in these proceedings does not alter this reasoning because many cosmetic companies also sell drug products. Two comments emphasized that although a notice was published in the Federal Register of December 12, 1972 (37 FR 26456), this notice gave no indication that FDA might attempt to reclassify, as drugs, articles historically regulated as cosmetics or otherwise to establish any requirements for cosmetics. The comments stated that (1) The notice invited submissions with respect to "sunburn prevention and treatment drug products" and (2) that there was no indication that manufacturers of cosmetic products containing sunscreens might be subject to the same compositional or labeling requirements as sunburn prevention products. The comments added that there were factors that could have led the cosmetic industry, including manufacturers of suntan products, to conclude that there was no need to submit data and information to the Topical Analgesic Panel concerning...
products traditionally regarded solely as cosmetics. These factors included FDA’s statement in the Federal Register of May 11, 1972 (37 FR 9473) in the procedural regulations governing the OTC drug review that it would not review products for which only cosmetic claims were made, FDA’s Trade Correspondence (Ref. 1), and FDA’s cosmetic product regulations. The comments stated that if FDA intends to regulate cosmetic products under the OTC drug regulations, the current proposal should be withdrawn and the Panel reconvened to consider submissions from cosmetic manufacturers, pursuant to a new and sufficient notice and request for information.

The agency does not agree with the comments. Both the public and the cosmetic industry have had and will continue to have the opportunity to participate fully in the process for developing the sunscreen monograph. The agency regularly published notices in the Federal Register announcing the dates of the Topical Analgesic Panel’s meetings. A part of each meeting was open to the public, and minutes of the meetings were available to the public. One of the industry liaison members on the Panel was nominated by the CTFA, the principal cosmetic industry trade association. Thus, adequate notice was provided for all parties, including cosmetic manufacturers, to present their positions to the Panel during its deliberations. Interested persons had a similar opportunity to comment and submit information to the agency following publication of the Panel’s report. Furthermore, in the Federal Register of September 4, 1987 (57 FR 33598), the agency announced that a public meeting to discuss sunscreen testing procedures would be held on January 26, 1988, and that the administrative record for sunscreen drug products would be reopened until April 2, 1988. Several cosmetic companies and the CTFA participated in that meeting and submitted written comments to the agency. Finally, the present tentative final monograph is a proposed regulation. Once again, all interested parties have an opportunity to participate and to make their views known before a final regulation (monograph) is issued.

The agency emphasizes that this rulemaking for OTC sunscreen products applies only to drug products that contain sunscreen ingredients, display labeling that identifies those active ingredients as sunscreens, or display labeling claims that allude to the sun-blocking or sun-protection properties of those active ingredients. The distinction between sunscreen-containing products that are drugs and those that are cosmetics is discussed in comment 27.

Reference

(1) "FD & C Act Trade Correspondence," United States Department of Agriculture, Food and Drug Administration, TC-61, February 15, 1940.

25. Several comments stated that many cosmetics are currently "represented" as aids in acquiring an even tan or as useful in screening the sun, but are not "represented" for the treatment or prevention of sunburn. The comments maintained that the proposed monograph should be clarified to eliminate ambiguity and to exclude cosmetic products (e.g., moisturizers, make-up, and lipsticks) more explicitly by revising the monograph to state that cosmetics are excluded. The comments stated that the proposed rule can have no application to cosmetic products as they are defined in the Federal Food, Drug, and Cosmetic Act (the act), and that the mandate of the OTC drug review is to evaluate the safety and effectiveness of acknowledged drugs, not to provide a means for the reclassification of products. Consequently, some comments suggested that proposed § 352.1 "Scope" be amended by: (1) Changing the term "sunscreen product" to read "drug represented for use in prevention of sunburn" and (2) adding at the end of § 352.1 the sentence "This part does not apply to cosmetic products such as shampoos, hair conditioners, or nail polishes may contain a sunscreen and bear only cosmetic labeling. These products are cosmetics and, therefore, are not within the scope of this monograph.

The agency disagrees with the comments that stated that the word "sunscreen" should be defined as pertaining to all products sold for use on the skin in connection with sunbathing, swimming, or other outdoor activity. The agency recognizes that many OTC products sold for use on the skin in connection with sunbathing, swimming, or other outdoor activity contain no sunscreen active ingredients, provide no sunscreening protection, and do not have drug labeling. In addition, as discussed in comment 27, some products such as shampoos, hair conditioners, or nail polishes may contain a sunscreen and bear only cosmetic labeling. These products are cosmetics and, therefore, are not within the scope of this monograph.

The agency believes that the revised "Scope" language being proposed in § 352.1 of this tentative final monograph will adequately define the coverage of this class of drugs.

26. Four comments suggested revising the statement of identity in § 352.50(a) to read "sunburn prevention product" (instead of "sunscreen") in order to distinguish between sunscreen-containing products that make a specific "representation" regarding usefulness in the prevention of sunburn (i.e., sunscreen drug products) and sunscreen-containing products that refer
Sunscreen active ingredients absorb products as "sunburn prevention" to produce a sunburn. To classify these skin. Sunscreens only extend the specific segments of the UV spectrum, sunlight impinging on the skin. The agency tentatively concludes that the term "sunscreen" appropriately describes the principal intended action of these drug products, and that this term is well understood by consumers. The comment also maintained that, according to an "FDA FD & C Act Trade Correspondence of 1940 (TC-61)" (Ref. 1), a product containing a sunscreen ingredient and representing an even tan (but not for the prevention or treatment of sunburn) is a cosmetic and not a drug. Some comments added that FDA regulations in 21 CFR 720.4(c), which establish cosmetic product categories, include "suntan and sunscreen preparations."

Several comments stated that the mere use of the term "sunscreen" or of a truthful reference to blocking the rays of the skin does not cause a product to be a drug. These comments asserted that only a product explicitly offered for use in preventing sunburn or other diseases may be categorized as a drug. The comments maintained that many products such as lipsticks, make-up preparations, and suntanning lotions that contain sunscreens have traditionally been regulated as cosmetics. The comments added that consumers use such products to avoid freckling, redness, or uneven coloration resulting from exposure to the sun.

According to the comments, such uses are cosmetic. Many comments implied that if a reference to sunscreen ingredients and sunscreen properties in the labeling of a cosmetic would cause the product to be a drug, then cosmetic manufacturers would have to exclude sunscreen active ingredients from their products. The comments added that FDA should encourage the use of sunscreen ingredients in cosmetic skin products because of the favorable impact of the use of such products on the incidence of skin cancer and premature aging of the skin.

One comment stated that the inclusion of sunscreens can be rationalized as contributing to tanning rather than preventing sunburn. The comment added that sunscreens allow the consumer to stay in the sun longer, which is necessary for a deep, long-lasting tan; consumers can use these products to plan a tan and to increase the time in the sun. According to the comment, consumers can thereby obtain an even tan and one that does not readily fade.

The Panel was charged with evaluating the safety, effectiveness, and labeling of OTC active ingredients intended to prevent injury from exposure to the sun. It concluded that
overexposure to the sun results in various kinds of skin damage including sunburn, premature aging of the skin, and skin cancer (43 FR 38206 at 38211). The Panel stated that the use of sunscreens mitigate the harmful effects of UV radiation from the sun on the exposed skin of susceptible individuals. The Panel recognized that many suntanning products had been traditionally regarded by FDA as cosmetics. However, the Panel believed that "regardless of the claims, products intended to be used for the prevention of sunburn or any other such similar condition should be regarded as drugs" (43 FR 38209). As discussed below, the agency concurs with this view.

After evaluating the active ingredients in the products submitted for review, the Panel stated:

These preparations reduce by varying amounts the radiation absorbed by the skin and thereby affect the physiological response and extent of the erythema reaction (redness) produced. Indeed, these products affect the structure and function of the body by screening, reflecting, or scattering the harmful, burning rays of the sun. This is a desirable alteration to a normal physiological response to solar radiation for individuals with sensitive and extra sensitive skin (43 FR 38209).

The Panel classified products intended to be used for preventing sunburn and similar conditions as drugs regardless of claims that were made for the products.

In a 1940 advisory opinion referred to as Trade Correspondence (TC-61 (Ref. 1), the agency stated its policy regarding the drug/cosmetic status of sunburn and suntan preparations. TC-61 holds that a product promoted for prevention of damage from sun is a drug, and a product that is promoted solely for the purpose of acquiring an even tan can be considered a cosmetic. Overexposure to the sun was not generally perceived to be harmful in 1940, and most of the products currently on the market were not available then. Since 1940, however, there has been a significant body of information developed on the harmful effects of the sun on human health and a significant change has occurred in consumer perception of the purpose of suntanning products. Today, consumers expect protection from a product that is promoted for suntanning. A letter from FDA to industry counsel, dated June 17, 1976 (Ref. 2), stated that the agency had changed the position set out in TC-61. FDA’s present policy, as expressed in the 1976 letter, is that a product containing a sunscreen ingredient, even when labeled solely as a tanning aid, is both intended and understood to be a sunburn preventive. Such a product, therefore, is a drug under the act.

Sunscreen active ingredients affect the structure and function of the body by screening, reflecting, or scattering the harmful, burning rays of the sun, thereby altering the normal physiological response to solar radiation. Use of these ingredients helps to prevent diseases such as sunburn and may help to reduce the chance of skin lesions and skin cancer. When used in a suntan product, sunscreen active ingredients may help to obtain a tan by permitting the user to remain in the sun for a longer time without burning. Their primary intended use, however, is as a drug: to screen out UV radiation during the extended time of exposure so as to prevent skin damage through overexposure. Further, the agency believes that consumers expect protection from a tanning product that contains a sunscreen, irrespective of the claims for which the product is promoted.

The agency finds that TC-61 is out of date with current scientific knowledge and is no longer applicable. The agency intends to revoke TC-61 in accordance with 21 CFR 10.85(g). A notice of revocation and the final monograph for OTC sunscreen drug products will be published concurrently.

When an ingredient can be used for either drug or cosmetic purposes, its regulatory status as a drug or cosmetic, or both, is determined by objective evidence of the distributor’s intent. As suggested by the comments, this includes, but is not limited to, the representations made by the manufacturer or distributor in the labeling or promotion of the product. The agency also considers that the use of the term "sunscreen" or similar terms that could be interpreted as claiming that the product functions as a sunscreen, such as "sun shield" or "UVA/UVB filter," they quite rightly expect the product to protect them in some way from the harmful effects of the sun, irrespective of other labeling statements. The agency believes that consumers equate the term "sunscreen" or similar terms with the mitigation of the harmful effects of the sun, such as sunburn, premature aging of the skin (or skin aging due to the sun), and skin cancer. Accordingly, the agency tentatively concludes, and is proposing in this tentative final monograph, that the use of the term "sunscreen" or a similar term on the label of a product causes that product to be a drug, except for specific nontherapeutic uses as discussed below. Likewise, similar claims, such as "shields from the sun," "blocks out the rays of the sun," "protects from the sun," "protects against UV rays," and "prevents freckling," "prevents redness," or "prevents uneven coloration" are drug claims. Such claims imply that exposure to the sun is harmful, and that blocking it will provide benefits. These claims also imply that the product affects a physiological function of the body. The agency also considers that the use of the term "SPF" or the use of any SPF value in the labeling of a product as a basis for the product to be considered a drug. An SPF value provides assurance that the product will protect the skin from sun damage and, thus, will help to prevent disease and will affect the structure and function of the body. The agency agrees with most of the comments that the inclusion of sunscreen ingredients in some cosmetic skin products is of benefit to the consumer. However, long-term use of products containing ineffective (or less then fully effective) sunscreen ingredients could result in a consumer being exposed to more UV radiation than the consumer would expect. Such use could have serious effects (e.g., increase the chance of skin lesions and skin cancer). The agency believes that all products containing a sunscreen active ingredient and claiming to protect the consumer from the sun or to enhance the consumer’s ability to obtain an effect from sun exposure (i.e., a tan) must be regulated as drugs in order to ensure the effectiveness of the sunscreen ingredient. Therefore, FDA tentatively concludes that, except for a few select exceptions discussed below,
all products that contain sunscreen active ingredients and bear labeling identifying these active ingredients as sunscreens are drugs. Likewise, sunscreens containing-products that bear claims alluding to the sun-blocking or sun-shielding properties of the products or claims promoting a product's ability to help the consumer stay in the sun longer without harmful effects are drugs. Such products may also be regulated, not solely, as cosmetics. Regarding the statement made by some comments that FDA regulations in 21 CFR 720.4(c) include suntan and sunscreen preparations, in the Federal Register of January 28, 1992 (57 FR 3128 at 3129), the agency revised § 720(c)(15) to delete sunscreen and suntan.

Regarding one comment's statement that sunscreens may be added to a product to contribute to the tanning process and not to prevent sunburn, the agency agrees that sunscreens may indirectly aid the tanning process by allowing a person to remain in the sun for a longer period of time without burning. However, the agency believes that tanning products that contain sunscreens are drugs because the inclusion of a sunscreen in a tanning product implies that the product will protect against harm from the sun while the user is tanning. For a further discussion of tanning products and claims, see comments 29 and 58.

The agency is aware that there are many skin products such as lipsticks and make-up preparations on the market that contain sunscreen, as well as other ingredients. The term “sunscreen” (or a similar term as discussed above) or “SPF” may be included in a product to protect the skin from sunburn or other adverse effects of the sun; therefore, it would be misleading to represent anything in the product's labeling that the sunscreen has any therapeutic purpose. However, the labeling could state that the product contains a sunscreen to inform consumers why the product would protect the hair. For example, the labeling might state: “contains a sunscreen to protect the hair from the damaging effects of sunning.”

The agency is proposing to amend 21 CFR part 700 in subpart B, Requirements for Specific Cosmetic Products, by adding new § 700.35, as follows:

(a) A product that includes a sunscreen active ingredient and the term “sunscreen” in its labeling or in any other way represents or suggests that it is intended to prevent, cure, treat, or mitigate disease or to affect a structure or function of the body comes within the definition of a drug in § 201(g)(1) of the Federal Food, Drug, and Cosmetic Act. Sunscreen active ingredients affect the structure or function of the body by screening, reflecting, or scattering the harmful, burning rays of the sun, thereby altering the normal physiological response to solar radiation. These ingredients also help to prevent diseases such as sunburn and reduce the chance of premature skin aging or skin cancer due to the sun. Moreover, when consumers see the term “sunscreen” on the label of a product, they expect the product to protect them in some way from the harmful effects of the sun, irrespective of other labeling statements. Consequently, the use of the term “sunscreen” in a product's labeling normally makes that product a drug. However, sunscreen ingredients may also be used in some cosmetic products.
for nontherapeutic uses. In order to avoid consumer misunderstanding, if a cosmetic product uses the term “sunscreen” anywhere in its labeling, the term “cosmetic” must be qualified by describing the cosmetic benefit provided by the sunscreen. For example: “This product contains a sunscreen that assists in protecting the hair from damage by the sun.”

(b) Any information describing the purpose of the sunscreen in the product shall appear in direct conjunction with the term “sunscreen.”

The final monograph will cover only the drug use of the active ingredients listed therein. The concentration ranges, limitations, warnings, and directions established for these ingredients in the monograph will not apply to the use of the same ingredients in products intended solely for use as cosmetics. Those products intended for both drug and cosmetic use will be required to conform to the requirements of the final monograph. However, such products, in addition to bearing the indications allowed for sunscreen drug products, may also be labeled for cosmetic use, in conformity with section 602 of the act (21 U.S.C. 362) and the provisions of 21 CFR parts 701 and 740.

In accordance with the revised labeling requirements for OTC drug products, it is the agency’s view that cosmetic claims may not appear within the box area designated “APPROVED USES.” As discussed in the final rule on the agency’s “exclusivity policy” (51 FR 16258 at 16264 (paragraph 14)), cosmetic terminology is not reviewed and approved by FDA in the OTC drug monographs and therefore could not be placed in the box. Cosmetic claims may appear elsewhere in the labeling, should manufacturers choose the labeling alternative provided in § 330.1(c)(2)(i) or (c)(2)(iii) for labeling drug/cosmetic products. Although the agency does not specifically prohibit commingled drug and cosmetic labeling in other than the indications section, such claims should be appropriately described so that consumers will more readily be able to differentiate the drug aspects from the cosmetic aspects of such labeling. If commingled drug and cosmetic labeling claims are confusing or misleading, the product’s labeling could be misleading within the meaning of the act and misbranded under sections 502(a) and 502(a) of the act (21 U.S.C. 352(a) and 362(a)).

References

(1) "FD & C Act Trade Correspondence," United States Department of Agriculture, Food and Drug Administration, TC-61, February 15, 1940.

(2) Letter from S. Fine, FDA, to R. Kingdom, Covington and Burling, dated June 17, 1976, OTC Vol. 9, ATFM, Docket No. 78N-0038, Dockets Management Branch.

28. Three comments, referring to the cosmetic portion of the labeling of a drug/cosmetic product, argued that the limitations set by the Panel for ingredients for drug use do not establish an inference with respect to the use of the same ingredient as a cosmetic. For example, § 352.10 of the Panel’s proposed monograph (43 FR 38206 at 38284) restricts red petroleum to use at a level of 30 percent or more in a sunscreen drug product, yet the same ingredient may be used properly at any safe level in a cosmetic. The comments also asserted that the warnings in proposed § 352.50(c) (43 FR 38268) do not establish any need for warnings on cosmetic products. Citing the Comptroller General’s “Report to the Congress” concerning cosmetics, HRD-78-139, August 8, 1978, pgs. 132, the comments added that FDA has recognized that a warning required for a particular ingredient in a drug product may not be appropriate when that ingredient is used in a cosmetic product. The comments maintained that FDA may not prohibit truthful and nonmisleading labeling concerning cosmetic aspects of a cosmetic that is also a drug, and that such labeling is subject to regulation by FDA under its cosmetic authority, not under its drug authority.

The agency agrees that this monograph applies only to sunscreen products that fall within the statutory definition of “drugs.” In order to make it clear that the scope of the monograph extends only to drug products, the agency is proposing that the word “drug” be added to § 352.50(c) (“Scope”), to read “An over-the-counter sunscreen drug product * * *” (See comment 25.)

29. Stating that tanning is in the cosmetic area, one comment opposed any requirement that a cosmetic suntan product contain a sunscreen agent at any concentration level. Conversely, a number of comments contended that allowing “tanning” products to be marketed without sunscreens is misleading because consumers would believe that they have protection against sunburn when in fact they do not. The comments maintained that such products would actually promote sunburn and its subsequent, serious side effects. The comments asserted that allowing a tanning claim for products without sun protective factors would be contrary to the best interest of the public. Expressing concern that products making “tanning only” claims would be exempt from the proposed OTC sunscreen standards, one comment contended that these regulations are designed to provide protection from the acute effects of UV radiation in the 290 to 320 nm range (UVB), and that tanning is a direct response to that radiation. The comment stated that for products to influence tanning, they can either accelerate, diminish, or have no effect on UVB radiation. The comment argued that “tanning only” products should either diminish the amount of “UV-B flux” or should be labeled “sunburn, this term and have a minimum SPF value of 2 or be deemed adulterated and/or misbranded.

One comment was opposed to the sale of “tanning” products, but felt that the government cannot restrict the sale of such products. The comment, therefore, suggested that tanning products be required to carry warning labels.

Another comment acknowledged that tanning products do not make a claim for sunburn protection, but suggested that, because of the consumer’s perception that such products will reduce the risk of sunburn, all tanning products should contain a sunscreen agent with a minimum SPF value of 2.

Another comment urged that any product that claims to promote or permit tanning be required to contain a sunscreen agent with a minimum SPF value of 2 are dangerous and pose serious health hazards. The comment stated that the agency banned the use of chlorofluorocarbon propellants because chlorofluorocarbons cause a decrease in the ozone layer which can result in an increase in UV radiation reaching the earth and increased skin damage. The comment contended that, from a public health viewpoint, a requirement of a minimum SPF value of 2 for suntanning products is as necessary to protect the skin as the ban of chlorofluorocarbon propellants. The comment cited research indicating that the use of certain suntanning products without sunscreens may increase the amount of UV radiation penetrating the skin by as much as 10 percent (Ref. 1). The comment added that the health hazards attributable to long-term overexposure to the sun have been proven conclusively, and that it is less than responsible to market products that promote tanning but afford no protection from overexposure to UV radiation. The comment further contended that a sunscreen-containing product with an SPF value of 2 will
afford 50 percent more protection from long-term and short-term harm induced by overexposure to the sun than products without sunscreens.

The comment claimed that a survey that it conducted (Ref. 2) involving 903 consumers (age 35 and under) who purchase products for use in the sun demonstrated that 52 percent felt that protection from sunburn, as well as tanning, are expected attributes of a tanning product whether or not the label claims protection. From the results of the survey, the comment concluded that consumers believe and expect that a product that promotes or permits tanning will also provide protection from sunburn and other harmful effects of the sun.

Although the comment felt that the Panel recognized that suntanning products should contain a sunscreen with a minimum SPF value of 2, the comment did not agree that suntanning products need to be regulated as drugs. The comment recommended an addition to the cosmetic regulations in 21 CFR part 700 that would define suntanning cosmetic products as articles making suntanning claims and formulated with a minimum SPF value of 2. The comment cited the following examples as precedent for such a regulation: (1) The banning of hexachlorophene in cosmetics except as a preservative at levels not higher than 0.1 percent, (2) the banning of halogenated salicylanilides in cosmetics, and (3) the defining of the term "egg" as a name in cosmetic products containing not less than 2 percent egg. The comment contended that failure to enact such a regulation will force manufacturers of sunscreen products to market more tanning products without sunscreens in order to compete with products making only tanning claims. The comment stated further that this action would increase consumer use of tanning only products (without sunscreens) and increase the number of consumers placed in danger from overexposure to the sun. The comment concluded that, if the agency does not promulgate the comment's recommended cosmetic regulation, suntanning products should be included within the scope of the proposed rule for OTC sunscreen drug products.

The agency recognizes that tanning products have traditionally been used for cosmetic purposes to help an individual acquire a tan. These products are of two basic types: those that contain sunscreen ingredients and those that do not. Suntanning products that contain sunscreen ingredients are designed to minimize the burning effects of the sun. They permit the user to stay in the sun longer without receiving a painful sunburn and still acquire the desired tan. Tanning products without sunscreen ingredients are designed primarily to condition the skin while sunbathing to acquire a tan. Although the agency does not believe that all suntanning products should be required to contain a sunscreen ingredient, it believes that all suntanning products that contain a sunscreen ingredient should be regulated as a drug product regardless of its claims because the inclusion of a sunscreen ingredient in a tanning product implies that the product will protect against harm from the sun while the user is tanning. Moreover, these products have a drug effect by reducing by varying amounts the UV radiation absorbed by the skin and affecting the physiological response and extent of the erythema reaction produced. Therefore, any tanning product that contains a sunscreen ingredient must comply with the monograph for OTC sunscreen drug products and must provide a minimal SPF of 2. A suntanning product that does not contain a sunscreen may be considered a cosmetic.

The agency believes that, as the data cited in the comments suggest, there has been a change in consumer perception regarding the purpose of suntanning products, and that the consumer expects a certain amount of protection from the sun from a product that is marketed for suntanning. The agency has tentatively defined a suntanning product that contains a sunscreen ingredient should be regulated as a drug product regardless of its claims because the inclusion of a sunscreen ingredient in a tanning product implies that the product will protect against harm from the sun while the user is tanning. Moreover, these products have a drug effect by reducing by varying amounts the UV radiation absorbed by the skin and affecting the physiological response and extent of the erythema reaction produced. Therefore, any tanning product that contains a sunscreen ingredient must comply with the monograph for OTC sunscreen drug products and must provide a minimal SPF of 2. A suntanning product that does not contain a sunscreen may be considered a cosmetic.

The agency recognizes that suntanning products containing no sunscreen ingredient are labeled with SPF 0 and SPF 1. The use of SPF values in the labeling of a suntanning product may lead the consumer to assume that the product contains a sunscreen ingredient when, in fact, it does not. Such labeling, especially SPF 1, could cause consumers to expect the product to provide some protection against the adverse effects of the sun. The agency considers such labeling on a suntanning product that contains no sunscreen ingredient to be false and misleading and causes the product to be misbranded under section 602 of the act (21 U.S.C. 362).

In addition, because suntanning products are marketed specifically for use in the sun or at commercial tanning facilities, the agency is concerned about the health hazards associated with using such products if they do not contain sunscreen ingredients. The agency believes that in the absence of labeling statements that inform the consumer of the amount of protection that can reasonably be expected from the use of these products, such products could be potentially dangerous. The agency tentatively finds that the majority of consumers expect sunburn protection from suntanning products, whether the product contains a sunscreen ingredient or not. Because of the serious consequences of overexposure to the sun, the agency believes that it is important for the consumer to know whether a suntanning product contains a sunscreen ingredient or not. Failure to contain such information would constitute a failure to reveal facts material in light of the representations that are made (e.g., "suntanning") and with respect to the consequences that may result from the use of the article.

Therefore, in conjunction with this tentative final monograph, the agency is proposing, under 21 U.S.C. 301(n), 362(a), and 371(a), to amend the cosmetic regulations in 21 CFR Part 700 by adding § 740.19 as follows:

"Suntanning preparations. The labeling of suntanning preparations that do not contain a sunscreen ingredient must display the following warning: "Warning—This product does not contain a sunscreen and does not protect against sunburn."

References

(2) Comment No. C00048, Docket No. 78N-0038, Dockets Management Branch.

C. Comments on Specific Sunscreen Active Ingredients

30. One comment recommended the use or creation of simpler names for many of the sunscreen active ingredients because simpler names would be more easily recognized by the public. Maintaining that sunscreens with simpler names have a marketing advantage over other sunscreen ingredients with more complex names, the comment contended that the variety of sunscreens available to the public will tend to become limited if some sunscreen ingredients have very complex names. The comment added that the variety of sunscreens available is very important to consumers with specific allergies or sensitivities. Stating that section 506 of the act (21 U.S.C. 356) clearly authorizes the assigning of simple names, the comment suggested establishing simple names for all approved ingredients by using CTFA names or abbreviations where available and by creating simple names using CTFA guidelines for the remaining compounds. The comment claimed that
the following names are unduly complex: diethanolamine p-methoxyccinnamate, ethyl 4-[bis(hydroxypropyl)]aminobenzoate; 2-ethylhexyl 2-cyano-3,3-
diphenylacrylate; and ethylhexyl p-methoxyccinnamate. The comment added that the CTPA name PABA for aminobenzoic acid is very widely recognized, and that elimination of this name would confuse many consumers. The comment argued that use of the name aminobenzoic acid for chemical accuracy seems ludicrous when proprietary names such as Padimate A are allowed.

Another comment urged that the name PABA or p-aminobenzoic acid be used rather than the chemical name aminobenzoic acid recommended by the Topical Analgesic Panel at 43 FR 38206 at 38219. The comment stated that the name PABA designates the para position of the amino group to the carbonyl group, that the U.S.P. uses the name PABA, and that other pharmacopoeias list the ingredient as a para derivative. The comment contended that this designation distinguishes the para-derivative from the ortho- and meta-derivatives of benzoic acid, which is a desirable distinction because the ortho derivative is potentially a photosensitizing agent.

Under section 502(e) of the act (21 U.S.C. 352(e)), any drug, including any sunscreen drug product, is deemed misbranded unless its label bears, to the exclusion of any other nonproprietary name, the established name of the active ingredient, if the active ingredient has an established name. Agency regulations (21 CFR 352.10(a), (2) octyl methoxyccinnamate for ethylhexyl p-methoxyccinnamate, (3) octyl salicylate for 2-ethylhexyl salicylate, (4) lawsone with dihydroxyacetone, as proposed by the Panel, (5) menthol anthranilate, as proposed by the Panel, (6) phenyl benzimidazole 5-sulfonic acid for 2-phenylbenzimidazole-5-sulfonic acid, and (7) red petrolatum, as proposed by the Panel.

The names used in cosmetic labeling for ethyl 4-[bis(hydroxypropyl)]aminobenzoate and glycercyl aminobenzoate are ethyl dihydroxypropyl PABA and glycercyl aminobenzoate, respectively (Ref. 5). As explained above in the discussion of aminobenzoic acid, the use of PABA as part of established names for sunscreen ingredients is obsolete. In correspondence with USAN (Ref. 6), the agency requested USAN names for ethyl 4-[bis(hydroxypropyl)]aminobenzoate and glycercyl aminobenzoate. USAN provided USAN Council Members two names for each ingredient and asked them to select the preferable names (Ref. 7). For ethyl 4-[bis(hydroxypropyl)]aminobenzoate, USAN suggested either ethyl dihydroxypropyl aminobenzoate or roxadimate. For the other ingredient, USAN suggested either glycercyl aminobenzoate or lidodinate. Currently, no final decision has been made regarding USAN names for these two ingredients. Therefore, in this tentative final monograph, the agency is using the names recommended by the Panel. When USAN designates new names for these ingredients, the agency will include these new names in the monograph for OTC sunscreen drug products.

References
but total between
isopropyl myristate is nearly total
statement: "The absorbance is nearly total. Therefore, the
they only demonstrate that the
cited data do not demonstrate total
the wavelength for maximum absorption
incorrectly reported, based on the data,
comment that the appropriate
the maximum at
less than
concentration in isopropyl myristate is
following statement: "The
extinction coefficients, not as a
38206
USAN
Dockets Management Branch.
Fragrance Association, Inc., Washington,
First Edition," The Cosmetic, Toiletry and
Consortium,
Names," United States Pharmacopeial
National Formulary XVI," United States
Pharmacopeial Convention, Inc., Rockville,
(4) "USAN and the USP Dictionary of Drug
Names," United States Pharmacopeial
(3) "USAN and the USP Dictionary of Drug
Names," United States Pharmacopeial
(2) "United States Pharmacopeial XXI-
National Formulary XVI," United States
Pharmacopeial Convention, Inc., Rockville,
(1) "USAN and the USP Dictionary of Drug
Names," United States Pharmacopeial

percent concentration in
isopropyl myristate is less than 10 percent at 270 and 338 nm,
but total between 280 to 320 nm with the
maximum at 310 nm." (43 FR 38222). The agency has reviewed the
data (Ref. 1) and agrees with the
comment that the appropriate
terminology for expressing absorbance values was not used in this statement.
The agency also notes that the
maximum wavelength of 310 nm was incorrectly reported; based on the
data, the wavelength for maximum absorption
should have been 308 nm. In addition,
the cited data do not demonstrate total absorbance between 280 and 320 nm;
ey only demonstrate that the absorbance is nearly total. Therefore, the
agency concludes that the relevant data

32. One comment submitted data
in support of the safety and effectiveness of
5-(3,3-dimethyl-2-norbornylidene)-3-
-1-one and requested that it be
classified from Category III to Category I
as an OTC sunscreen drug product
ingredient. The data included one
effectiveness study and several safety
studies, i.e., skin irritation,
phototoxicity, photosensitization, acute
oral toxicity, and eye irritation tests
(Ref. 1). "Bornelone" is currently the official
title for this ingredient in the USAN and the USP
Dictionary of Drug Names (Ref. 2). The Panel found bornelone safe in the
dosage range used as a sunscreen
ingredient (43 FR 38257). The agency
concurs with the Panel's evaluation and
also finds that the additional safety data
submitted by the comment further
support the Panel's recommendation.
The agency has reviewed the
efficacy study submitted by the comment and
determined that the data are inadequate
to support the reclassification of
bornelone from Category III to Category I.
The test protocol used was deficient
because it failed to specify the
experimental conditions, i.e., the
emittance specifications of the light
source, the film thickness of the test
material (amount applied per skin area),
the distance between the light source and the exposure surface, and the skin
types of the test subjects. In addition,
the study lacked a control standard
sunscreen to validate the experimental
data. As a result, the data are
insufficient to establish the effectiveness
of bornelone as an OTC sunscreen drug
ingredient. Based on the data reviewed,
the agency is proposing to classify
bornelone in Category III for
effectiveness as a sunscreen ingredient.
The agency's detailed comments and
evaluation of the data are on file in the
Dockets Management Branch (Ref. 3).

References
(1) Comment No. C00066, Docket No. 78N-
0038, Dockets Management Branch.
(2) "USAN and the USP Dictionary of Drug
Names," United States Pharmacopeial
Convention, Inc., Rockville, MD, p. 82, 1989.
(3) Letter from W. E. Gilbarton, FDA, to
E. R. Yubas, Dragoco, Inc., coded LET016,
Docket No. 78N-0038, Dockets Management
Branch.

One comment questioned the
effectiveness of lawsone with
dihydroxyacetone against UVA
radiation (320 to 400 nm), especially
when photoprotection against a
photosensitization reaction induced by
UVA radiation plus orally administered
drugs such as declomycin or psoralen is
investigated. The comment stated that the
Panel should have investigated
photoprotection against drug-induced
photosensitivity reactions, which are
usually caused by UVA radiation. The
comment contended that the Panel
should not have approved a claim of
photoprotection against UVA radiation
until the product is tested and the data
are submitted for evaluation and
approval. The comment stated that,
although people with Skin Types I and II
can normally tolerate up to 30 to 40
j/cm² of UVA radiation, if such a person
has ingested or applied a
photosensitizing agent, he or she may
tolerate less than 3 to 5 j/cm² of UVA
radiation. Contending that in such
situations only careful testing can
demonstrate whether a product protects
against UVA, the comment contended
that a testing procedure for a claim of
UVA photoprotection should be
include in the Panel's recommendations.

In its discussion of Category I
screening ingredients (43 FR 38206 at
38235), the Panel referred to a report
(Ref. 1) that the use of lawsone with
dihydroxyacetone is effective against
both UVB radiation (320-330 nm) and
UVA radiation (320-400 nm). In
evaluating the effectiveness of Category I
screenings, the Panel determined
whether the individual sunscreen
ingredients absorbed UV radiation in
the UVB band, the range between 290 and
320 nm (43 FR 38218). This spectrum is most likely to cause
sunburn in normal individuals (43 FR
38209). The Panel did not evaluate
sunscreen ingredients for protection
against photosensitization reactions,
which are normally induced by
radiation in the UVA band (i.e., 320-400
nm) (Ref. 2). Accordingly, the Panel
did not include in § 352.50(b) a claim of
photoprotection against UVA radiation
for lawsone with dihydroxyacetone or
for any other Category I sunscreen
drug product. However, as stated in comment
53, the agency believes that claims
related to UVA protection are important
information for consumers because UVA
radiation has been shown to be harmful
to the skin in that it contributes to both
acute and chronic skin damage.
Therefore, the agency is proposing in
this tentative final monograph that a
product may, in certain circumstances,
include UVA protection claims in its
labeling. The ingredient(s) used in such
products must have an absorption
spectrum that extends to 360 nm or
above in the UVA range, and the
product must demonstrate UVA
protection using appropriate testing
procedures that the agency is proposing
developed and included in the
monograph for OTC sunscreen drug
products. (See comment 55 and 73.)
Therefore, the combination of lawsone
with dihydroxyacetone could display
UVA protection claims if it fulfills the above requirements.

The agency acknowledges that some Category I sunscreen ingredients may protect the user from drug-induced photosensitization reactions caused by UVA radiation (43 FR 38206 at 38235, 38239, 38249, and 38250). However, the agency is aware that numerous chemicals, including ingredients in soaps and perfumes as well as therapeutic drugs, can induce photosensitivity reactions in a person exposed to UVA radiation (Refs. 2 and 3). Furthermore, depending upon the absorption spectrum of the photosensitizing compound, the photosensitivity reaction may be elicited by different wavelengths (Ref. 3). If a sunscreen ingredient does not protect against the appropriate wavelength for a specific ingredient, it will not protect against a photosensitivity reaction to that ingredient. Many variables are involved in the relationship between the photosensitizing chemicals, the UV radiation, and the host, and the consumer is often unaware of these relationships (Ref. 3). Factors related to the chemical include the route of administration, ability to penetrate the skin, formulation, interaction with skin, metabolism and elimination, absorption spectrum, and quantum yield of the parent chemical and its metabolites. The radiation variables include the spectral irradiance of the source, dose and rate of delivery, number and frequency of exposures, the timing of the radiation relative to the presence of the chemical, and optics of the skin. Host factors include thickness and hydration of stratum corneum, melanization of the epidermis, integrity of the skin, and immune status (Ref. 3). Even when a patient reports a skin eruption to a physician, the etiologic role of sunlight may not be immediately apparent to the physician. Therefore, the agency concludes that claims for protection against drug-induced photosensitization reactions induced by UVA radiation should only be made in professional labeling; such information should not be included in labeling directed to the general public. The Panel did not include professional labeling in its proposed monograph, and at present the agency does not have adequate data for developing such labeling in this tentative final monograph. The agency invites comment on this matter and will consider professional labeling for claims of protection against photosensitization reactions in the final monograph for OTC sunscreen drug products, if adequate data are submitted in response to the tentative final monograph. (See comment 69.)

References

(4) One comment requested that 3-(4-methylbenzylidene)-camphor be included in the monograph as a Category I sunscreen. The comment stated that it had submitted data (Ref. 1) on this ingredient to the Panel, and, at its fourteenth meeting, the Panel had classified the ingredient in Category III based on a lack of in vivo data to demonstrate effectiveness in man or animals (Ref. 2). The manufacturer submitted additional data that included controlled studies in seventy subjects performed in three independent investigations (Ref. 3). Based on these data, the Panel reclassified 3-(4-methylbenzylidene)-camphor 0.1 to 2.5 percent to Category I at its twenty-first meeting (Ref. 4). The comment explained that it assumed from the minutes of that meeting (Ref. 4) that this classification was settled. The comment stated it was surprised when the advance notice of proposed rulemaking stated that the ingredient 3-(4-methylbenzylidene)-camphor was not generally recognized as safe and effective for OTC use, and lacked a lack of clinical and marketing data, and the ingredient was classified in Category II (43 FR 38206 at 38255).
One comment (Ref. 5) stated that 3-(4-methylbenzylidene)-camphor had been marketed in the United States and throughout the world under the trade name Eusolox 6300 since December 1973. The manufacturer also indicated that approximately 350,000 units of an OTC sunscreen product containing 3 percent Eusolox 5300 were sold at retail in the United States during 1974 to 1978 (Ref. 5). The comment provided letters from distributors and manufacturers of OTC sunscreen drug products who used 3-(4-methylbenzylidene)-camphor as a sunfilter in their products. One manufacturer stated that some sunscreen drug products containing 3-(4-methylbenzylidene)-camphor were distributed in Europe as well as marketed in North America under different trademarks.

The comment contended that general recognition of the safety of a product could, in fact, be based in part or in whole upon foreign experience, and that the relevance of foreign experience would depend not upon geography alone, but upon a scientific and medical judgment. The comment cited the case of FMAI Herb, Inc. v. Heckler, 715 F.2d 1385 (9th Cir. 1983) as support for its argument.

The comment subsequently provided additional marketing history information for 3-(4-methylbenzylidene)-camphor (Ref. 6). However, the manufacturer was unable to provide documentation to substantiate the dates of the labeling presented at the meeting. Therefore, the agency concluded that no decision could be made until the manufacturer was able to document the marketing history of 3-(4-methylbenzylidene)-camphor. To date, no new data or information has been submitted to support the reclassification of 3-(4-methylbenzylidene)-camphor from Category II to Category I.

Three similar petitions have requested the agency to reopen the administrative record for this rulemaking to include additional ingredients. One petition (Ref. 7) requests that the agency include the ingredient ethoxylated ethyl-4-aminobenzoate (PEG-25 PABA) as Category I in the monograph for OTC sunscreen drug products. The petition contends that the extensive marketing experience of ethoxylated ethyl-4-aminobenzoate in Europe as an OTC sunscreen ingredient since the early 1950's and the available data supporting the safety and effectiveness of this ingredient satisfy the statutory and regulatory criteria for inclusion of this ingredient in the OTC drug review.

The second petition (Ref. 8) requests that the agency include the ingredient isoamyl-p-methoxycinnimate in Category I. The petition states that isoamyl-p-methoxycinnamate has been marketed in Europe since 1976 and is not a new drug because there is general recognition among experts that the drug is safe and effective for its intended use. The petition contends that the available data for this ingredient conform to the standards for safety and effectiveness set forth in the agency's review of OTC sunscreens.

The third petition (Ref. 9) requests that the agency include the ingredient avobenzone (Parsol 1789), a UVA absorber, in Category I. The petition states that since avobenzone was introduced in 1981, it has been continuously used throughout the world, including Europe, Africa, Asia, Australia, South America, and Canada. The petition noted, however, that the United States is the only country in

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35. Two comments contended that padimate A is phototoxic and is inappropriate for use as a Category I sunscreen ingredient. One comment cited a study by Kaidbey and Kligman (Ref. 1) as evidence that padimate A is phototoxic to humans. The comment stated that padimate A be removed from the list of safe and effective sunscreen active ingredients. The other comment noted that the Panel was apparently unaware, at the time of its deliberations, of subsequently published reports by Kaidbey and Kligman (Ref. 1) and by Emmett, Taphorn, and Kominsky (Ref. 2) which documented the phototoxic properties of padimate A. The comment stated that these reports should be fully considered by the Commissioner prior to final categorization of this sunscreen ingredient as safe for use in drug products. The comment concluded it is inappropriate to permit any active ingredient that has been demonstrated to be phototoxic to be used in products intended for use in direct sunlight.

Stating that padimate A is safe at concentrations up to 3 percent, another comment contended that it is an irritant, especially on the face, at the maximum 5-percent concentration recommended by the Panel. Remarking that 5 percent padimate A can be an irritant to 70 percent of users who swim in chlorinated pools, the comment stated that several published studies (not identified in the comment) indicate that 5 percent padimate A causes burning, itching, and contact and photococontact irritation reactions. The comment claimed that many manufacturers have reduced the concentration or discontinued the use of padimate A because of its irritating effect. Noting that the Panel determined that padimate A is a dose-related irritant, the comment stated that a safe concentration needed to be resolved.

A reply comment stated that studies done in its own laboratories, as well as a review of the raw data for the study conducted by Kaidbey and Kligman (Ref. 1) and discussion of that study with the authors, supported its belief that padimate A is not a phototoxic agent at the concentrations in which it is used in sunscreen products. A second reply comment referred to the submitted reports (Refs. 1 and 2) and stated that the ingredient in the Emmett, Taphorn, and Kominsky study is not padimate A, but a mixture of the para and ortho isomers of amyl dimethylaminobenzoate containing a substantial quantity of the ortho isomer. The reply comment explained that padimate A is the para isomer, while the ortho isomer is phototoxic and is not used in sunscreen products. The reply comment submitted a report on a padimate A phototoxicity test on mice and swine by Forbes (Ref. 3) and contended that the test results refute the claim that padimate A is a weak phototoxic agent. Further studies are necessary to determine the drug’s phototoxic potential at lesser concentrations. The comment added that 12 years of marketing over 250 million packages also support the evidence against phototoxicity.

The Panel classified 1 to 5 percent padimate A in Category I as a sunscreen ingredient. The agency has reviewed the literature submitted by the comments and believes that there is sufficient evidence that padimate A at a 5-percent concentration is a weak phototoxic agent. Further studies are necessary to determine the drug’s phototoxic potential at lesser concentrations. The Panel classified 1 to 5 percent padimate A in Category I as a sunscreen ingredient. The agency has reviewed the literature submitted by the comments and believes that there is sufficient evidence that padimate A at a 5-percent concentration is a weak phototoxic agent. Further studies are necessary to determine the drug’s phototoxic potential at lesser concentrations. The Panel classified 1 to 5 percent padimate A in Category I as a sunscreen ingredient. 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Further studies are necessary to determine the drug’s phototoxic potential at lesser concentrations.
only products containing padimate A exhibited a phototoxic reaction. In this test, 4 out of 9 subjects responded positively to one product containing padimate A alone; 9 out of 13 subjects responded positively to another product containing padimate A alone; and 6 out of 10 subjects responded positively to a product containing a combination of aminobenzoic acid and padimate A. Products containing aminobenzoic acid alone, padimate O alone, glyceryl aminobenzoic acid alone, and sulisobenzone alone did not cause a positive response.

The solar simulator used in the study by Kaidbey and Kligman (Ref. 1) did not emit a spectrum with the same proportions of UVA, visible, and infrared radiation as present in natural sunlight. The wavelength range of most importance when considering the question of phototoxicity is the UVA range. The UVA radiation emitted by the light source used in these studies is sufficiently comparable to natural UVA to make the use of this source valid. The amount of UVA used was approximately 30 J/cm², which is a very large amount, equal to several hours of UVA from sunlight on a sunny summer day in the northeastern U.S., and approaches the MED for UVA in some light-skinned individuals (43 FR 38206, 38209). This dose, however, did not elicit erythema in the sites used as controls or in the sites to which other sunscreen agents had been applied.

In the Kaidbey and Kligman study (Ref. 1), the test materials were applied and occluded for 6 hours prior to radiation exposure. Occlusion enhances penetration and would tend to maximize the responsiveness to the applied agent. In practice, sunscreen products are rarely occluded; therefore, the phototoxicity resulting from occlusive test methods may be more severe than that obtained during normal use patterns. However, the Kaidbey and Kligman study shows that it is possible to elicit human cutaneous phototoxicity with 5 percent padimate A at UVA doses that may be encountered by individuals during prolonged, intense sunlight exposure. Therefore, the agency believes that this study does indicate that 5 percent padimate A is a phototoxic agent, although a weak one.

The Emmett, Taphorn, and Kominsky study (Ref. 2) used mixed para and ortho isomers of aminy dimethylaminobenzoate, as stated by the second reply comment. However, the investigators also tested the phototoxicity of the aminy para dimethylaminobenzoate isomer, which is known as padimate A. In this study, an in vitro test of padimate A using Ehrlich ascites cells showed phototoxicity. In the human photopatch testing, patches containing the test agents were applied to the skin of four normal subjects (i.e., subjects free of photosensitivity) for 24 hours. Subsequently, the subjects were exposed to clear noonday sunlight for 30 minutes. The reactions observed 24 hours later showed that the mixed ortho and para isomers of aminy dimethylaminobenzoate resulted in a phototoxic response (marked erythema and/or edema) in three of four subjects, and one subject experienced mild erythema in reaction to the purified amyl dimethylaminobenzoate. The authors concluded that the phototoxic reaction on human skin with pure amyl para-dimethylaminobenzoate was less marked than with the mixed isomer preparations, suggesting that ortho isomers may be the most important phototoxic agent.

The testing of mice and swine by Forbes (Ref. 3) showed that padimate A was not phototoxic to those animals. However, the agency does not believe that the Forbes study demonstrates that padimate A is not a phototoxic agent at concentrations and light exposures that may be encountered by humans using padimate A in the concentrations recommended in the trade. From the information submitted, it is not possible to determine what concentrations of the active ingredients were applied to the mice and swine used in these experiments. The dose of UVA radiation used (36x10⁷ J/m²=3.6 J/cm²) is much less than that used in the Kaidbey and Kligman study (Ref. 1). Also, it is not easy to quantitatively relate dose/response from animal models to human skin, except in a general sense.

The weight of these studies suggests that padimate A is phototoxic in humans at concentrations in the 5 percent range if sufficient UVA exposure occurs, particularly if the test is maximized by occlusive techniques. However, lesser concentrations and/or lesser UVA exposures may not produce sufficient damage to be appreciable at a clinical threshold. There is no evidence to indicate that phototoxicity is truly absent at any specific concentration, because an increased UVA dose may be able to elicit such reactions. For example, if 5 percent padimate A and a 5- to 10-J/cm² UVA dose produces no visible reaction, but 5 percent padimate A and a 30-J/cm² UVA dose produces visible phototoxicity, will 3 percent padimate A and a 40- to 50-J/cm² UVA dose be phototoxic? Although these higher doses of UVA approach the minimal erythema dose for UVA in some individuals, one can conceive of circumstances in which individuals could encounter such levels from natural sunlight (e.g., lifeguards, equatorial vacationers, etc.).

From the information available, the agency cannot determine a "safe" level of padimate A. The agency believes the available evidence shows that 5 percent padimate A is a weak phototoxic agent. Large but obtainable doses of UVA in human subjects are required in order to elicit clinically-evident effects from padimate A, particularly if maximization factors are present (such as occlusion, multiple applications during sunbathing, or hydration of skin after bathing but before application). The agency is not aware of any padimate A phototoxicity studies more recent than the 1978 Kaidbey and Kligman study (Refs. 1 and 4). Furthermore, the agency has been informed that manufacturers in the U.S. no longer use padimate A in sunscreen drug products and that the ingredient has been banned from use by the European Economic Community (Ref. 5).

Therefore, in this tentative final monograph, the agency is classifying padimate A at 5 percent and higher concentrations in Category II and in concentrations less than 5 percent in Category III. Further studies are required to determine the phototoxic potential of padimate A at less than 5 percent concentrations. Human studies should be designed to test these lower concentrations, using maximization as well as "normal use" procedures. The Kaidbey and Kligman study (Ref. 1) can be used as a suitable model of a maximization study. Reproducibly negative tests done with a statistically sufficient number of light-skinned individuals would tend to indicate levels of padimate A that would be "safe," as defined by a lack of clinically observable toxicity. The agency's detailed comments on the data are on file in the Dockets Management Branch (Ref. 6).

References


36. One comment noted that zinc oxide had been present in earlier lists of sunscreen ingredients, but was not included in the final list of active sunscreen ingredients recommended by the Panel in § 352.10. Stating that zinc oxide ointments and creams have a long history of use as a sunblock, as well as a skin protectant, the comment requested that the original data on the drug be reviewed and that zinc oxide be listed as a sunscreen active ingredient in the monograph.

FDA listed zinc oxide as an active sunscreen ingredient in its request for data on OTC topical analgesic drug products, which included antihypertensive, otic, burn, sunburn prevention and treatment drug products (37 FR 26434). Zinc oxide was a labeled ingredient in marketed products submitted for review to the Panel (Refs. 1 through 4). The Panel that reviewed these drug products evaluated both sunscreen and skin protectant drug products. After reviewing the submitted data, the Panel classified zinc oxide at concentrations of 1 to 25 percent as a Category I skin protectant (43 FR 34624 at 34648). Although zinc oxide was a labeled ingredient in a marketed sunscreen product (Ref. 3), the Panel classified zinc oxide as an inactive ingredient in the advance notice of proposed rulemaking for OTC sunscreen drug products (43 FR 38206 at 38208).

The comment did not present any data or information to support the use of zinc oxide as a sunblock, i.e., sunscreen opaque sunblock ingredient. The agency has reviewed the data in a study by Luckiesh et al. (Ref. 5), which had been submitted to the Panel (Ref. 3), in which zinc oxide was used alone and in combination with phenyl salicylate, another sunscreen ingredient. The study was designed to measure the ability of zinc oxide at concentration levels from 15 to 33.3 percent, as well as other ingredients, to absorb UV radiation over a broad range of wavelengths. Zinc oxide (33.3 percent) was the only test preparation that was studied as a single ingredient.

All subjects in the study developed skin erythema after 15 seconds of exposure to a lamp that was a source of UV radiation intensity equivalent to sixty times the most intense sunlight measured in Cleveland, Ohio over a 4-year period. One minute exposure to the lamp was determined to be equivalent to 1 hour of exposure to that sunlight. The subjects were then treated on the upper arm with a thin coating of the sunscreen test preparations. A thin coating was defined as one which was rubbed out quite well, corresponding to the thinnest coating which is likely to be applied on the skin. The sunscreen properties of zinc oxide at 33.3 percent in white petrolatum test was zero transmission of 33.3 percent zinc oxide in combination with 10 percent phenyl salicylate in white petrolatum there was zero transmission of UV energy at various wavelengths between 296.7 and 313 nm, and 0.8 and 3 percent transmission at 334.2 and 365 nm, respectively. When the concentration of zinc oxide was reduced to 15 percent in a sunscreen product with 10 percent phenyl salicylate, the UV energy transmission of the 0.03 mm coat was then 0.02, 0.04, 0.1, 6, and 44 percent at 296.7, 302.2, 313, 334.2, and 365 nm, respectively. When the test product demonstrated sunscreen properties, results from one subject alone are insufficient to support effectiveness of this ingredient as a sunblock.

Using a thin-film spectrophotometric method, Luckiesh et al. (Ref. 5) recorded the UV radiation transmitted by the test ingredients at wavelengths from 296.7 to 365 nm. The study revealed that with a 0.03 millimeter (mm) thickness cost of 33.3 percent zinc oxide in combination with 10 percent phenyl salicylate in white petrolatum there was zero transmission of UV energy at various wavelengths between 296.7 and 313 nm, and 0.8 and 3 percent transmission at 334.2 and 365 nm, respectively. When the concentration of zinc oxide was reduced to 15 percent in a sunscreen product with 10 percent phenyl salicylate, the UV energy transmission of the 0.03 mm coat was then 0.02, 0.04, 0.1, 6, and 44 percent at 296.7, 302.2, 313, 334.2, and 365 nm, respectively. When the test product demonstrated sunscreen properties, results from one subject alone are insufficient to support effectiveness of this ingredient as a sunblock.

The agency recognizes that the range of UV radiation absorbance reported in this limited study is similar to the UV radiation range reported for other sunscreen products reviewed by the Panel. The agency is aware that for many years zinc oxide has been used by consumers as a sunblock (Refs. 6 through 10). However, the agency concludes that the data submitted on zinc oxide in this rulemaking are insufficient to support its effectiveness as a Category I sunscreen as a sunblock because the effectiveness data for this ingredient when used alone are limited to one subject. Studies to demonstrate the effectiveness of zinc oxide as a Category I sunscreen should follow the requirements of the testing procedures in Subpart D of this tentative final monograph.

Therefore, because the available data are insufficient to demonstrate the effectiveness of zinc oxide as a sunscreen active ingredient, the agency is proposing to classify zinc oxide in Category III.

References
(1) OTC Vol. 060007.
(2) OTC Vol. 060137.
(3) OTC Vol. 060154.
(4) OTC Vol. 060001.

D. Comments on Dosages for Sunscreen Drug Products

37. One comment contended that the minimum dosage requirement for sunscreen active ingredients in § 352.10 is unnecessary and should be deleted. The comment proposed that a manufacturer be permitted to use an ingredient at any lower concentration which provides an SPF of at least 2. The comment provided an example where a manufacturer may wish to combine two or more active sunscreen ingredients in a formulation that would provide an acceptable SPF value of 2, but would be unable to do so because using the minimum allowable concentrations of the active ingredients would result in a preparation with an SPF value greater than 2. The comment added that such...
A second comment also questioned the necessity of the lower dosage limits because all sunscreen products must be tested for effectiveness. The comment pointed out that the recommended lower dosage limits would not allow 1 percent aminobenzoic acid preparations even though the products may show an effectiveness data submitted for its review. The agency, however, agrees with the comments that a sunscreen active ingredient's performance is not totally dependent upon the concentration of the active ingredient in the product. Because the formulation of a sunscreen drug product influences the effectiveness of the active ingredient in the product, the Panel recommended final product testing of each formulation to determine the SPF and to assure proper use (43 FR 38206 at 38221). It set the minimum concentration of aminobenzoic acid at 5 percent for any sunscreen product. The comment stated that the effectiveness of aminobenzoic acid as a sunscreen is dependent on the vehicle used and not just on the concentration of the active ingredient. As an example, the comment stated that aminobenzoic acid is less effective in certain vehicles than even if the product contains 20 percent aminobenzoic acid. The comment added that the range of concentrations given in § 332.10 of the Panel's monograph does not ensure effectiveness, but that determination of SPF values for individual products will ensure effectiveness.

A reply comment supported the position that the effectiveness of sunscreen products, not the amount of sunscreen in the products, is the standard by which performance efficacy is measured. The comment recommended that the minimum dosage requirement be deleted because it will not affect product safety or efficacy. Two comments, submitted in response to the public meeting held on January 26, 1986, to discuss appropriate sunscreen testing methods, also requested that no minimum dosages be required for sunscreen ingredients. These comments urged FDA in determining effectiveness to rely solely on the product's performance as established by appropriate SPF testing. One comment stated that the requirement to meet a minimum dosage level can have an impact on formula flexibility and safety and is not scientifically sound because a specific product's performance is dependent upon the formulation rather than simply on the amount of active ingredient.

Stating that the SPF value is a better and more accurate measure of the effectiveness of a sunscreen drug product, the comment recommended that §§ 352.10 and 352.20 be amended to eliminate the lower dosage range for each of the listed active sunscreen ingredients.

The Panel recommended minimum concentrations for all Category 1 sunscreen ingredients based on effectiveness data submitted for its review. The agency, however, agrees with the comments that a sunscreen active ingredient's performance is not totally dependent upon the concentration of the active ingredient in the product. Because the formulation of a sunscreen drug product influences the effectiveness of the active ingredient in the product, the Panel recommended final product testing of each formulation to determine the SPF and to assure proper use (43 FR 38206 at 38221). The agency is aware that the presence of a required minimum amount of a sunscreen ingredient in a drug product does not guarantee effectiveness; final product testing can ensure effectiveness. Therefore, the agency agrees with the comments that the effectiveness requirements, i.e., the determination of an SPF value for a sunscreen product, make the use of minimum concentration requirements unnecessary for single ingredient products.

However, the agency is concerned that each ingredient in a sunscreen combination product contributes to the overall effectiveness of the product. To require no minimum contribution at all could allow the use of amounts so small as to be misleading and deceptive to the consumer and could permit the inclusion of ingredients solely for promotional purposes. In addition, this could result in the consumer's exposure to an additional ingredient or ingredients with minimal additional benefit being provided. The agency believes that a minimum amount of each sunscreen ingredient should be present in a combination sunscreen product. The agency has looked for similar situations in other OTC drug monographs and notes that OTC antacid ingredients have no minimum dose stated for the individual ingredients in the final monograph. (See 21 CFR 331.11.) One or more antacid active ingredients may be combined within any maximum daily dosage limit established provided each ingredient is included at a level that contributes at least 25 percent of the total acid neutralizing capacity of the product. The antacid monograph also provides a test for determining the percent contribution of an antacid ingredient in the combination product. (See 21 CFR 331.21.) The agency believes that sunscreen manufacturers who wish to market a combination sunscreen product should be required to determine that each ingredient in the sunscreen combination contributes in some way to the effectiveness of the product, e.g., that the combination of ingredients produces a higher SPF value than any of the ingredients alone used at monograph concentrations in a single ingredient product or that the combination product protects against a wider range of UV radiation than any of the ingredients alone. Such a requirement is consistent with Part 3 of the agency's "General Guidelines for OTC Combination Products," which states: "Category I active ingredients from the same therapeutic category that have the same mechanism of action may be combined in selected circumstances if the combination meets the OTC combination policy in all respects, the combination offers some advantage over the active ingredients used alone, and the combination is, on a benefit-risk basis, equal to or better than each of the active ingredients used alone at its therapeutic dose" (Ref. 2).

Because the agency agrees with the deletion of the minimum strength requirements for sunscreen ingredients, only maximum concentrations for individual active ingredients are being proposed in § 352.10. However, because of its concern that each ingredient in a combination drug product contributes to the overall effectiveness of the product, the agency concludes that a method must be developed that demonstrates the contribution of each ingredient in a combination sunscreen product before the minimum doses for sunscreen ingredients in combination can be deleted from the monograph. At this time, the agency is unaware of any existing method for determining the contribution of each sunscreen ingredient in a combination sunscreen product. Therefore, although the agency is not including minimum doses for individual sunscreens in proposed § 352.10, it is including minimum doses for sunscreens used in combination with one another in § 352.20(d). The agency invites manufacturers and sunscreen testing laboratories to comment on this matter and to propose an appropriate test method for determining the contribution of each sunscreen ingredient in a combination sunscreen product.

References

(1) Willis, L., and A.M. Kligman, "Aminobenzoic Acid and Its Esters: The
38. One comment stated that the dosage limits for sunscreen active ingredients in the Panel's recommended monograph do not provide protection from ineffective products. The comment explained that the vehicle can have a tremendous effect on product efficacy and that some of the approved sunscreens are used primarily in combinations because they are not sufficiently effective when used alone in the currently recommended lower dosage.

The agency concludes that the lower dosage limits recommended by the Panel for sunscreen active ingredients are effective when properly formulated in a product that provides an SPF of at least 2. As the Panel pointed out, the effectiveness of all Category I sunscreens has been demonstrated by appropriate studies. The UV absorbance of the individual sunscreen between 290 and 320 nm was established and, in most instances, data were available from studies on human subjects treated either with artificial sunlight or with natural-sunlight (43 FR 38206 at 38218).

The agency agrees that the vehicle can have a significant effect on the product's effectiveness. However, the influence of the vehicle on the effectiveness of a sunscreen drug product is accounted for in the SPF testing procedure because the test is done on the final formulation of a sunscreen product. As provided in § 352.10, a final sunscreen drug product must have an SPF value of not less than 2. Any product that can demonstrate that it meets the labeled SPF value is considered to be effective.

E. General Comments on Labeling for Sunscreen Drug Products

39. One comment contended that FDA does not have the authority to legislate the exact wording of OTC labeling claims. The comment objected to the agency limiting the labeling claims to the exact terminology of the monograph and rejecting all other terminology, regardless of accuracy. The comment requested that more flexibility in labeling be permitted by adding to the approved indications a statement as follows: "* * * or similar indication statements which are in keeping with the Panel's report.

In the Federal Register of May 1, 1986 (51 FR 16258), the agency published a final rule changing its labeling policy for stating the indications for use of OTC drug products. Under 21 CFR 330.1(c)(2), the label and labeling of OTC drug products are required to contain a prominent and conspicuous location, either (1) the specific wording on indications for use established under an OTC drug monograph, which may appear within a boxed area designated "APPROVED USES"; (2) other wording describing such indications for use that meets the statutory prohibitions against false or misleading labeling, which shall neither appear within a boxed area nor be designated "APPROVED USES"; or (3) the approved monograph language on indications, which may appear within a boxed area designated "APPROVED USES," plus alternative language describing indications for use that is not false or misleading, which shall appear elsewhere in the labeling. All other OTC drug labeling required by a monograph or other regulation (e.g., statement of identity, warnings, and other regulations (e.g., statement of identity, warnings, and directions) must appear in the specific wording established under the OTC drug monograph or other regulation where exact language has been established and identified by quotation marks, e.g., 21 CFR 201.63 or 330.1(g). The proposed rule in this document is subject to the labeling provisions in § 330.1(c)(2); the wording in § 332.52 is consistent with these regulations.

40. A number of comments requested that the labeling of sunscreen products contain more information for using these products. The requests included the following: information on the effectiveness of sunscreens when used for different skin types, or on different parts of the body, or with moisturizers, makeup, or cola drinks, or when used in water, chlorine, or sea spray; more information concerning safe and effective use; labeling which would permit consumers to choose a sunscreen product appropriate for their skin sensitivity; and labeling products with the names and percentage composition of ingredients.

The Panel considered some of the above factors in making its labeling recommendations, e.g., use in water and skin type. The Panel recommended labeling concerning a sunscreen's resistance to its removal by water, i.e., sweat resistance, water resistance, and waterproof properties (43 FR 38206 at 38268). The Panel also recommended that the labeling contain a guide that relates skin type and product category designations to the type of sunscreen product needed for protection (43 FR 38269). The agency agrees that the labeling for sunscreen products should contain such information to aid consumers in choosing the most suitable sunscreen for their needs. Therefore, the agency is proposing these labeling recommendations. The Panel did not discuss the impact of all the factors mentioned by the comments that may interfere with a sunscreen's effectiveness; factors such as beverages ingested, sea spray, and chlorine were among those not considered. The agency is only proposing those factors in the Panel's recommended labeling that directly relate to the safe and effective use of sunscreen drug products. The agency recognizes that information about other factors may be useful in product selection. However, the agency does not believe that it is practical or necessary to include all of these possible factors in the monograph.

Statements and terms outside the scope of the monograph may be included elsewhere in the labeling, provided they are not false or misleading. Such statements or terms will be evaluated by the agency on a product-by-product basis, under the provision of section 502 of the act (21 U.S.C. 352) relating to labeling that is false or misleading. Even though it is true and not misleading, any statement or term that is outside the scope of the monograph may not appear in any portion of the labeling required by the monograph and may not detract from such required information.

Other OTC advisory review panels have recommended, as did the Topical Analgesic Panel, that manufacturers list all inactive ingredients in the labeling of OTC drug products. However, the act does not require the identification of all inactive ingredients in the labeling of OTC drug products.

The act specifies the requirements for ingredient labeling of OTC drug products. Section 502(e) of the act (21 U.S.C. 352(e)) requires that all active ingredients and certain other ingredients, whether included as active or inactive, be disclosed in the labeling. The act also limits the requirement for stating quantity of ingredients in OTC drug products to those specifically mentioned in section 502(e). Although the act does not require for full labeling of ingredients, as requested by the comment, the SPF value of a sunscreen drug product does provide a quantification of the protection afforded by the active ingredient(s).

Although the act does not require the disclosure of all inactive ingredients in the labeling of OTC drug products, the agency agrees with the Panel that listing of inactive ingredients in OTC drug product labeling would be in the public interest. Consumers with known allergies or intolerances to certain ingredients would then be able to...
identify substances that they may wish to avoid.

The NDMA (formerly "The Proprietary Association"), the trade association that represents approximately 85 OTC drug manufacturers who reportedly market between 90 and 95 percent of the volume of all OTC drug products sold in the United States, has announced that its member companies would voluntarily begin to list inactive ingredients in the labeling of OTC drug products under guidelines established by the Association (Ref. 1). Under another voluntary program begun in 1974, the member companies of NDMA have been including the quantities of active ingredients on OTC drug labels.

The agency commends these voluntary efforts and urges all other OTC drug manufacturers to voluntarily label their products in accordance with NDMA’s guidelines.

Reference
(1) "Voluntary Codes and Guidelines of the OTC Medicines Industry," Nonprescription Drug Manufacturers Association, Washington, DC, pp. 18 and 19, copy included in OTC Vol. 34, Docket No. 78N-0036, Dockets Management Branch.

41. One comment contended that a package insert is essential for OTC sunscreen drug products. The comment stated that because uncontrolled exposure to the sun leads to premature aging of the skin and skin cancer, all sunscreen drug products should have "danger signs" about solar radiation and artificial UV light sources, instructions for regular use of sunscreens, and guidelines to create public awareness about the ways to prevent the effects of the sun’s damaging rays. The comment felt that substantial information about solar radiation and UV radiation should be provided to consumers and that precautions such as the following should be included in a package insert for sunscreen drug products: "apply sunscreens uniformly and liberally before every sun exposure," "reapply after swimming or perspiration," "wear *** lightly [lightly] woven clothing," "protect the eyes with ultraviolet opaque sun goggles," "beware of reflective surfaces [sand, snow, water, etc.]," "use sunscreens even on cloudy or hazy days," "avoid tanning parlors." The comment added that OTC drugs such as aspirin, antihistamines, nasal decongestants, and antifungal agents have package inserts. A second comment opposed the requirement of a package insert because it would single out sunscreens as the only OTC drugs requiring this extraordinary labeling.

The agency agrees that educating the public about the dangers of excessive sun or UV radiation exposure is important. However, a number of the items that the comment suggested for inclusion in a package insert, while useful, go beyond the necessary information required for the safe and effective use of these drug products. Examples include the statements about wearing certain types of clothing and avoiding tanning parlors. After evaluating the comment’s other suggestions for information to be contained in a package insert, the agency believes that the labeling proposed in this tentative final monograph addresses many of these items and it is not necessary specifically to require a package insert for these products. One example is the “alert” statement being proposed in this document, which states: "SUN ALERT: The sun causes skin damage. Regular use of sunscreens over the years may reduce the chance of skin damage, some types of skin cancer, and other harmful effects due to the sun." (See comment 56.) A statement similar to this currently appears in the labeling of many marketed sunscreen drug products. In addition, the directions for use being proposed in this tentative final monograph advise the consumer to apply the sunscreen liberally, generously, smoothly, or evenly before exposure to the sun and after swimming, excessive sweating, or towel drying. (See comment 66.)

The agency encourages manufacturers to provide consumers useful information and does not oppose the inclusion of a package insert containing additional information. As noted in comment 40, other statements may be included in labeling provided they are not false or misleading.

Although package inserts are not essential for OTC sunscreen drug products, there may be cases where it is necessary for the manufacturer to use a package insert or other mechanism to provide the required monograph labeling for an OTC drug product. For example, when an OTC drug product is packaged in a container that is too small to contain the required labeling, it should be enclosed in a carton or be accompanied by a package insert that provides the labeling required by the monograph. This type of packaging is likely to be necessary for sunscreen drug products marketed specifically for application to the lips or nose.

42. One comment stated that the labeling requirements for sunscreen drug products do not include provisions for small packages, and that alternatives should be developed because all of the required statements will not fit on small packages. A reply comment added that sunscreen-containing products are often marketed in sizes too small to accommodate the full product performance statement (recommended by the Panel in §352.50(e)) on the principal display panel. This comment objected to the Panel’s requirement that product performance statements be placed on the principal display panel, arguing that these statements are quite long and that it is repetitious to require them in addition to the indications in §352.50(b). The reply comment suggested that the labeling on the principal display panel be limited to the product’s PCD and SPF designations, e.g., “extra protection-SPF 6,” with the remainder of the performance statement permitted to appear elsewhere in labeling.

The agency has reviewed the Panel’s recommended labeling and, wherever possible, has revised and clarified the labeling so that only essential information is required. The product performance statements proposed in this tentative final monograph (§352.52(a)) cover the following four areas: (1) a statement of the PCD, e.g., “Minimal Sun Protection Product,” (2) a statement of the product’s resistance to removal by sweat or water, e.g., “sweat resistant;” (3) a compilation of skin types and recommended PCD’s, e.g., “tend to burn rapidly ** ** Minimal,” and (4) a statement for sunscreens that contain an opaque sunscreen, i.e., “Sunblock.” The agency concludes that the labeling information in §352.52(e)(1), (e)(2), (e)(3), and (e)(6) is useful but not essential; therefore, the agency is proposing that this information be optional and may be used in labeling if a manufacturer wishes. The information in §352.52(e)(4) is essential and must be displayed on a sunscreen drug product, but it does not need to be on the principal display panel of the product.

The indications in §352.52(b)(1) include a series of statements concerning sunburn and protection from the harmful effects of the sun. The manufacturer must use any one or more of those indications in the labeling of sunscreen drug products. The indications in §352.52(b)(2) are “Additional Indications” that are optional statements which may be used on a sunscreen drug product in addition to any of the statements in §352.52(b)(1).

The agency does not consider the proposed product performance statements in §352.52(e) to be repetitions of the required indications in §352.52(b)(1) and (b)(2). The proposed
indication section § 352.52(b)(1) and (b)(2) provide the consumer with a variety of information. The product performance statements in § 352.52(e) include information on the product’s water resistance capability and a compilation of skin types and PCD’s; the indications do not include similar information.

The agency has recently promulgated guidelines for industry to consider when examining product labels for readability and legibility (Ref. 1). These guidelines are designed to assist manufacturers in making the labels of OTC drug products as legible as possible. The agency commends this voluntary effort and urges all OTC drug manufacturers to examine their product labels for legibility.

The Panel concluded that informative labeling should be provided to consumers to aid in the selection of the most appropriate sunscreen product. The Panel recommended that such labeling be placed on the principal display panel of a product where it is most likely to be read. The agency is proposing labeling for the principal display panel of all sunscreen drug products in § 352.50 of this tentative final rule that includes SPF values and water resistance information. PCD information is not required to be placed on the principal display panel. (See comments 45 and 51.)

The labeling provisions in part 201 (e.g., §§ 201.10(l), 201.15, 201.60, 201.61, and 201.62) address various requirements for labeling drugs including drugs packaged in containers too small to accommodate a label with sufficient space to bear all the information required for compliance with various regulations. In those instances where an OTC sunscreen drug product is packaged in a container that is too small or otherwise unable to include all of the required labeling, the product can be enclosed in a carton or be accompanied by a package insert that contains the information complying with the monograph. Manufacturers are also encouraged to print a statement on the product container label, carton, or package insert suggesting that the consumer retain the carton or package insert for complete information about the use of the product when all the required labeling does not appear on the product container label. However, the principal display panel must contain certain information, e.g., statement of identity (§ 201.61) and SPF and water resistance information (proposed § 352.50).

The NDMA has recently promulgated guidelines for industry to consider when examining product labels for readability and legibility (Ref. 1). These guidelines are designed to assist manufacturers in making the labels of OTC drug products as legible as possible. The agency commends this voluntary effort and urges all OTC drug manufacturers to examine their product labels for legibility.

Reference


43. Two comments objected to the Panel’s list of skin types (43 FR 32066 at 32313) and to the recommended labeling of sunscreen products according to these skin types. Another comment requested that the Roman numeral designation for skin types be replaced by Arabic numbers. One of the comments suggested that the numbering of skin types should relate directly to the numbered grades of sunscreen protection, i.e., the most sensitive skin, Type I, requiring the “number 1” or highest protection sunscreen and that the skin type list should be shortened so that the information could be presented in large print on the sunscreen label. The comment also felt that skin type VI (“Never burns; deeply pigmented (insensitive)”) is unnecessary and offered the following list for sunscreen labeling:

- "I for those who burn easily and never tan. Grades 1–2 sunscreen."
- "II for those who burn easily and tan minimally. Use grades 3–4."
- "III for those who burn when first exposed and tan gradually. Use grades 5–6. etc. for the rest."

Stating that the SPF is more useful for the research and development of sunscreen products than for the labeling of sunscreen products, another comment argued that the consumer would be confused when confronted with a choice of five protection levels and five skin types on a sunscreen label. The comment suggested that skin types be classified in relation to a standardized sunscreen formulation (e.g., the formulation given at 43 FR 38259) as follows:

- Very Sensitive Skin—Skin that needs more protection than that provided by the standardized sunscreen formula. Moderately Pigmented—Skin burns moderately during the first exposures to sun (before skin becomes tan); after tan, skin doesn’t burn unless exposed to intense sun.
- Insensitive Skin—Rarely visible burns.

In this suggested system, the protection afforded by each sunscreen product would also be in reference to the standard formulation, e.g., a product offering twice the protection of the standard formulation would be labeled 2X standard. The comment felt that this approach would provide the consumer with a better method for choosing a sunscreen as well as a measure of a sunscreen product’s bioequivalence to a well-studied standard formulation.

The agency notes that the Roman numeral designation of skin types found objectionable by some comments is not included in the Panel’s recommendations for sunscreen labeling. These type designation were only included in the Panel’s report (43 FR 38265 at 32313) for completeness of information as part of a table which relates skin type to recommended sunscreen products. The Roman numeral skin type designations are also found in the selection of test subjects under the general testing procedures (43 FR 3265). The Panel did recommend that information on skin types and PCD statements be included in sunscreen labeling as a guide to the consumer (43 FR 38214). The agency agrees with the Panel that such information aids the consumer in choosing an appropriate product. However, in this tentative final monograph, the agency is proposing that PCD labeling be optional, and therefore, PCD labeling might not be included in the labeling of all products. (See comment 44.) The agency is proposing that an SPF value be displayed on the principal display panel of all sunscreen drug products. (See comment 45.) The agency has determined that the product guide recommended by the Panel would be more useful in aiding consumers to choose an appropriate product if the guide included SPF ranges rather than PCD categories. Furthermore, the agency is proposing to replace the Panel’s recommended word “never” in “always burns easily; never tans” with the word “rarely” because “never” is an absolute term, and such an absolute condition is unlikely to be fulfilled. In addition, the agency is adjusting the proposed SPF ranges to more accurately reflect the protection potential of currently marketed sunscreen drug products and the amount of protection needed by the various skin types.

The agency believes that the information in the product guide should be presented in a manner that captures consumers’ attention and allows them to quickly ascertain which type of product is appropriate for their skin types. Therefore, the agency is proposing in § 352.52(e)(4) that the following recommended Sunscreen Product Guide appear in the labeling of all sunscreen drug products:

**Recommended Sunscreen Product Guide**

<table>
<thead>
<tr>
<th>Sunburn and tanning history</th>
<th>Recommended sun protection product</th>
</tr>
</thead>
<tbody>
<tr>
<td>Always burns easily; rarely tans.</td>
<td>SPF 20 to 30.</td>
</tr>
<tr>
<td>Always burns easily; tans minimally.</td>
<td>SPF 12 to under 20.</td>
</tr>
</tbody>
</table>
The agency points out that the sunburn and tanning history of skin type VI ("Never burns; deeply pigmented (insensitive)") is not included in the proposed guide. The Panel stated that no sunscreen use was indicated for this skin type (43 FR 38206 at 38213); thus it did not include skin type VI in its Recommended Sunscreen Product Guide (43 FR 38269). The agency requests comment on whether such information should be added to the guide.

The alternative statements offered by one comment as shorter than the Panel's recommended statements actually contain more words, e.g., "For those who burn easily and never tan" to replace "Always burns easily; never tans." In addition, in this comment's alternative statements, the PCD statements (maximal, ultra, etc.) are replaced with undefined numerical grades of sunscreen protection level.

The alternative statements offered by another comment only included three skin types that would be defined according to a standardized sunscreen formulation. The agency believes that the consumer requires information on more than three skin types and that the proposed compilation of five skin types based on sunburn and tanning history and five SPF ranges offers more thorough and more useful information than the alternatives suggested by the comments.

Furthermore, since 1980, the labeling of most sunscreen products in the United States has voluntarily included SPF values and sometimes has also included PCD statements. (For a discussion of SPF values and PCD statements, see comment 44.) For over a decade, consumers have used and become accustomed to choosing sunscreen products based on this system. The agency believes that consumers are familiar with choosing sunscreen products according this system and that it would be confusing and unnecessary to introduce an entirely new system for grading protection as suggested by the comments without additional justification. In addition to required SPF values and optional PCD statements proposed in this tentative final monograph for OTC sunscreen drug product labeling, the agency believes that the labeling of Recommended Sunscreen Product Guide, which relates skin type to the amount of protection needed (i.e., SPF value), will provide consumers with the necessary information from which to choose the sunscreen product best suited for their skin type.

F. Comments on SPF and PCD Labeling for Sunscreen Drug Products

44. In response to the Panel's report, numerous comments "fully supported" the proposed SPF numerical rating system in sunscreen product labeling, indicating that such information will be most helpful to consumers, especially those with fair and sensitive skin. One comment emphasized the necessity for a numerical rating system of no less than 4 categories of protection if the proposed range of 6 to 15 ratings was unacceptable. Several comments believed that a numerical rating system should be correlated with both efficacy and skin types. Two comments stated that there are too many number categories for the sun protection factor. Another comment suggested alternative labeling based on a numerical rating or a comparison of sunscreen products by reference to a FDA standard sunscreen formula, adding that this approach recognizes the validity of the agency's emphasis on bioequivalence. The comment maintained that the SPF values are more related to research than to practical approaches for labeling. Two comments suggested that, to avoid confusion by the consumer, SPF values should be included in the labeling on sunscreen products and one comment provided the following examples: "I—Always burns easily, never tans. Use sunscreens grade 9-14." "II—Always burns easily, tans minimally. Use grades 6-7." "III—Burns moderately, tans gradually. Use grades 4-5 ** ** etc." Two comments opposed the system recommended by the Panel because they believed it was confusing and unnecessary. One comment felt that there is no need to a double scale to exist, i.e., a numerical rating system with SPF values and a classification system, composed of PCD statements. In response to the notice of public meeting to discuss appropriate testing procedures for OTC sunscreen drug products, published in the Federal Register of September 4, 1987 (52 FR 33586), several comments discussed the relative merits of using PCD's and/or SPF values in the labeling of sunscreen drug products. Many of the comments supported the use of the PCD on the label, either alone or in addition to the SPF number. One comment maintained that use of both SPF values and PCD in the labeling of sunscreen products is more useful to the consumer than the SPF, which the comment contended is information used by less than 10 percent of the consumers. Acknowledging that the PCD's are not as widely recognized by consumers as is the SPF numbering system, another comment maintained that PCD's are, nevertheless, useful for standardizing product claims and SPF values and should be retained. One comment contended that numerical SPF values are more meaningful to the consumer than PCD's, but supported retaining the PCD as an optional label statement because these "descriptives" are currently used on some products and have been for many years.

Another comment maintained that the agency should continue to permit the use of both SPF values and PCD's in the labeling of sunscreen drug products because each has meaning and usefulness to both consumer and industry. The comment recognized the need to ensure that sunscreen products are classified into some type of category system that is meaningful to the consumer and that adequately protects the public health. However, the comment argued that SPF values help best to accomplish these goals because they are used (1) to compare the effectiveness of existing products, (2) to monitor product performance over time, and (3) during product development to distinguish the best available formulation. The comment added that SPF values have been in use for 10 years, and the consumer has become accustomed to using these values when selecting products. The comment mentioned data from a consumer survey (Ref. 1) that shows that SPF values are a major factor in a consumer's selection of a sunscreen product. The comment asserted that a review of educational literature published by organizations such as The Skin Cancer Foundation, American Institute for Cancer Research, American Cancer Society, and others indicates that the SPF is discussed more often than the PCD.

One comment maintained that the PCD labeling serves no useful purpose and may be confusing and misleading. In place of the PCD's, the comment recommended that manufacturers continue to use SPF values to provide the sun protection value of a sunscreen formulation. The comment maintained that this would be the simplest and most straightforward manner of
describing a product so that consumers can choose the product appropriate for their needs by comparing the protection offered by one product with another. Stating that consumers are aware of SPF values and base their purchase decisions on these factors, another comment maintained that consumers are largely unaware of PCD's, that PCD's are redundant and less informative than SPF values, and that nothing would be lost by dropping them. Two other comments proposed eliminating the PCD's because they serve no useful purpose and may be misleading and confusing. One comment maintained that manufacturers should continue to use SPF values as the sole means of disclosing the sun protection value of a product. The comment stated that sunscreen testing procedures provide an accurate and reproducible measure of the erythema protection performance of the products tested and that the consumer is familiar with the SPF as a measure of the relative protection offered by various products. The comment added that the consumer has been exposed to the SPF concept for 10 years or more and is well acquainted with the degrees of protection provided by products with different SPF values. Maintaining that the terms (e.g., "ultra," "maximal," and "extra") applied to the different PCD's have no intrinsic meaning that would allow the consumer to make an educated comparison between products, the comment recommended that SPF values alone be used to convey the sun protection performance of a sunscreen product. The comment felt that consumers were sufficiently well-educated regarding SPF values of sunscreens so that PCD's are redundant.

The agency agrees with many comments that the SPF provides consumers with important information. The SPF value is based on a numerical index designed to tell consumers how much protection from the sun a product will provide. The SPF value is defined as the ratio of the amount of energy required to produce a MED or minimal sunburn through a film of a sunscreen drug product to the amount of energy required to produce the same MED without any treatment (43 FR 38206 at 38213). The SPF values are correlated to the efficacy of the sunscreen product and thus are helpful to consumers in identifying the proper product for their needs. This information is especially important to consumers with fair or sensitive skin. The Panel's recommended SPF system contains an SPF scale with values of 2 to 15, i.e., products providing a minimal amount of protection to products providing the maximum amount of protection. The agency has further determined for the reasons more fully described below that an SPF scale with values up to and including SPF 30 is appropriate. (See comments 46 and 47.)

The agency believes that PCD's are useful for descriptive terms for standardizing the labeling of sunscreen drug products but should not be mandatory labeling. Although PCD labeling may provide useful information to the consumer, it is not necessary for the safe and/or effective use of the product provided an SPF value is included in the products labeling. A single PCD is established for each product after determining the product's SPF value. The five PCD statements being proposed by the agency in this tentative final monograph are as follows: Minimal (SPF 2 to under 4), moderate (SPF 4 to under 8), high (SPF 8 to under 12), very high (SPF 12 to under 20), and ultra high (SPF 20 to 30). (See comment 45.) The PCD and SPF of a sunscreen drug product determines which of the additional indications proposed by the agency in § 352.52(b)(2) corresponding to the appropriate SPF values are correlated to and the expected length of exposure time to direct sunlight. The agency concludes that sunscreen drug product labeling based on such a system will make it easier for consumers to select the proper sunscreen drug product. Accordingly, the agency is including the SPF rating system and the Recommended Sunscreen Product Guide so that consumers can select the most appropriate sunscreen drug product based on skin type (sensitivity) and the expected length of exposure time to direct sunlight. The agency in this notice public meeting to discuss appropriate testing procedures for sunscreen drug products (52 FR 33598 at 33602), the agency noted that the Panel's recommended PCD's may not adequately accommodate sunscreen drug products with high SPF values of 25 or 30. The agency requested comment on how the PCD's might be modified to include higher SPF values.

Several comments supported retaining the five PCD's that were recommended by the Panel. One comment suggested that products with SPF values of 15 or higher should continue to be designated as "ultra." One comment recommended that for those products that have SPF values over 15, the monograph should be changed to read "15 and above" for the "ultra" PCD.
One comment suggested that the ultra category should be comprised of sunscreens with SPF values between 15 and 30+. The comment maintained that retaining the currently proposed designations has a significant benefit in that current products would not need to be relabeled with the category designation and consumer reeducation would not be necessary. It added that the PCD’s as currently proposed do encompass all SPF ranges without the necessity for a change. One comment suggested the addition of an SPF 25+ value to the ultra protection category.

Several comments suggested revisions to the PCD’s that were recommended by the Panel. One comment maintained that the system found in Australian Standard AS2604 is readily understood by consumers, precludes ambiguity, and is compatible with SPF labeling in excess of 15. It recommended the following categories: (1) Minimal (SPF 2 to less than 4); (2) Moderate (SPF 4 to less than 8); (3) High (SPF 8 to less than 15); and (4) Maximum (SPF 15 and over). Another comment suggested revised wording for the PCD’s as follows: (1) low (SPF 2 to under 4); (2) medium (SPF 4 to under 8); (3) high (SPF 8 to under 15); (4) very high (SPF 9 to under 15); and (5) maximal (SPF 15 and above). The comment maintained that this revised wording would be more comprehensible to the consumer than the descriptive terms recommended by the Panel. A third comment stated that PCD’s should be divided as follows: (1) minimal (SPF 2 to under 3); (2) moderate (SPF 5 to under 10); (3) extra (SPF 10 to under 15); (4) maximal (SPF 15 to under 25); and (5) ultra (SPF 25 and above).

Noting that the suggested category designations in the September 4, 1987 notice (52 FR 33602) had deleted the SPF 15 category, one comment strongly recommended that the SPF 15 category be retained. The comment cited a survey of dermatologists and pediatricians (Ref. 1) that indicates that they usually recommend SPF 15 sunscreens to their patients. The comment favored retaining the current PCD ranges to maintain continuity, suggested two additional categories, and suggested revising the SPF 15 or greater category to accommodate currently marketed products as follows: for the PCD comprising SPF 15 to under 25, the labeled SPF should be 15; for the PCD comprising SPF 25 to under 30, the labeled SPF should be 25; and for the PCD comprising SPF values of 30 or greater, the labeled SPF should be 30+. However, the comment did not provide any names to be used for its additional PCD’s.

One comment recommended that the following classes be used to designate categories rather than the Panel’s recommended PCD’s: (1) Class 1 (SPF 15 and more); (2) Class 2 (SPF below 15 to SPF 8); (3) Class 3 (SPF 8 to 15); (4) Class 4 (SPF 15 to 25); and (5) Class 5 (SPF below 4). The comment further suggested that each class could be given a specific name which may represent the sensitivity of the skin (e.g., Class 1 would be for very sensitive skin and/or extreme solar conditions; Class 2 would be for sensitive skin and/or moderate solar conditions; Class 3 would be for low sensitive or tanned skin; Class 4 would be for low sensitive or unsensitive skin; and Class 5 would be for minimal sun protection). Adding that Classes 3, 4, and 5 only protect in mild solar intensity, the comment further defined extreme solar conditions as those corresponding to 15 to 25 MED per day for sensitive skin, moderate solar conditions as those equal to about 10 MED per day for sensitive skin, and low solar conditions as those corresponding to about 5 MED per day for sensitive skin.

Some comments argued that the PCD descriptive terms recommended by the Panel (i.e., “minimal,” “moderate,” “extra,” “maximal,” and “ultra”) are confusing, misleading, and ambiguous, and should not be included in the labeling of sunscreen drug products. Two comments contended that, by definition, the word “maximal” should be the highest rating category, but it fails in the middle of the Panel’s recommended SPF range. The comments added that consumers have been educated to purchase products based upon SPF values. Another comment stated that the Panel’s report permits a product with an “ultra” PCD to characterize itself as providing the “most protection against sunburn,” the “greatest protection against sunburn,” or the “highest degree of sunburn protection.” The comment stated that these claims are potentially confusing because the product may provide less total sunscreen protection than a higher SPF product or a product with more UVA protection. The comment added that consumers cannot distinguish the true value or degree of protection suggested by these terms because it is not clear whether a “maximal” sunscreen provides greater or less protection than either an “extra” or “ultra” protection product. Another comment maintained that “maximal” and “ultra” each imply the most possible.

One comment maintained that labeling with SPF numbers using the fixed values set forth in the PCD labeling recommended by the Panel in its proposed monograph is appropriate. Another comment favored the restriction of labeled SPF values to the lowest value of the PCD range. The comment felt that allowing the actual incremental SPF values within a category to be displayed on the principal display panel becomes a marketing ploy that would unnecessarily confuse the consumer. Stating that it is unlikely that meaningful differences in protection exist between products with SPF 9 and 11, for example, the comment stated that labeling the products as such would be misleading and that labeling both products with SPF 8 would be a more appropriate and conservative approach. A third comment recommended that for all PCD’s, either the actual SPF value, as determined by testing, or the lowest SPF number in the PCD would be appropriate for label claims. The comment added that a cap should be set at SPF 30 and any tested value higher than 30 should be expressed on the label only as 30+.

One comment maintained that the PCD’s recommended by the Panel are not adequate to allow consumers to evaluate sunscreen drug products for effectiveness. Stating that consumers have a good basic knowledge of the SPF system, the comment suggested that actual SPF ratings, in whole number increments, should be allowed on all sunscreens so that accurate comparisons can be made. Another comment maintained that the consumer relies more on the actual SPF of a product than the PCD. The comment stated that providing the actual SPF on the label along with the appropriate PCD is in the best interest of the consumer.

The agency believes that the Panel’s recommended PCD’s should be revised slightly in order to better accommodate SPF values above 15. The agency believes that a modification of the PCD ranges will ensure that the protective qualities of a sunscreen drug product will be more accurately described. For example, the Panel recommended that SPF 15 sunscreens should be allowed to display the claim “Affords the most protection against sunburn.” As stated in comment 46, the agency believes that SPF values above 15 are justified in part because an SPF 15 sunscreen drug product may not provide “the most protection against sunburn” for some fair-skinned persons or under certain circumstances. In the 12 years since the Panel’s report on OTC sunscreen drug products was published, advances in technology have produced dramatic improvements in the effectiveness of
sunscreen preparations. Such products have become integral features in public health statements. The National Institutes of Health (NIH) Consensus Development Conference Statement and the AAD both recommend the use of sunscreens with SPF ratings of 15 or higher (Refs. 2 and 3). The Panel recommended that products providing an SPF value can be described by the state "Affords maximal protection against sunburn" and that products providing an SPF value of 15 or greater could state "Affords the most protection against sunburn." Because the agency is proposing a revised SPF system in this tentative final monograph, it is also proposing to revise the PCD ranges and to use several different descriptive terms in place of those recommended by the Panel.

Regarding the terms used for PCD categories, the agency agrees with the comments and believes that some of the comparative terms recommended by the Panel (i.e., such as "a," "extra," "maximal," and "ultra") to identify PCD's are confusing and may be misleading to the consumer. It should be noted that the Panel was proposing a new labeling concept, and at the time of its deliberations, such terms were not commonly found in the labeling of sunscreen products. The agency agrees that it is especially difficult to distinguish between the term "maximal" and "ultra" because both would seem to indicate that the sunscreen drug product offers the most protection possible. The agency believes that the terms "minimal" and "moderate" as used by the Panel are clear and that these terms properly indicate the performance that consumers may expect from a sunscreen drug product in these SPF ranges. The agency is, therefore, proposing that the terms "minimal," "moderate," and "ultra" be retained. However, the agency proposes that the higher PCD's be identified as "high," "very high," and "ultra high." These terms should assist consumers in making a more informed comparison between sunscreen drug products. The agency invites specific comment on this issue. As mentioned above, the agency does not consider these terms as essential as SPF values and is proposing that the PCD labeling recommended by the Panel in § 352.50(e) of its monograph, as revised above, be optional. (See comment 44.)

In § 352.50(e) of its recommended monograph, the Panel proposed that sunscreen drug products be categorized into PCD's according to their tested SPF and that these products use the lowest SPF value in the applicable PCD as their labeled SPF number. For example, if a product's test SPF value were 14, the product was categorized into the maximal PCD (i.e., SPF 8 to under 15) and used SPF 8 in its labeling. The agency now believes that the product may display instead its tested SPF value up to SPF 30. (In this tentative final monograph, the agency is proposing that SPF values up to and including SPF 30 are justified. See comments 46 and 47.) A water resistant or very water resistant product must display both its static SPF value (up to SPF 30) and its SPF value that has been determined after the appropriate water immersion test. (See comment 51.) Such labeling will more accurately inform the consumer of the protection offered by a sunscreen drug product, especially for those products in the higher PCD categories, such as "very high," where SPF values may range from SPF 12 to under 20, or "ultra high," where SPF values range from 20 to 30.

Although PCD statements are proposed as optional in this tentative final monograph, the agency believes that SPF values need to be displayed on the principal display panel of OTC sunscreen drug products. Therefore, the agency is proposing a new § 352.50 entitled "Principal display panel of all sunscreen drug products" to include labeling that is required to appear on the principal display panel of all OTC sunscreen drug products as follows: "For products that do not satisfy the water resistant or very water resistant sunscreen test procedures in § 352.76. 'SPF (insert tested SPF value of the product up to 30).'" (For labeling required for the principal display panel of OTC sunscreen drug products that satisfy the water resistant and very water resistant testing procedures in § 352.76, see comment 51.)

Because of the addition of this new labeling section, the agency is proposing to renumber the Panel's recommended § 352.50 "Labeling of sunscreen products" as § 352.52.

In addition, in this tentative final monograph the agency is revising the Panel's recommended PCD labeling in § 352.50(e) and including it in § 352.52(e), as follows:

(ii) For products containing active ingredient(s) that provide an SPF value of 2 to under 4. 'Minimal Sun Protection Product.'

(iii) For products containing active ingredient(s) that provide an SPF value of 4 to under 8. 'Moderate Sun Protection Product.'

References


46. In the notice of public meeting to discuss sunscreen testing procedures (52 FR 33598 at 33599), the agency noted the proliferation of OTC sunscreen drug products that display SPF values greater than 15, which was the Panel's highest recommended classification. Stating that consideration should be given to modifying the Panel's recommended monograph to address these higher SPF values, the agency asked the following: "What benefit is provided to the consumer by sunscreen drug products claiming to have SPF values greatly in excess of 15 (i.e., 23 or even 30) if, as the Panel claims, SPF 15 offers the maximum possible protection?" (See 52 FR 33602.)

47. Most comments submitted in response to the public meeting maintained that sunscreen drug products with SPF values above 15 are beneficial and justified. One comment asserted that such products provide better protection against the deleterious effects of the sun than do sunscreen drug products with lower SPF values.

Two comments noted that, at the time the Panel made its recommendations, SPF 15 was the highest value commercially available. Since that time, newer research and formulation techniques have made it possible to formulate sunscreen products with proven efficacy at SPF levels well above 15. One comment added that these newer products are more protective than those initially contemplated or reviewed by the Panel in the 1970's. Another comment remarked that because of advances in technology, the Panel's proposed labeling that "SPF 15 provides the highest degree of sunscreen protection" is now inaccurate and needs to be corrected.

Several comments pointed out that sunscreen drug products with an SPF of 15 will not offer maximal protection to
a person with extremely sensitive skin (i.e., an individual with Skin Type I who always burns and never tans) and noted that American consumers may be exposed to increased doses of sunlight when on vacation in sites like Hawaii, the Caribbean, and Mexico. One comment added that not only is the intensity of the sun greater in such areas, but the duration of hours in such places may stay out in the sun longer. Another comment stated that the potential for sunburn cannot be avoided completely by using a product with a lower SPF value and reapplying it frequently, and that products with SPF values higher than 15 provide an extra measure of protection for people who either do not want to be or who should not be exposed to the sun. One comment stated that although a product with an SPF of 15 provides significant protection from sunburn, the extra margin of protection afforded by a product with an SPF value in excess of 15 is useful to those sun-sensitive individuals desirous of all-day protection.

One comment stated that products with the higher SPF values screen out more of the sun's total UV radiation spectra responsible for both immediate burning and long-term damage such as photaging and skin cancers. Another comment submitted several published scientific studies purporting to indicate the benefits of sunscreens in terms of skin cancer protection (Refs. 1 through 4), protection against photaging (Refs. 5 and 6), and protection of the cutaneous immune functions (Ref. 7). Another comment noted that the medical community has continued to stress the importance of adequate sun protection throughout one's lifetime to reduce the risk of skin cancer and premature aging of the skin, and that products with an SPF above 15 would better provide this protection.

One comment maintained that there is ample documentation to indicate that an SPF value of 15 is not adequate protection for a sizeable proportion of the United States population (Refs. 8 through 11). Based on these data, the comment maintained that the average midsummer MED available per day range from 19 in Bismark, North Dakota, to 44 in El Paso, Texas, for skin Type II individuals. The comment pointed out that although these are sunrise to sunset measurements, 75 percent of the sunburning radiation dose is delivered between 9 a.m. to 3 p.m. During that time period individuals are most active outdoors, and there is a potential exposure in the 30-MED range. The comment also submitted 1980 Census Bureau data that indicate that 39.3 percent of the United States population is of Celtic origin and would be classified into the lower skin type categories (i.e., Skin Types I or II) (Ref. 12). One comment stated that it had conducted an attitude and use survey in 1987 among 585 sunscreen consumers who were asked, "How important is an SPF of 15 or greater to you in a sunscreen?" The comment stated that 75 percent of the subjects responded positively by selecting either "extremely important" (48 percent) or "very important" (29 percent).

One comment maintained that the AAD and other scientific organizations recognize the need for high SPF products. The comment stated that the German sunscreen standard (DIN 607501) and the Austrian standard (AS 2604) recognizes that products need to be formulated to meet the needs of consumers with varying skin types. The comment added that, in addition to normal variations in skin type and susceptibility to sunburn, a substantial segment of the population appears to be sun sensitive (Ref. 13) and needs high SPF products to provide adequate protection.

One comment submitted the results of a nationwide random survey of 101 pediatricians and 99 dermatologists to determine their sunscreen recommendations to patients (Ref. 14). The survey found that 21 percent of pediatricians and 40 percent of dermatologists usually recommend products with SPF values higher than 15, and that 75 percent of dermatologists recommend products with SPF values higher than 15. Only 11 percent of pediatricians and 20 percent of dermatologists felt that sunscreens with SPF values higher than 15 were not medically necessary. The comment maintained that these results indicate that the majority of these medical specialists recognize that products with SPF values above 15 are valuable. Another comment submitted a study (Ref. 15) that investigated the risk reduction for nonmelanoma skin cancers associated with the childhood use of sunscreens. Using a mathematical model based on epidemiological data, the authors quantified the potential benefits of using an SPF 15 sunscreen and estimated that the regular use of such a sunscreen during the first 18 years of life reduced the lifetime incidence of nonmelanoma skin cancer by 76 percent.

Conversely, two comments were opposed to the availability of sunscreen drug products with SPF values higher than 15. One comment questioned the need for sunscreen drug products with high SPF values (i.e., 25 to 30) when people are not exposed to greater than 15 MED's in a day. The comment maintained that sunscreen drug products with an SPF of 15 are adequate for the average needs of all people. The comment felt that people with highly sun-sensitive skin are given a false sense of protection when the industry recommends sunscreen drug products with SPF values of 25 or 30, and that this section endorses increased sunbathing. Such sun-sensitive persons are at greatest risk of developing acute and chronic skin changes and should not indulge in prolonged sunbathing or remain outdoors for long periods of time. The comment asserted that prolonged sunbathing should be discouraged and the regular use of sunscreen drug products should be encouraged in order to control the increasing trend of actinic keratoses, skin cancer, and the early onset of photoaging. Another comment submitted in response to the Panel's report contended that sunscreens with SPF values greater than 10 are not necessary because people with very sensitive skins with a "disposition to light disease" should use opaque sunscreens.

The agency agrees with the majority of comments that SPF values higher than 15 are justified. The agency notes that in the United States there are enormous variations both in skin type in the population and in the amount of UV radiation to which a person may be exposed, because of differences in geography. Many of the comments submitted to the agency indicated varying seasonal daily doses of UV radiation ranging from approximately 9 to 44 MED's depending upon location, latitude, and season. The agency believes that there are situations where consumers routinely are exposed to sufficient UV radiation may require sunscreen drug products with SPF values greater than 15.

Since the Panel's report on OTC sunscreen drug products was published, advances in technology have produced dramatic improvements in the effectiveness of sunscreen preparations. Several elements have contributed to these advances, e.g., development of solar simulators, more knowledge of the optical properties of the skin, greater skills in formulating sunscreen drug products, and greater awareness of the importance of the vehicle in such products (Ref. 16). The agency believes that sunscreen preparations with SPF values above 15 are important from a public health standpoint. According to an NIH Consensus Development Conference Statement (Ref. 17), the average
American's exposure to UVB radiation has increased considerably over the past several decades due to changing lifestyles, i.e., more outdoor recreational activities, more emphasis on tanning, scantier clothing, and a population shift to the sunbelt. In addition, recent satellite measurements indicate a worldwide decrease in stratospheric ozone over the last decade. This reduction increases the amount of UV radiation that reaches the earth's surface. If this layer continues to be depleted, human exposure to UV radiation will increase correspondingly.

There are serious risks involved with increased exposure to UV radiation. Sunscreen preparations with SPF values higher than 15 are necessary to provide fair-skinned individuals with maximum protection. A large proportion of the United States' population is of Celtic origin (Ref. 12). Such fair-skinned people burn very easily (i.e., in as little as 10 minutes (43 FR 38206 at 38210)) and are most susceptible to the adverse effects of sunlight, such as skin cancer and premature aging of the skin. Therefore, the agency believes that many people in the United States need more protection than that provided by an SPF 15 sunscreen. This need is especially important when people are being exposed to intense sunlight, such as that found in the southern portion of the United States and in many popular vacation areas where consumers normally receive even greater amounts of UV radiation. The NIH Consensus Development Conference Statement recommends the use of sunscreens with SPF ratings of 15 or higher (Ref. 17). It also recommends daily use of these products during appropriate times of the year and states that sunscreens should be applied before exposure, with frequent reapplications thereafter. The agency agrees that sunscreens should be applied frequently and is proposing such in the directions included in § 352.52(d) of this tentative final monograph. (See comment 68.) The AAD also recommends the use of sunscreens with SPF factors of at least 15 to protect against premature aging of the skin and skin cancer (Ref. 12).

The agency also believes that sunscreen drug products with SPF values above 15 may offer better protection to consumers who may not apply a sunscreen as liberally as they should or who do not always reapply a sunscreen as frequently as they should. For such consumers, a sunscreen with an SPF of 20 or 25 may offer an important extra margin of safety. The agency concludes that OTC sunscreen drug products with SPF values higher than 15 are beneficial to consumers and is proposing that the upper limit for SPF values be 50. (See discussion of proposed SPF 30 upper limit in comment 47.)

In regard to the one comment's concerns about individuals with a "disposition to light diseases," the agency has discussed such photosensitization reactions in comments 33 and 69.

References

47. Several comments discussed whether or not there should be an upper limit to SPF values. The Standards Association of Australia submitted a copy of its revised standard for sunscreen products (Ref. 1) and stated that it has deliberately restricted SPF factor claims to a maximum of 15+ to prevent the "inevitable number chasing" that is "now occurring in the USA." The comment stated that this restriction prevents products from being "loaded" with sunscreen ingredients for which chronic dermal toxicology data are often lacking.

Two comments believed that SPF values should be capped at 20. One comment stated that the most that it had measured with a Robertson-Berger meter in the tropics on Mauna Loa (19° North latitude, 12,000 feet elevation) was 27 MED's, on a flat surface, from sunrise to sunset. The comment maintained that because a human in the upright position receives at most 60% of the ambient UV radiation, a full day's dose would not exceed 16 MED's for a Skin Type I individual. The comment contended that sunscreen drug products with SPF values greater than 20 will only increase cost and make the possibility of irradiation from multiple sunscreen ingredients and their photo-breakdown products more likely.

Another comment maintained that unless one is at a high altitude (e.g., 15,000 to 20,000 feet), one is unlikely to receive UV radiation flux exceeding 15 MED on a clear, bright day. The comment asserted that an average person rarely stays out in the sun for more than 4.5 hours and thus would only receive a maximum dose of 10 to 12 MED. The comment urged the agency to adopt a maximum SPF value of 20, contending that it is not necessary to have "extra potent" sunscreens with SPF values of 25, 30, or 35 and to subject the consumer's skin to potentially toxic effects of high concentrations of chemicals.
Another comment stated that an upper limit of SPF "25+" should be established to ensure adequate sunscreen protection for highly sensitive skin in order to prevent exposing consumers to unnecessarily high levels of sunscreen active ingredients. The comment expressed concern that many companies manufacturing sunscreen drug products have embarked upon an SPF "numbers game," leaving consumers with the impression that the higher the SPF number the better the product. The comment felt that such marketing strategies are not rational and expose consumers to excessive levels of sunscreen ingredients that may potentially cause more problems (e.g., invisible dermatitis) than are justified by the benefits. The comment added that placing the upper SPF limit at "25+" would provide industry with an opportunity to reasonably protect the consumer from UV radiation while restricting the current industry marketing movement toward very high SPF values, which needlessly confuse the user.

Several comments believed that SPF claims should be capped at 30. Stating that the trend toward higher SPF values has reached unjustifiable levels, one comment stated that the benefits derived from very high SPF values by the vast majority of consumers are negligible, and that many consumers think that they are getting much more protection than they actually are. Another comment suggested that products with SPF values greater than 30 cannot be justified on a risk/benefit basis because achieving SPF values higher than 30 requires unnecessary exposure to increased levels of sunscreen, while increasing overall protection by an insignificant degree. As an example, the comment noted that an SPF 30 sunscreen drug product blocks 96.7 percent of the incident UVB energy whereas an SPF 40 sunscreen drug product only increases this level of protection to 97.5 percent, and the amount of additional sunscreen ingredient "load" in the product to increase the SPF to 40 could realistically increase by up to 25 percent. The comment added that, in the extreme, an SPF 70 would block 98.6 percent of the UV energy versus 96.7 percent blocked by an SPF of 30. The comment maintained that such extra protection is not necessary and that sunscreen drug products with SPF values higher than 30 represent unnecessary and ill-advised exposure to increased sunscreen ingredients at a time when dermatologists and skin cancer groups are recommending that sunscreens be applied daily to minimize the adverse effects of the sun. The comment concluded that this additional unnecessary exposure to more sunscreen ingredients is ill-advised.

One comment stated that a reasonable basis for selecting an SPF cap is the level of protection required for an average consumer who spends an entire day in the sun in a sub-tropical region of the United States such as Florida or Hawaii. The comment maintained that measurements of UV radiation taken in these areas have found that the average consumer can be exposed to as much as 20 MED's. The comment recommended an SPF cap of 30 because this is the maximum amount needed to protect the vast majority of consumers (including Skin Type I individuals) from sunburn under stress conditions of UV exposure. One comment stated that proponents of high SPF values often cite as justification the needs of people with Skin Type I and people prone to skin cancer. The comment maintained that a sunscreen drug product with an SPF of 30 can adequately protect most of these individuals and added that it is not good public policy to expose most of the population to unnecessarily high levels of sunscreens to protect a very few. The comment contended that people can be misled into a false sense of security when told that a single application of a very high SPF product will protect them all day. In reality, the comment asserted these products are subject to washing or rubbing off, thereby reducing their effective level of protection. The comment stated that the needs of special groups would be better served if they were encouraged to reapply their sunscreen products because two applications of an SPF 30 sunscreen drug product will provide more protection under real usage conditions than a single application of a higher SPF product. Another comment stated that individuals who are so sensitive as to need higher than SPF 30 protection should be encouraged to severely limit their sunlight exposure and to use a product with an SPF of 30 when they are necessarily exposed to sunlight. The comment concluded that SPF 30 should be sufficient for all-day sunburn protection for the vast majority of the population under maximum sun exposure conditions.

One comment argued there are data (Ref. 2) demonstrating that enough sunlight exists on many days during the summer months in various locations to permit exposure in excess of 25 MED's for the average Skin Type II and III individual. By extrapolation, the comment maintained that a Skin Type I individual could be exposed to approximately 30 MED's during this same time frame. The comment acknowledged that these calculations are based upon exposure of an individual lying in a quiet, prone position from sunup to sundown, and may be somewhat inflated. Nevertheless, the comment maintained that these data provide a convincing rationale for an SPF 30 sunscreen drug product that would permit even a Skin Type I to achieve all-day protection as well as allowing for an extra margin of protection to accommodate weather conditions that cannot be factored into SPF testing.

Several comments advocated that no upper limit be set on SPF values. One comment maintained that scientific information is not available to demonstrate a "no-effect" level of sun exposure, especially when considering the sun's contribution to photoaging and the risk of skin cancer. The comment provided a pamphlet from the AAD (Ref. 3) to substantiate its position. The comment suggested that, in the absence of a demonstrable safety risk, it would be contrary to public policy and to consumers' best interest to preclude manufacturers from offering truthfully labeled sunscreen formulations with as much sun protection as is technologically feasible.

Citing an article by Urbach and Berger (Ref. 2) and stating that a person with average, untan skin may receive 22 MED's of UV radiation in one day in El Paso, Texas, another comment supported an open-ended numbering system for SPF values, or as an alternative, an upper limit of not less than 40. The comment maintained that limiting the highest allowed SPF number would prevent those consumers who want and need a high level of protection from making valid comparisons among the highest SPF products available.

A comment from an institute that deals with systemic lupus erythematosus and discoid lupus research (diseases associated with photosensitivity) mentioned the need for a sunscreen drug product with an SPF value of up to 40. The comment maintained that the use of such sunscreen drug products would prevent the triggering of the onset of these diseases. The comment included abstracts of scientific publications that include information on the relationship between photosensitivity and lupus and that suggest that sunblocks may be essential for sensitive lupus patients (Ref. 4). Although the agency has concluded that the available scientific data demonstrate that sunscreen drug products with SPF values above 15 are
reasonable and justified (see comment 46). It finds that SPF values above 30 are not necessary because the available data clearly indicate that a sunscreen drug product with an SPF of 30 assures adequate protection for the majority of consumers even under extreme conditions. As pointed out by one comment, an SPF 30 sunscreen drug product blocks 96.7 percent of the incident UVB energy, whereas an SPF 40 sunscreen drug product only increases this level to 97.5 percent. Further, data compiled by Berger and Urbach in 1982 (Ref. 2) demonstrated that approximately 25 MED's is the highest dose of UVB radiation that an individual with average Caucasian skin can expect to receive in Mauna Loa, Hawaii. In the southern states of the continental United States, an individual can be exposed to approximately 22 MED's in the hottest part of the summer. A sunscreen drug product with an SPF 30 provides all-day protection for all skin types. Such a product also provides an extra margin of protection that allows for the possibility that the product may be inadequately applied and accommodates weather conditions that cannot be factored into the SPF testing procedures that are done with artificial light sources.

Scientific evidence shows a point of diminishing returns at levels above SPF 30; any benefits that might be derived from using sunscreens with SPF values higher than 30 are negligible. The agency does not believe that an "open-ended" approach to SPF values is beneficial to consumers. The difference in protection provided by a sunscreen drug product with an SPF 40 or 50 compared to the protection offered by a product with an SPF 30 is so small as to be nonexistent, especially when one considers that biological variability inherent in an individual's response to the protective quality of sunscreen drug products. (See also discussion in comment 48.)

Regarding the use of high SPF sunscreen drug products to protect consumers with photosensitivity diseases, the agency notes that the exact etiology of these light-related diseases is not known. (See comment 69.) The fact that a sunscreen has a high SPF may not be as important to the consumer with a photosensitivity disease as the UV wavelengths that are absorbed or reflected by the sunscreen ingredient in the product. The agency does not believe that, apart from whatever ingredients may be in the formulation, an SPF 40 sunscreen drug product provides significant benefits that are not also provided by an SPF 30 sunscreen drug product. Unless such benefits can be shown, the agency believes that an SPF 30 sunscreen drug product provides adequate protection for a consumer with a photosensitivity disease provided that the appropriate wavelength is absorbed or reflected.

Based upon the above, the agency is proposing an upper limit of 30 for SPF values and is proposing to revise the Panel's recommended § 352.50(b) to reflect this maximum SPF value. (See comments 45 and 57.)

Several comments questioned the safety aspect of sunscreen drug products with extremely high SPF values (e.g., 25, 30, or higher). This issue is discussed in comment 48.

References
(1) Comment No. C00082, Docket No. 78N-2038, Dockets Management Branch.
(4) Comment No. C00094, Docket No. 78N-2038, Dockets Management Branch.

48. In response to the notice of public meeting to discuss appropriate testing methods for OTC sunscreen drug products (52 FR 33596), some comments expressed concern regarding the possible toxicity of OTC sunscreen drug products with high SPF values. Maintaining that there is no safety or toxicological data pertaining to "these new sunscreens with high SPF values that contain high concentrations of UV-absorbing and UV-reflecting chemicals," one comment expressed concern about the long-term effects of these preparations. The comment specifically mentioned that little is known about the long-term effects of the small concentration of lead in zinc oxide and titanium dioxide and stated that this may be especially harmful to children. Stating that the constant presence of chemicals on skin is potentially harmful, the comment questioned how many fair-skinned individuals might develop phototoxic reactions by using potent, high SPF sunscreen drug products. The comment suggested that the agency recommend certain test procedures in an animal model system to ensure the safety of high SPF sunscreen drug products when used on a long-term basis.

One comment stated that, at the January 26, 1988 public meeting, some of the discussion of possible safety issues relating to high SPF sunscreen drug products missed the point of the relevant benefit-risk analysis. The comment stated that, although products with SPF values greater than 15 utilize Category I ingredients within approved concentration ranges, the total sunscreen load tends to increase significantly. For example, in comparing similar lotion formulations, a sunscreen with an SPF of 15 may utilize 11.5 percent total sunscreen ingredients while a sunscreen with an SPF of 40 may require over 22 percent total sunscreen load. The comment stated that the consumer is therefore exposed to greater total levels of active ingredients, and an incremental difference in protection from UVB rays becomes increasingly smaller. For example, a sunscreen with an SPF of 15 screens 93 percent of UVB rays, a sunscreen with an SPF of 25 screens 96 percent of UVB rays, while a sunscreen with an SPF of 39 screens 97.44 percent of UVB rays. The comment stated that the obvious benefit-risk issue is whether the extremely modest increased protection from sunburn justifies the increased exposure to sunscreen ingredients that may cause skin irritation.

One comment pointed out that the level of sunscreen active ingredients allowed in a sunscreen drug product is now regulated by the advance notice of proposed rulemaking published in 1978 (43 FR 38206) and that all sunscreen drug products, even those with very high SPF values, are limited by these proposed rules. The comment maintained that advances in formulation technology have allowed manufacturers to develop products with relatively low levels of sunscreen active ingredients and still maintain high SPF values. The comment stated that responsible manufacturers test finished products to establish safety prior to marketing, in addition to adhering to the limits established in the proposed rules. The comment added that, although product safety is a very important consideration, limiting the SPF claim on sunscreen drug products will not have a substantial effect on the overall safety of these products.

The comment noted that three speakers at the public meeting suggested that skin irritation might result from use of sunscreen drug products with high SPF values. The comment cited the following three specific statements: (1) "the use of larger numbers and more sunscreen probably will only lead to trouble with photochemical reactions, * * * irritation * * *"; (2) "[in work with] patients who experience skin cancer or melanoma sore, [he] recommend[s] the use of 15 SPF and more, but at least 10 percent of [the subjects] have an irritation with this type of product;" and (3) "[he] recommended SPF-15 sunscreens and
**without sunlight exposure**

*The subjects had contact irritational reaction, no sensitization,*" (Ref. 1). The comment stated that no data were submitted to support these statements. The comment added that the patients to whom the last two statements applied had skin diseases and, thus, had compromised skin integrity. The comment maintained that, even if valid and documented scientific studies showed skin irritation in such subjects, there is no reason to believe that any significant irritation would result from the intended use of sunscreen by individuals with healthy skin.

The comment asserted that some of the reactions discussed at the public meeting were described as "some irritation," "minor to some discomfort," "some burning sensation, a little bit of redness," and "discomfort, a little bit of redness" (Ref. 1). The comment contended that these reactions do not demonstrate a significant irritation problem with sunscreen drug products. The comment added that, in one case, the sunscreen preparations were European formulas, the active ingredients may not have been Category I ingredients, and the concentrations of the active ingredients in the products used were not provided (Ref. 1). The comment added that, as with any dermatological product, the irritation may have been caused by the inactive ingredients and not necessarily by the active sunscreen ingredients. The comment concluded that these speculative comments, by themselves, do not raise any significant safety concerns nor do they warrant any kind of additional warnings on OTC sunscreen drug products.

The comment stated that the Topical Analgesic Panel carefully evaluated the safety of the Category I ingredients included in the OTC drug review. The comment maintained that in the data base considered by the Panel no studies raised any serious concerns about skin irritation with these ingredients. The comment added that two commentators at the public meeting had said the following: (1) "We have not seen any problems in either human or animal safety testing," and (2) "in our experience with many, many customers and many cosmetic houses which use sunscreens, there is a negligible risk of exposure to the standard consumer, which actually is so small that it cannot be measured statistically" (Ref. 1).

Maintaining that all drug products cause some type of adverse reaction in particular individuals, the comment added that the question is whether, when balanced against the benefit of the drug product, an adverse reaction is significant, taking into account the size of the affected population. The comment stated that sunscreen drug products provide not only protection against sunburn but also against development of skin cancer and other kinds of damage to the skin. The comment argued that these benefits greatly outweigh instances of minor, transitory skin reactions that may occur.

The comment stated that manufacturers report a low incidence of consumer complaints about significant skin irritation resulting from the use of OTC sunscreen drug products. The comment maintained that, if there were significant problems with skin irritation, industry and the agency would have heard of them. The comment added that the Panel's recommended monograph requires the label of a sunscreen drug product to display the following warning: "Discontinue use if signs of irritation or rash appear" (43 FR 38206 at 38268). The comment concluded that there are no valid data in the record that sunscreen drug products currently marketed in the United States pose a risk of significant skin irritation.

One comment submitted data purporting to demonstrate that sunscreen drug products with an SPF above 15 are no more irritating than products with an SPF below 15 (Ref. 2). A 21-day cumulative patch-test procedure was used to determine if there is a correlation between the SPF of a sunscreen and its irritation potential. Five pairs of sunscreens were tested, each pair (from a different manufacturer) consisting of a high and a low SPF product in identical or almost identical vehicles. The study demonstrated that the degree of irritation was sometimes slightly greater in the higher SPF product and sometimes slightly greater in the lower SPF product. The investigator concluded, therefore, that the SPF and the irritation potential have no correlation.

The agency has extensively reviewed the available data and does not believe that sunscreens with SPF values higher than 15 (up to SPF 30) pose any significant safety problems. None of the comments that expressed concern regarding the safety of high SPF products submitted any data or information to substantiate their concerns or to show that higher SPF sunscreen drug products pose a greater safety risk.

In §352.20 of its recommended monograph, the Panel established no upper limit to the number of sunscreen active ingredients that a product may contain. In the absence of any data to the contrary, the agency agrees with the Panel that any number of sunscreen active ingredients may be combined in a product and is so proposing in §352.20(a) of this tentative final monograph. Combining various sunscreen ingredients in a product can result in a product that provides protection against a wider spectrum of UV radiation than does a product containing a single sunscreen ingredient. Combinations of sunscreen ingredients, along with improved formulations, also result in products with higher SPF values and afford consumers more protection. However, because the agency requires that each ingredient in a product contribute to the effectiveness of the product, it is proposing in §352.20(c) of this tentative final monograph that each ingredient in a combination sunscreen drug product should have a minimum concentration. (See comment 37.)

The agency argues that advances in formulation technology have allowed manufacturers to develop products with relatively low levels of sunscreen active ingredients and still achieve high SPF values. The agency is aware of studies demonstrating the importance of the vehicle on the final performance of a sunscreen drug product. There is a lack of data showing a significant relationship between sunscreen ingredient concentration and the final SPF of a product. In one study (Ref. 3), designed to update performance data of a number of "high potency" sunscreens, the SPF and substantivity of several sunscreens were evaluated according to the testing procedures recommended by the Panel in its report on OTC sunscreen drug products (43 FR 38206 at 38267). The study demonstrated that formulation and vehicle design have a profound effect on SPF values. This was especially evident in the case of three sunscreens, each containing 8 percent padimate O (octyl dimethyl (PABA)) and 8 percent oxybenzone, that were found to have SPF values of 7.85, 15.85, and 18.43. Another sunscreen with a lower total concentration of the same active ingredients (i.e., 8 percent padimate O and 3 percent oxybenzone) had an SPF of 21.

The agency does not believe that increasing the concentration of active ingredients in a sunscreen drug product will necessarily make the product more irritating. The addition of another active ingredient to a drug product always has the potential to increase the risk of increased adverse effects. However, based on the study above (Ref. 3), there may not be any more of a problem in products with SPF values over 15 (up to SPF 30) than there is in products with...
lower SPF values. The other study (Ref. 2) also supports this position.

The agency believes that the benefits derived from using a sunscreen drug product with an SPF value up to 30 outweigh any risk that may be present (see comment 46). As stated in comment 47, the agency believes that SPF values should be capped at 30, that any benefits that might be derived from using sunscreen drug products with SPF values higher than 30 are negligible, and that above SPF 30 the risk of added ingredients begins to outweigh the benefit of added protection.

The agency agrees with one comment that stated that the warning recommended by the Panel in § 352.50(c)(1)(iii) protects consumers by informing them to discontinue using a sunscreen drug product if signs of irritation or a rash appears. The agency is proposing in this tentative final monograph to expand the Panel's recommended warning by adding a sentence that informs consumers to consult a doctor if the irritation or rash persists. (See comment 63.)

References


2) Comment No. C00096, Docket No. 78N-0038, Dockets Management Branch.


G. Comments on Water Resistant Labeling for Sunscreen Drug Products

49. Referring to recommended § 352.50 "Labeling of sunscreen products," one comment recommended allowing use of the word "perspiration" for "sweat" and the word "perspiring" for "sweating." The comment maintained that because the alternative words are synonymous and are well understood by consumers, they will not mislead or confuse consumers.

The agency concurs with the comment's recommendation and is proposing to allow manufacturers the option of using the words requested. In the labeling for the principal display panel in § 352.50(b) and (c), the "Directions" in § 352.52(d), and the "Statement on product performance" in § 352.52(e)(2), the agency is providing the option of using the terms "perspiration" and "perspiring" in place of the terms "sweat" and "sweating."

50. One comment stated that "water-resistance" is the strongest claim that should be permitted for any sunscreen drug product. The comment asserted that the use of "waterproof" sunscreen can result in occlusion of sweat ducts and hair follicles, contact dermatitis (contact and delayed hypersensitivity), and vesicular dermatitis secondary to the trapping of sweat at some point in the skin. The comment added that the closure of sweat pores can also cause milia crystallina and milia rubra (prickly heat).

Several comments maintained that consumers do not differentiate between the terms "water resistant," "waterproof," and "sweat resistant." One comment recommended reducing the number of "water related" claims from three to one (i.e., "water resistant"). One comment stated that the Australian standard AS2604-1986 allows only the claim "water resistant" because it was felt that the claim "waterproof" is an absolute claim and would be construed by consumers that, once applied, the product need not be reapplied. This could be particularly dangerous given the possibility of removing the product while towel drying off. The comment felt that the term "water resistant" indicated that some caution was still needed.

Another comment maintained that use of the terms "water resistant" and "waterproof" in sunscreen labeling is confusing and "potentially misleading" to consumers. The comment noted that an attitude and usage survey conducted in 1984 of 564 sunscreen users indicated that both of these terms seem to convey the same idea (i.e., that the product will not wash off during swimming). However, the comment stated that there was slight evidence suggesting that the term "waterproof" implies greater continued protection from the sun after being wet and that consumers preferred products that were labeled waterproof. The comment suggested that using only one term would benefit consumers. The comment asserted that because the waterproof methodology is the more stringent of the two, only products providing protection after the 80-minute water immersion tests should be allowed to make a claim and that claim should be "waterproof." The comment also suggested that the term "sweat resistant" is rarely used in labeling by any manufacturer and suggested that this term be deleted from the monograph. One comment stated that subjecting products to the more stringent standard of waterproof testing would provide a more conservative measure of the substantivity of the product and, therefore, provide the consumer with the most meaningful and accurate information on product performance.

In the Panel's recommended monograph, a "water resistant" sunscreen was described as one which
can withstand 40 minutes of water immersion (§ 352.46(a)); a “waterproof” sunscreen was described as one which can withstand 80 minutes of water immersion (§ 352.46(b)). The first comment did not submit any data or literature references demonstrating that any sunscreen products, including those described by the Panel as waterproof, occlude sweat ducts or hair follicles, or cause contact dermatitis, vesicular dermatitis, miliaria crystallina, or miliaria rubra. The Panel did not identify these conditions as occurring from the use of such products. The other comments also did not submit any data to substantiate their claims that consumers prefer the term “waterproof” or that consumers do not distinguish between “water resistant,” “waterproof,” or “sweat resistant.” The agency therefore has no reason, based on safety concerns or consumer preference, to restrict sunscreen drug products to only “water resistant” or “waterproof” labeling claims.

The agency is concerned, nevertheless, that the term “waterproof,” as used in the Panel’s recommended monograph, may be confusing or misleading to consumers because of the manner in which consumers may consider this term. The term “waterproof” is defined as “impenetrable to or unaffected by water” (Ref. 1). The agency notes that the Commonwealth of Australia allows only the use of the term “water resistant” in its regulatory standards for sunscreen products (AS 2604-1986) (Ref. 2). According to the Australian Society of Cosmetic Chemists which assisted in the development of these standards, it was decided to recommend against allowing the term “waterproof” because it was an absolute claim whose meaning could be easily misconstrued by consumers (Ref. 3). The agency believes that the term “waterproof” could be interpreted by consumers to mean something that is completely resistant to water regardless of time of immersion, a meaning which is not consistent with the meaning of the term in the Panel’s recommended monograph. Therefore, the agency is not proposing the labeling claim “waterproof,” but is proposing instead the term “very water resistant.” The term “water resistant” is defined as “resistant to wetting but not waterproof.” (For a discussion of water resistant and very water resistant testing, see comment 103.)

Regarding the use of the term “sweat resistant,” the agency is proposing in this tentative final monograph to permit the use of the terms “sweat resistant” or “resists removal by sweating” for a sunscreen drug product that qualifies for the claims of “water resistant” or “very water resistant.” (See comment 100.)

51. In the notice of public meeting to discuss appropriate testing procedures for OTC sunscreen drug products (52 FR 35398), the agency stated that there may be situations in which use of the Panel’s recommended criteria for a product to be labeled as “sweet resistant,” “water resistant,” or “waterproof” could lead to labeling that would be misleading to the consumer. For example, a product in the “moderate” PCD (SPF 4 to under 6) that maintained its PCD after 40 minutes of water immersion could be labeled “water resistant” whereas a product in the “ultra” PCD (SPF 15 or greater) that fell into the “maximal” PCD (SPF 8 to under 15) after the water immersion test could not. The agency was concerned that the Panel’s recommended labeling would not reflect that the latter product would provide more sun protection after immersion than would the former. The agency suggested that a possible way of avoiding such a situation would be to label a product with a PCD established under the ordinary test conditions and with a PCD established under the “sweat resistant,” “water resistant,” or “waterproof” test conditions (52 FR 33602).

Several comments were opposed to the idea of including two PCD’s or two SPF values in the labeling of OTC sunscreen drug products. Most felt that such labeling would lead to consumer confusion. Stating that there is a history of consumer use of products with only one SPF on their label, one comment contended that providing the consumer with two numbers—one representing the SPF value before water immersion and the other after water immersion—would be confusing and would require a major re-education campaign to facilitate the public’s understanding of the new labeling. Another comment stated that much effort has been made to educate the consumer to discern between waterproof and nonwaterproof products. The comment maintained that the labeling requirement for one SPF value recommended by the Panel is appropriate and represents a more conservative (and safer) approach to sunscreen products and consumer expectations. The comment suggested that not only should one SPF number be used on the principal display panel, but also that the description “waterproof,” “water resistant,” or “nonwaterproof” should be used in the label to qualify the conditions under which the SPF was tested. The comment believed that such labeling would eliminate the possible confusion of the conditions to which the claims applied. Another comment suggested that the agency require a manufacturer to label a sunscreen drug product with the most conservative SPF value that reflects a product’s performance. For example, if a product has waterproof properties, then the product label should display a single SPF value determined under the immersion criteria.

One comment stated that using two sets of PCD’s or SPF values on a label is inherently misleading and may cause confusion because the consumer may interpret the static SPF (i.e., the initial SPF of a product before water immersion testing) as applying to the waterproof or water resistant claim on the same label. One comment argued that dual labeling is a concession to those manufacturers unable to properly formulate a product with a comparable static or waterproof SPF value. The comment added that if a dual performance standard were imposed, manufacturers would be required to double the number of exposures to each test subject or, alternatively, double the number of test subjects that must be exposed in order to determine the static and water immersion SPF value.

One comment stated that there is no need to provide dual labeling of static and waterproof SPF values. The comment asserted that the label of a waterproof product only needs to display the waterproof SPF value (and not the static test value). Another comment stated that current labeling of sunscreen drug products makes it clear that the SPF value on the label is the SPF that is to be expected after water immersion. Another comment stated that if a manufacturer wants to make an SPF claim higher than the postimmersion SPF value of the product, the label should not contain “water related” claims. One comment recommended that the value of the SPF be tied to claims for sweat resistance, water resistance, or waterproofing. For example, if an SPF 15 sunscreen displays the claim “water resistant,” then the SPF value on the label should reflect the SPF value after 40 minutes of water immersion. Similarly, a “waterproof” sunscreen should be labeled with the SPF obtained after 80 minutes of water immersion.
would alleviate the need for water resistance claims to be tied to PCD's. It would also eliminate the possibility of an SPF 15 sunscreen decreasing to an SPF 8 after 40 minutes of water immersion and still being labeled as "water resistant."

Conversely, two comments agreed with the agency's proposal that sunscreen drug products should be labeled with both a static and a postimmersion SPF value. One comment stated that consumers would best be served by receiving complete information regarding the degree of protection that they can expect under various conditions, and dual labeling would allow consumers to make an informed purchase decision. The comment maintained that displaying only the waterproof SPF on waterproof sunscreen drug products is potentially misleading and confusing to consumers. The comment feared that a second SPF scale for waterproof products would be created, that it would be difficult for consumers to become aware of this scale, and that consumers would not be given enough information to compare sunscreen drug products on different scales. For example, consumers trying to choose between a static SPF 25 and a waterproof SPF 15 could easily choose the higher number even though its performance in water may be worse. The comment maintained that this result would be avoided by providing the option to list both static and waterproof SPF values for products that have also been tested for waterproofing. The comments added that this option would create consumer awareness of the two scales and would provide enough information for the consumer to make a rational product selection. Another comment proposed that when both static and waterproof SPF values are available for a product, both values should be permitted on the label if there is a difference in SPF levels of more than 5.

One comment stated that it did not believe that a dual labeling of static and waterproof SPF values is necessary. However, the comment maintained that, in special situations where a manufacturer wishes to label its product with both static and waterproof SPF values that are clear, truthful, and not misleading, it should be permitted to do so. The comment added that because such situations would be relatively uncommon, the dual labeling should be optional and not required. The comment supported the concept that truthful and nonmisleading optional labeling of dual static and waterproof SPF values should be allowed but should not be required. The comment added that an SPF value is deemed to be a static, nonwaterproof value unless the waterproof claim is affirmatively made.

The agency does not agree with the comments that dual SPF labeling of sunscreen drug products would be confusing to consumers. Although there is a history of sunscreen products with only one SPF value in their labeling, the agency believes that displaying two SPF values on water resistant and very water resistant sunscreen drug products will help to avoid consumer confusion when trying to determine which sunscreen to purchase (e.g., whether a non-water resistant SPF 25 or a water resistant SPF 15 is a more appropriate product for use). Including both a static SPF value and a water resistant or very water resistant SPF value in the labeling of water resistant sunscreen drug products will provide consumers with more information and assist them in selecting the type of product that they desire when purchasing a sunscreen drug product. Because this information involves the SPF values of the product, the agency is proposing that it appear on the principal display panel of the labeling of the product. Furthermore, the agency does not agree with some of the comments that such labeling should be optional. If dual labeling were optional, it would be confusing to the consumer because some water resistant products might display two SPF values while other water resistant products would display only one SPF value. One comment suggested that the description "waterproof," "water resistant," or "nonwaterproof" be used in the label to qualify the conditions under which the SPF was determined. In § 352.52(e) (2) and (3) of this tentative final monograph, the agency is proposing claims for sunscreen drug products that include "water resistant" for products that satisfy the water resistant testing procedures and "very water resistant" for products that satisfy the very water resistant testing procedures. In the absence of these claims, the agency does not believe that the consumer will expect the product to be water resistant or very water resistant. Regarding the use of the term "sweat resistant," the agency is proposing in this tentative final monograph to permit the use of the terms "sweat resistant" or "resists removal by sweating" for a sunscreen drug product that qualifies for the claims of "water resistant" or "very water resistant." (See comment 100.)

Regarding the comment that manufacturers would be required to double the number of exposures to each test subject or double the number of test subjects if dual SPF labeling were adopted, the agency notes that water resistant and very water resistant testing requires that two SPF values be determined. As the Panel recommended in its discussion of water immersion testing (40 FR 38206 at 38209) and the agency is proposing in this tentative final monograph, a sunscreen drug product must retain the same PCD after the water immersion testing as it had before water immersion testing. (See comment 101.) Therefore, for all water immersion testing, either double the number of exposures or double the number of test subjects is necessary.

In this tentative final monograph, the agency is proposing the following labeling in § 352.50, Principal display panel of all sunscreen drug products:

"(b) For products that satisfy the water resistant sunscreen product testing procedures in § 352.76.

(1) 'Water Resistant.'

(2) 'SPF=(insert SPF value before water resistant testing) before' (select one of the following: 'sweating' or 'perspiring') 'or going into the water. SPF=(insert SPF value resulting from water resistant testing) after 40 minutes of (select one of the following: 'sweating' or 'perspiring') 'or activity in the water.'"

(c) For products that satisfy the very water resistant sunscreen product testing procedures in § 352.76. (1) 'Very Water Resistant.'

(2) 'SPF=(insert SPF value before very water resistant testing) before' (select one of the following: 'sweating' or 'perspiring') 'or going into the water. SPF=(insert SPF value resulting from very water resistant testing) after 80 minutes of (select one of the following: 'sweating' or 'perspiring') 'or activity in the water.'"

H. Comments on Labeling for Drug/Cosmetic Sunscreen Products Such as Lipsticks, Make-Up Preparations, and Lip Balms

52. Several comments suggested that certain specific types of products containing sunscreens should be exempted from some of the labeling recommended by the Panel for sunscreen drug products. One comment maintained that much of the labeling information required by the Panel's recommended monograph was developed for beach products that are used to acquire a suntan and to prevent painful sunburn. According to the comment, such labeling is "irrelevant, inappropriate, and misleading" for everyday use of nonbeach beauty products that contain a sunscreen but that are not represented for use in the prevention of sunburn.
One comment maintained that the Panel's recommended rules are designed for the labeling of sunscreen lotions, liquids, and creams that are used over large areas of the body for the prevention of sunburn. It emphasized that lip balms are formulated in a small solid stick form that is used primarily as a skin protectant on a limited, specific part of the body, and protection from the sun's rays is a significant but secondary purpose. Therefore, according to the comment, lip balms should be exempted from some of the labeling recommended by the Panel. Another comment asserted that the Panel did not take the lip balm dosage form into consideration. This comment stated that not only is it physically impossible to place all of the recommended labeling requirements on a lip balm tube, but also several of the labeling requirements are inappropriate for lip balm products.

Another comment requested that lip balm products be exempted from the "Statement on Product Performance" requirements and the SPF numbering system. The comment cited the small surface area covered when lip balms are used and asserted that the SPF standards for skin protection would not apply to the lip balm's intended use on lip surfaces. The comment stated that an exemption could be based upon the designation of the product as a lip balm and/or a maximum quantity limitation such as 6 g of total ingredients or 100 mg of sunscreen ingredient.

Three comments suggested that the general warnings in § 352.50(c)(1) are not appropriate for lip balms. Specifically, one comment contended that the warning "For external use only, not to be swallowed" in § 352.50(c)(1)(i) is inappropriate and contradictory for balms. The comment asserted that people ingest minute quantities of the product under normal use conditions and that inclusion of the warning on the label would unnecessarily alarm and confuse consumers. A second comment stated that lip balms should be exempted from eye warning requirements because lip balms are not used close to the eyes. Another comment added that the warning "Avoid contact with the eyes" in § 352.50(c)(1)(i) is unnecessary for a product that is intended for use exclusively on the lips and that is formulated in a solid dosage form that cannot be splashed into the eyes. The comment added that lip balms have been marketed for a number of years and, consequently, consumers are aware of their use and application. The comment maintained that because lip balms are applied to small areas and are formulated with the same type base that has been used for decades without a significant number of adverse reactions, the warning "Discontinue use if signs of irritation or rash appear" in § 352.50(c)(2)(ii) should not be required for lip balms.

Another comment maintained that the warnings required by § 352.50(c)(2)(i) and (c)(2)(ii) should not apply to lip balms. Stating that although it is unlikely that the need for using a lip balm on a child 6 months of age or younger would arise, if such a need did arise, the attention of a physician would not be necessary prior to prophylactic use on the child's lips and the safety of this use would be the responsibility of the physician. Another comment requested that lip balm products be exempted from the directions for use on large skin areas when swimming or sunbathing around water, one comment requested that lip balms be exempted from the directions for use recommended by the Panel. Another comment suggested placing only essential information on the label because of the limited label area, and it submitted proposed labeling for its product. Because lip balms are not designed for use on large skin areas when swimming or sunbathing around water, one comment requested that lip balms be exempted from the directions for use recommended by the Panel. Another comment requested that lip balm products be exempted from the directions for use recommended by the Panel. Another comment suggested placing only essential information on the label because of the limited label area, and it submitted proposed labeling for its product.

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Because lip balms were not designed for use on large skin areas when swimming or sunbathing around water, one comment requested that lip balms be exempted from the directions for use recommended by the Panel. Another comment requested that lip balm products be exempted from the directions for use recommended by the Panel. Another comment suggested placing only essential information on the label because of the limited label area, and it submitted proposed labeling for its product.

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most part, primarily intended for use under extreme conditions, such as a day at the beach. Since then, as more information has become available regarding the adverse effects of daily exposure to the sun, more and more daily use products have been formulated to contain sunscreens. (For a further discussion of the adverse effects of sunlight, see comments 46, 53 and 56.) Such products may be primarily cosmetics to which sunscreens have been added to provide protection against UV radiation. The agency now tentatively concludes that these products are drugs because they contain sunscreens and bear drug claims.

The agency believes that some of the indications recommended by the Panel in §352.50(b)(1) (e.g., “Sunscreen to help prevent sunburn,” and “Screens out the sun’s harsh and often harmful rays to prevent sunburn”) were intended primarily for traditional sunscreen products. Given the range of products that now contain sunscreens, these indications are not appropriate for use on all of those products. Therefore, the agency is proposing to revise the Panel’s recommended §352.50(b)(1) by adding new indications to be used on the labeling of lipsticks, make-up preparations, lip balms, and other “nonbeach” products that contain sunscreen ingredients and is moving these indications out of §352.50. The agency is placing these indications in §352.52 as follows: §352.52(b)(1)(iv) (Select one of the following: “Filters” or “Screen”) “out the” (select one of the following: “sun’s rays,” “sun’s harsh rays,” or “sun’s harmful rays”) “to help prevent” (select one or more of the following: “lip damage,” “skin damage,” “freckling,” or “uneven coloration”), and §352.52(b)(1)(vi) (Select one of the following: “Protects from” or “Shields from”) (select one of the following: “the harmful rays of the sun” or “the sun”) “to help prevent” (select one or more of the following: “lip damage,” “skin damage,” “freckling,” or “uneven coloration”). The agency agrees with the comments that the PCD labeling statements in §352.50(e) of the Panel’s recommended monograph are not appropriate or relevant to the use of “nonbeach” products such as make-up preparations, skin preparations, lipsticks, or lip balms that contain sunscreens. The agency is proposing that PCD statements for these products, as well as for other sunscreen products, be optional information that may be used in labeling if a manufacturer wishes. (See comment 44.)

The agency believes that sunscreen-containing drug products that are formulated as lip balms and lipsticks do not require the warning “For external use only, not to be swallowed” recommended in §352.50(c)(1)(i) of the Panel’s monograph. During normal use some of the product will invariably be swallowed; therefore, the above warning might be confusing to consumers. Only minuscule amounts of a sunscreen-containing lip balm or lipstick are likely to be swallowed, and the agency believes that these amounts pose no risk to the user. Consequently, the agency tentatively concludes that the warning is not necessary for the safe use of such products. Furthermore, in the tentative final monograph for OTC skin protectant drug products published in the Federal Register of February 15, 1983 (48 FR 6820 at 6829), the agency also concluded that lip balm drug products do not require the warning “For external use only” to assure safe use. Therefore, in this tentative final monograph, the agency is proposing to add §352.52(c)(3), “For products containing any ingredient identified in §352.10 formulated as a lip balm or lipstick. The warning in paragraph (c)(1)(i) of this section is not required.”

The agency believes that any sunscreen-containing drug product that may be used near the eyes should be required to display the warning in §352.52(c)(1)(ii) of this tentative final monograph, “Avoid contact with the eyes. If contact occurs, rinse eyes thoroughly with water.” (See comment 62.) In addition to ocular irritancy problems, a product that is not formulated specifically for the eyes could cause problems because it is not sterile. Therefore, the product should not be permitted for use near the eyes and consumers should be warned against “contact with the eyes” in the labeling of any product that is intended for use near the eyes. The agency is aware that, although lipsticks are not intended for use near the eyes, there are sunscreen-containing lip balms that are indicated for use on “other sunsensitive areas of the face” such as the nose (Ref. 2). Such lip balms could be used near the eyes, as could other lip balms. Consequently, the agency is proposing to require that these products display the warning.

On the other hand, the agency believes that this warning is not necessary for OTC sunscreen drug products such as lipsticks that are not normally used near the eyes. Therefore, the agency tentatively concludes that lipsticks that contain sunscreen ingredients should not be required to display the warning “Avoid contact with the eyes. If contact occurs, rinse eyes thoroughly with water.” The agency is proposing new §352.52(c)(4) as follows: “For products containing any ingredient identified in §352.10 formulated as a lipstick. The warning in paragraph (c)(1)(ii) of this section is not required.”

The agency believes that the warning in §352.50(c)(1)(iii) of the Panel’s proposed monograph, “Discontinue use if signs of irritation or rash appear,” is an appropriate warning for any product that contains a sunscreen ingredient. Any product intended for use on the skin may contain ingredients that cause irritation or allergic reactions in susceptible consumers. The appearance of irritation or a rash may be the result of a toxic or allergic reaction to an ingredient in a product; consumers should be adequately warned to discontinue use if such signs appear. The agency is also proposing to revise the Panel’s recommendation by adding the sentence “If irritation or rash persists, consult a doctor.” (See comment 63.) Therefore, the agency is proposing the following warning in §352.52(c)(1)(iii): “Discontinue use if signs of irritation or rash appear. If irritation or rash persists, consult a doctor.” The agency is proposing to require this warning for all drug products that contain a sunscreen, irrespective of whether the product is intended for beach or nonbeach use.

The agency believes that the specific warnings proposed by the Panel in §352.50(c)(2)(i) and (c)(2)(ii) that refer to the use of sunscreen ingredients in children are not relevant to the use of sunscreen-containing make-up products such as foundations or lipsticks that display sunscreen drug claims and that are not normally used only in the adult female population. However, the agency concurs with the Panel’s age limit recommendations for sunscreen-containing lip balms and skin preparations that display drug claims because such products are more likely to be used on children. The Panel found no convincing evidence that sunscreen ingredients are safe for use on children under the age of 6 months, or that sunscreen products with an SPF value of less than 4 provide reasonable protection for children between 6 months and 2 years of age. The agency has not been presented with any such evidence since the Panel completed its review. In order to be consistent with other recently published documents, the agency is deleting the Panel’s recommended warnings in §352.50(c)(2)(i) and (c)(2)(ii), as discussed below, and is including the content of the warnings in the proposed directions in §352.52(d). (See comments 61 and 68.)

The agency agrees with the comments that the directions proposed by the
Panel are not relevant to the use of sunscreen-containing drug products, such as lip balms, make-up preparations, and skin preparations, which are not intended for beach use and do not claim to prevent sunburn. Given the similarity in products, the agency believes that the directions for skin protectants proposed in § 347.50(d) of the tentative final monograph for OTC skin protectant drug products (48 FR 6820 at 6833) are appropriate to the above dosage forms if the directions are revised to include age limitations relevant to the dosage forms. Therefore, the agency is proposing in § 352.52(d) the following directions for sunscreen-containing drug products such as lip balms, make-up preparations, skin preparations, and lipsticks:

(4) For products containing any ingredient identified in § 352.10 labeled with only the indications in § 352.52(b)(1)(v) and/or (vi) and formulated as a make-up preparation or lipstic, “Apply liberally as often as necessary.”

(5) For products containing any ingredient identified in § 352.10 labeled with only the indications in § 352.52(b)(1)(v) and/or (vi) and formulated as a lip balm or skin preparation. “Adults and children 6 months of age and over: Apply liberally as often as necessary. Children under 2 years of age should use sunscreen products with a minimum SPF of 4. Children under 6 months of age: consult a doctor.”

References

(1) Comment No. SUP004, Docket No. 78N–0036, Dockets Management Branch.

(2) OTC Vol. 060004

I. Comments on Indications for Sunscreen Drug Products

53. One comment stated that the primary emphasis of the Panel's report was on protection against UVB radiation but that the Panel should have addressed the question of photoprotection against UVA radiation (320 to 400 nm). The comment added that UVB radiation shorter than 310 nm contributes only 1.65 percent of the solar energy at the earth's surface. The comment maintained that although UVA radiation is less erythemogenic than UVB radiation, UVA radiation contributes to sunburn reactions when skin is exposed to the sun for prolonged periods (60 to 120 minutes). The comment stated that approximately 8 to 10 percent of the solar energy at the earth's surface is in the UVA range. The comment contended that those UVA wavelengths can stimulate the production of new melanin, are responsible for most of the phototoxic and photosensitivo skin reactions, and can contribute to wrinkling and actinic elastosis. Stating that the Panel's report contained no recommendations for the evaluation of sunscreens that absorb radiation in the UVA range, the comment offered to assist in formulating such procedures. In response to the notice of a public meeting to discuss OTC sunscreen testing procedures (52 FR 33598) and to the January 26, 1988 meeting, the agency received several comments regarding the use of sunscreens to protect individuals against UVA radiation. One comment stated that until recently sunscreens were formulated to protect individuals against UVB radiation (290 to 320 nm) and to allow the transmission of UVA radiation (320 to 400 nm) into the skin for stimulating melanogenesis (tanning reaction). The comment stated that recent evidence appearing in recognized journals of dermatology and photobiology indicates that UVA radiation is erythromogenic and carcinogenic and that it promotes photoaging. The comment added that the growing popularity of high-intensity UVA sources for "cosmetic tanning" has raised serious concerns among dermatologists regarding the potential hazards of UVA radiation to the skin, eyes, and immune system. The comment acknowledged that "a manufacturer must obtain an IND (Investigational New Drug) application to justify its claims" for new UVA absorbing compounds. However, the comment noted that if a company manufactures a sunscreen using the "existing 21 compounds which have been approved by the FDA," the manufacturer may market a UVA sunscreen without an "IND." The comment added that the Photobiology Task Force of the AAD is interested in recommending approaches to the evaluation of UVA absorbing sunscreens and is willing to submit such recommendations to the agency if so directed.

Another comment urged the agency to reopen the administrative record to include the "labeling, evaluation, etc." of "broad-spectrum" sunscreens and to develop a detailed system for adding new active ingredients to the monograph. A third comment stated that the issues of broad spectrum sunscreens are of increasing importance to consumers, but were not directly considered in the submissions to the Panel or in the Panel's recommended rule. These issues include UVA protection and the contribution of UVA radiation to premature aging, wrinkling, and skin cancer. The comment maintained that these issues represent a long-term, chronic health problem that should be addressed by the agency. A fourth comment requested that the agency publish a separate call for data to address sunscreens that provide UVA protection and to discuss methodologies and claims that can be made for these sunscreens.

Data and labeling regarding UVA protection were submitted to the Panel (Refs. 1 through 5), and the Panel discussed UVA radiation in its report (43 FR 38206 at 38209). Several of the 21 sunscreen active ingredients classified as Category I by the Panel have absorption spectra that extend into the UVA range. For example, dioxybenzone (260 to 380 nm) (Ref. 6), methyl anthranilate (290 to 360 nm) (Ref. 7), oxybenzone (270 to 350 nm) (43 FR 38239 and Ref. 6), sulisobenzone (270 to 360 nm) (Ref. 6), red petrolatum (260 to 380 nm) (Ref. 6), titanium dioxide (290 to 700 nm) (Ref. 6), and the Panel stated that sunscreens protect against "sunburn," the "sun's burning rays," or the "sun's harsh and often harmful rays." Since the Panel's report was published (1978), many reports have been published in the scientific literature indicating that UVA radiation, like UVB radiation, is harmful to the skin. (See comment 86.) Thus, the agency believes that consumers will benefit from labeling on OTC sunscreen drug products that clearly indicates if a
product provides protection against UVA radiation.

The agency is aware that UVA radiation contributes to both acute and chronic skin damage such as erythema, melanogenesis, carcinogenesis, drug-induced photosensitivity, photoaging, and morphological alterations of Langhans cells (Ref. 6). Although UBV radiation is much more erythrogenic than UVA radiation, the large amount of UVA radiation present in the solar spectrum at the earth's surface results in a significant contribution to erythemogenesis. In fact, UVA radiation may contribute 15 percent of the erythemal effectiveness of the solar spectrum at noon. At other times of the day, because of the greater atmospheric attenuation of shorter wavelengths with increasing zenith angle, the contribution of longer wavelengths may be relatively greater (Ref. 10). It has also been reported that UVA radiation penetrates the skin more efficiently than UBV. Approximately 40 to 50 percent of UVA radiation is transmitted through Caucasian epidermis compared to 10 to 30 percent of UVB radiation (Refs. 11 and 12). UVA radiation penetrates more deeply into the skin than does UVB radiation (Ref. 12). In addition, the agency is concerned that sunscreens with higher SPF values allow consumers to remain in the sun for longer periods of time without burning, thus increasing UVA exposure. Accordingly, protection against UVA radiation is much more important than previously realized. The agency believes that protection against UVA radiation may be as important to consumers' well-being as protection against UVB radiation.

The agency wants to ensure that a sunscreen ingredient claiming to protect consumers against UVA radiation truly offers such protection. According to a 1989 NIH consensus development statement on sunlight, UV radiation, and the skin, recent evidence suggests that the longer UVA wavelengths (i.e., UVA I, 340 to 400 nm) are less damaging than shorter UVA wavelengths (i.e., UVA II, 320 to 340 nm), but further research is needed to confirm the distinction (Ref. 13). It has been reported that long wavelength UVA radiation induces connective tissue damage that is related to human photoaging (Ref. 14) and that wavelengths longer than 340 are effective in producing tumors (Ref. 15).

Sunscreen ingredients whose spectra extend only into the lower UVA range (i.e., oxybenzone and possibly lawson with dihydroxyacetone) may not absorb sufficient UVA radiation to provide an adequate level of protection against that radiation. Thus, UVA protection claims in the labeling of products containing such ingredients would be partially false and would be misleading. To ensure that sunscreen products displaying UVA protection claims offer significant UVA protection, the agency is proposing that a Category I OTC sunscreen ingredient must have an absorption spectrum extending to 360 nm or above in the UVA range (e.g., dioxybenzone, lawson with dihydroxyacetone, octocrylene, octyl methoxycinnamate, red petrolatum, sulisobenzone, and titanium dioxide), and (2) the product containing the ingredient demonstrates UVA protection using appropriate testing procedures that the agency is proposing be developed. The labeling for acceptable products would include the following: (Select one of the following: “Protects against,” “Absorbs,” “Screens out,” or “Shields from”) “UVA” (select one of the following: “Rays” or “radiation”). A product that contains ingredients that absorb and/or reflect both UVA and UVB radiation may also display the following labeling: “Broad spectrum sunscreen: provides protection against UVB and UVA radiation.” As noted in comment 73, there is a lack of adequate information for FDA to propose a method for determining UVB protection. Accordingly, although these indications are discussed in this document for public comment, they are not currently included in the tentative final monograph. At this time, OTC sunscreen drug products may bear UVA claims provided that they (1) Contain sunscreen active ingredients that absorb UVA radiation (e.g., dioxybenzone, lawson with dihydroxyacetone, octocrylene, octyl methoxycinnamate, red petrolatum, sulisobenzone, and titanium dioxide), and (2) meet the agency’s enforcement policy which allows claims that were available in labeling prior to the beginning of the OTC drug review to appear in the labeling of currently marketed products until the rulemaking for OTC sunscreen drug products is completed, and the regulation for this class of products becomes effective (Ref. 16).

The agency does not believe that a separate call for data is necessary to address OTC sunscreens that provide UVA protection. Some data have already been submitted to this rulemaking, and this publication informs interested persons how the agency is proceeding. Any interested person may submit data and information in response to the publication of this proposed rule. If necessary, an amendment to this tentative final monograph will be published in a future issue of the Federal Register to address any comments concerning UVA claims and testing procedures received in response to this proposal.

The agency emphasizes that ingredients not included in the monograph, and new chemical entities that protect against UVA exposure, are considered to be new drugs; as new drugs they must be the subject of an approved application before they may be marketed in the United States with UVA claims. The agency’s detailed comments on the data are on file in the Dockets Management Branch (Ref. 17).

References

(1) OTC Vol. 060037.
(2) OTC Vol. 060006.
(3) OTC Vol. 060125.
(4) OTC Vol. 060015.
(5) OTC Vol. 060154.
(12) Kligman, L.H., F.J. Akin, and A.M. Kligman, "The Contributions of UVA and


(16) "Food and Drug Administration Compliance Policy Guides 7132b.15 and 7132b.16," in OTC Vol. 06ATFM, Docket No. 78N–0038, Dockets Management Branch.


54. One comment suggested that the first sentence of the indications section (§ 352.50(b)) be revised as follows: "The labeling of the product contains a statement of the indications under the heading 'Indication(s)' and is limited to one or more of the following phrases, which may be combined to eliminate duplicative words or phrases. The comment contended that the phrase 'which may be combined to eliminate duplicative words or phrases' appears in other OTC drug monographs and allows the inclusion of all pertinent information without redundancy. The agency agrees that wherever practicable duplicative words and phrases in the indications should be eliminated. The agency has applied this principle in developing the indications proposed in this tentative final monograph. The agency has combined some of the Panel's recommended indications, revised others, and provided several optional ways for stating some indications. (See comments 56, 57, and 58.) Additionally, the agency has revised its labeling policy to allow for more alternatives in stating the indications for all OTC drug products. (See comment 39.) Therefore, it is not necessary to make the revision suggested by the commenter.

55. One comment believed that sunscreen drug products with an SPF of 2 should not be allowed to make a claim for sunburn protection. The comment felt that the laboratory conditions under which an SPF is determined are artificial and are not likely to duplicate actual usage conditions. The comment stated that sunbathers apply sunscreens while in constant physical activity, and therefore rubbing against clothing, towels, etc., is almost unavoidable. This activity plus high temperature, humidity, and sweating collectively reduce the efficacy of a sunscreen in sunlight. The comment submitted a published paper (Ref. 1) discussing studies that it contended found a poor correlation between the indoor (laboratory) SPF value and the SPF value determined in sunlight. The SPF value determined in sunlight was significantly lower, which the authors attributed to heat, perspiration, etc., during outdoor testing. Thus, according to the comment, a product with a laboratory SPF of 2 will provide virtually no protection in sunlight, and a consumer using such a product will have "a false sense of safety." The comment stated that it is widely recognized that chronic UV radiation damage is a cumulative phenomenon, with every exposure contributing to the final damage. The comment contended that individuals who are allegedly "not sun-sensitive" and use sunscreen products with low SPF values are at risk if they use products with an SPF of 2. The comment stated that every effort should be made to "spare" individuals from unnecessary UV exposure and, therefore, the lowest allowable SPF value should be 4.

The Panel discussed various skin types and the categories of sunscreen products recommended for each skin type (43 FR 38206 at 38213 to 38215). The Panel determined that there are six skin types based on the different reactions of individuals to sunlight, i.e., whether they burn easily, moderately, or not at all. Of the six skin types, the Panel listed three types, i.e., IV, V, and VI, for individuals who burn minimally, rarely burn, or never burn. For Skin Types IV and V, the Panel recommended sunscreen products that provide a minimal amount of protection with SPF values of 2 to under 4. For individuals with Skin Type VI, the use of a sunscreen product was not recommended.

Because there is a population who could use sunscreen products providing minimal protection, the agency believes that it would be inappropriate to eliminate these products from the marketplace. Such products offer protection to those individuals who burn minimally or rarely burn. Therefore, the agency does not accept the comment's recommendation. The agency is proposing a product category designation of "minimal" for sunscreen drug products that have an SPF value of 2 to under 4 and offer minimal protection against sunburn. As part of required labeling information, the agency is proposing a Recommended Sunscreen Product Guide that will provide consumer information on skin types and corresponding recommended SPF values of sunscreen drug products. (See comment 43.)

The agency has considered the paper submitted by the comment that shows a difference between the indoor (laboratory) SPF value and the outdoor (sunlight) SPF value (Ref. 1). The agency notes that the authors stated that the study demonstrated that the solar simulator can accurately reproduce the sunburn erythemogenic effect of natural solar radiation. However, the authors also stated that factors other than UV radiation enter into the determination of the SPF of a sunscreen product (e.g., environmental factors, such as skin temperature). The authors contended that if these environmental conditions are controlled, the SPF value obtained with a solar simulator is similar to that obtained using natural sunlight. A later study by some of the same authors (Ref. 2) showed good correlation between the indoor and outdoor SPF's of sunscreens with high substantivity. (See comment 79 for further discussion of this subject.)

References


56. Several comments urged the agency to adopt the Panel's recommended labeling in § 352.50(b)(1)(iv) that states, "Overexposure to the sun may lead to premature aging of the skin and skin cancer. The liberal and regular use over the years of this product may help reduce the chance of these harmful effects," and in § 352.50(b)(1)(v) that states, "Overexposure to the sun may lead to premature aging of the skin and skin cancer. The liberal and regular use over the years of this product may help reduce the chance of premature aging of the skin and skin cancer." One comment noted that a final rule published in the Federal Register of April 29, 1977 (42 FR 22018) required a warning on the labels of aerosolized products containing chlorofluorocarbons. In that rule, the agency stated that the use of aerosols containing those ingredients could contribute to degradation of the earth's ozone layer, resulting in an increase in UV radiation and a possible increase in...
information to the Panel's statement that "Premature aging due to overexposure to the sun. Stating that this "warning/indication" labeling is based on clear and convincing scientific evidence, the comment objected to the Commissioner's statement in the preamble to the Panel's report (43 FR 38206) that this labeling might be misleading or confusing to consumers.

A second comment contended that the Commissioner based his statement concerning the aging/cancer warning/indication labeling in part on a minority report of three of the seven Panel members, who were opposed to the use of these statements. The comment argued that the minority report did not question the conclusion of the Panel majority. According to the comment, the minority report addressed the majority's presupposition that a person will use a sunscreen product correctly and that there may be skin alterations not yet manifested that could result in skin cancer whether or not the product is used. With respect to pre-existing skin conditions that could lead to cancer, the comment stated that "no drug product will aid in the prevention of a disease condition once that condition has occurred." The comment further stated that the minority report did not fully consider the language of these statements. The comment explained that, although the statements inform the consumer that the product may help prevent the harmful effects of the sun, they do not promise that the product will absolutely prevent the harmful effects. The comment urged the Commissioner to discount the minority report and to adopt the labeling recommended by the Panel majority. The comment concluded that the proposed statements would be an effective means of educating the public to use a sunscreen product early, regularly, and liberally in order to minimize the detrimental effects of long-term overexposure to UV radiation from the sun.

The comment also suggested adding to the above statements terminology that describes premature aging of the skin due to overexposure to UV radiation, e.g., "wrinkling of the skin." Noting the Panel's statement that "Premature aging of the skin refers to the thinning, dryness, and fine wrinkling produced by the exposure of the skin to sunlight" (43 FR 38206 at 38211), the comment contended that addition of such information to the Panel's recommended statements would aid consumers' understanding of the consequences of overexposure to the sun, and would implement the Panel's recommendations.

Two comments objected to labeling sunscreen drug products with claims concerning premature aging of the skin and skin cancer. One comment maintained that such labeling is unnecessary because everyone knows that exposure to the sun may lead to premature skin aging and skin cancer. The other comment stated that sunscreen products will not prevent skin cancer on skin that sunburns easily. That the comment argued that any mention of helping to prevent cancer on the label of sunscreen products should be avoided because it may mislead people into a false sense of security. Referring to a sunscreen lotion labeled with the statement "May help prevent harmful effects of sun," the comment recommended that the qualifying phrase "In high altitude" be added to the label. Referring to personal experience, the comment added that a basal cell epithelioma still developed even though a sunscreen lotion was used all summer and sun exposure was avoided between the hours of 10:00 a.m. and 4:00 p.m. Three comments supported the indication "may reduce harmful effects of the sun" recommended by the Panel minority (43 FR 38212). One comment added that the recommended indication would be good if the word "may" is legible because consumers do not read fine print. A second comment suggested combining this indication with part of the Panel's recommended indications in §352.50 (b)(3)(iv) and (b)(3)(v), as follows: "May reduce harmful sun rays that may lead to premature aging of the skin and skin cancer." A third comment suggested that the recommended indication in §352.50 (b)(3)(iv) and (b)(3)(v), which refer to "liberal and regular use," should be revised to state "proper and regular use" or "when used regularly as directed."

Another comment contended that the wording of the Panel's recommended statements in §352.50 (b)(3)(iv) and (b)(3)(v) will be exploited by advertisers and that consumers will be misled. The comment stated that it agreed to a certain extent with the report of the Panel minority (43 FR 38206 at 38212) in that "any claim of this nature should only be approved if it is supported by experimental data." According to the comment, it is not scientifically correct to state that any sunscreen will reduce the harmful effects of the sun because the protection afforded by a sunscreen product with an SPF value of 8 or more (PFD designation maximal, ultra) is being equated with that afforded by a product having an SPF value of 2. In addition, the comment stated that the term "skin cancer" in the indication statement should be changed to "nonmelanoma skin cancer" because the claim that the regular use of sunscreens may help reduce the chance of melanoma skin cancer should be investigated before approval. Stating that the word "nonmelanoma" has no meaning to consumers, a reply comment disagreed with the recommendation that "skin cancer" be changed to "nonmelanoma skin cancer." The reply comment also contended that even an SPF of 2 will provide twice the skin's natural protection from disease states that may be caused by long-term overexposure to UVB radiation.

The agency has reviewed recently published literature (Refs. 1 through 11) that was not available to the Panel. This literature supports the Panel's view that (1) exposure to sunlight/UV radiation is related to skin cancer and premature aging (i.e., skin aging), and (2) the regular use of sunscreens will reduce individuals' risk of skin aging and skin cancer due to the sun (43 FR 38206 at 38210 to 38211). The Panel recommended that the labeling of sunscreen drug products should alert the consumer to the harmful effects of sunlight (43 FR 38211); however, the indications suggested by the Panel in §352.50 (b)(1)(vi) and (b)(1)(vii) of its monograph are optional labeling. The agency agrees with the Panel that consumers should be alerted to the risks of premature skin aging and skin cancer due to exposure to the sun. The agency also agrees with one comment that such labeling would be an effective means of educating the public to use sunscreens to minimize the detrimental effects of long-term exposure to the sun. Because of the seriousness of these adverse effects, the agency is proposing labeling in this tentative final monograph that will require all sunscreen drug products to inform consumers that the sun may damage the skin and that using sunscreens may help to reduce the risk of damage. After carefully considering the Panel's recommendations in §352.50 (b)(1)(iv) and (b)(1)(v), which identified the risks of skin aging and skin cancer due to the sun, the recommendations of the Panel minority which did not identify the specific risks (43 FR 38206 at 38212), the available literature (Refs. 1 through 11), and the comments regarding these labeling recommendations, the agency is proposing to revise the Panel's recommendations in §352.50 (b)(1)(iv) and (b)(1)(v) (as described below) and
including the revised statement in § 352.52(e)(6) of this tentative final monograph.

The agency disagrees with the comment that stated the indications that warn of harmful effects of the sun should not apply to all sunscreens, because sunscreens with low SPF values are not equivalent in protection to sunscreens with high SPF values. While the use of sunscreens with high SPF values provides greater protection from the harmful effects of the sun, any reduction in exposure to the sun, regardless of SPF value, may be of benefit in reducing the risks of harmful effects. Furthermore, consumers with nonsensitive skin who only need to use sunscreens with low SPF values should also be warned of the harmful effects of sunlight. In addition, the agency believes that a statement relating to the harmful effects of the sun should be required in the labeling of all sunscreen drug products.

The agency does not agree that the indications recommended by the Panel in § 352.50 (b)(1)(iv) and (b)(1)(v) should warn the consumer that the sunscreen product will not help protect the consumer from skin cancer at high altitudes. The amount of incident light is affected by many factors, only one of which is altitude. While the comment has merit, the agency finds it impractical to include in the labeling just one of many factors that may increase exposure. Further, this information could be misleading unless all factors that may increase exposure were included. The agency sees no reason to require such labeling.

However, the agency is not opposed to such descriptive information appearing in the labeling of sunscreen drug products if manufacturers wish to include it, provided that the information does not appear in the required labeling, is truthful, and is not misleading.

The agency does not believe that “premature aging” of the skin should be defined as “wrinkling” in the high indications recommended by the Panel in § 352.50 (b)(1)(iv) and (b)(1)(v). Wrinkling is only a part of the process of premature aging of the skin due to excessive exposure to UV radiation and should not be elevated to greater significance than other signs of premature skin photosaging. In addition to wrinkling, photosaged skin displays a variety of benign, premalignant and malignant neoplasms, accentuated skin furrows, sags and bags, and a leathery, nodular, yellow sun-damaged telangiectatic (i.e., a vascular lesion formed by the dilation of a group of small blood vessels) traceries. The most drastic of these visible aspects reflect the profound structural changes in the dermis (Ref. 5). (For a discussion of the agency’s tentative conclusion regarding the use of the term “anti-aging” or similar terms in the labeling of OTC sunscreen drug products, see part II, paragraphs B.51, 52, and 53—Summary of the Agency’s Changes.)

The agency believes that changing the term “Skin cancer” to “Nonmelanoma skin cancer” in the indications recommended by the Panel in § 352.50 (b)(1)(iv) and (b)(1)(v), as suggested by one comment, is unnecessary. Most consumers are not likely to recognize the term or would need a specific definition to decide whether or not to use sunscreens to help reduce the chance of skin cancer. To avoid misleading those consumers who are aware of specific types of skin cancer, the agency is proposing language that refers to “some types of skin cancer” rather than “skin cancer.”

The agency agrees with one of the comments that the indications proposed by the Panel in § 352.50 (b)(1)(iv) and (b)(1)(v) should be revised and is proposing to replace the Panel’s recommended phrase “the liberal and regular use over the years” with the phrase “regular use ** over the years” because regular use is more important than liberal use. The agency notes that proper use of some sunscreen formulations does not require “liberal” application. In this tentative final monograph, the agency is proposing directions for OTC sunscreen drug products that are applicable to various dosage forms. (See comment 66.) Because this proposed statement combines the attributes of an indication and a warning and is informational in nature, the agency believes that the statement should stand on its own and be distinctive in labeling. The agency is aware that some marketed products contain labeling entitled “Red Alert” to remind consumers to avoid the sun when the skin begins to burn (turn red). The agency agrees with using the term “ALERT” to readily gain consumers’ attention when reading a label. However, the agency believes that for these products the term “SUN ALERT” is more informative to consumers. Further, consumers should be advised to be careful regarding all sun exposure, not only exposure after the skin has begun to burn. Therefore, in this tentative final monograph, the agency is proposing a new heading, “SUN ALERT.”

The agency is further proposing that the heading “SUN ALERT” be followed by a statement that has been developed by simplifying the “skin aging/cancer” indications recommended by the Panel in § 352.50 (b)(v) and (b)(v)]. This revision begins with a positive statement for which extensive scientific evidence exists: “The sun causes skin damage.” The agency has determined that the term “overexposure,” recommended by the Panel, is not necessary in this statement because any amount of sun exposure can potentially harm the skin. The amount of sun exposure that will cause harmful effects is relative to a person’s skin type and predisposition to skin damage, and thus is not appropriate in labeling. The term “premature” has also not been included in the proposed statement because the agency believes that this term has different meanings to different individuals. The agency is not aware of any data showing that the term is generally understood by consumers when describing effects of the sun on the skin.

The new proposed statement includes the phrase “regular use of sunscreens over the years,” which implies that any sunscreen may reduce the chance of the harmful effects due to the sun. Otherwise, the Panel’s recommended statement “regular use over the years of this product” constitutes an endorsement of the sunscreen drug product on which the labeling statement appears. Evidence shows that any sunscreen when properly applied may help reduce the chance of the harmful effects of the sun. In addition, the term “liberal” has not been included in the statement because individual products provide adequate directions for use.

The agency invites specific comment on this proposed new “SUN ALERT” labeling statement. The agency encourages manufacturers to include this statement in the labeling of all sunscreen drug products. Until the final rule for OTC sunscreen drug products is published, manufacturers may use either the Panel’s earlier recommended statement or this proposed “SUN ALERT” statement in their products’ labeling. The final rule will state the exact language that will need to be used when it becomes effective. (For further discussion of the “SUN ALERT” statement, see part II, paragraphs B.51, 52, and 53—Summary of Agency Changes.)

The agency has carefully examined the wording of the indications proposed by the Panel in § 352.50 (b)(1)(iv) and (b)(1)(v) and has revised the language to eliminate vague or unnecessary terms resulting in a single required statement. The agency believes that this statement should appear verbatim on all sunscreen drug products, regardless of any other labeling, and should be preceded by the
phrase "SUN ALERT." Any language in the product's labeling that does not relate skin aging or skin cancer as being "due to the sun" will cause the product to be misbranded under section 502 of the act (21 U.S.C. 352). (See Part II, paragraphs 5.1, 52, and 53—Summary of the Agency's Changes, for labeling information that is appropriate for daily use (nonbeach products) as well as for products that are intended for occasional use (beach products).)

Therefore, in this tentative final monograph, the agency is proposing to replace the Panel's recommended § 352.50(b)(1)(iv) and (b)(1)(v) with the following statement in § 352.52(b)(6): For products containing any ingredient in § 352.10, the following statement may be used: "SUN ALERT: The sun causes skin damage. Regular use of sunscreens over the years may reduce the chance of skin damage, some types of skin cancer, and other harmful effects due to the sun."

The agency is also proposing to include in § 352.52(e)(7) the following statement: For products containing any ingredient identified in § 352.10. Any variation of the statement in § 352.52(e)(6) that does not relate skin aging or skin cancer as being "due to the sun" will cause the product to be misbranded under section 502 of the act (21 U.S.C. 352).

References

(10) "Focus on Photodamage," edited by the Skin Photomedicine Foundation, in OTC Vol. 68.ATPM, Docket No. 78N–0038, Dockets Management Branch.

57. One comment questioned the use of the word "before" in § 352.50(e), which states that the user may "Stay in the sun twice [4 times, etc.] as long as before without sunburning." The comment argued that "before" is very vague and could imply that the product is twice as effective as other products. The comment suggested that the statement should reflect the wording recommended by the Panel under "Additional indications" (§ 352.50(b)(2)) by stating that the user "could stay in the sun two (four, six, etc.) times longer than without sunscreen protection." Another comment suggested that the statement "Provides ___times your natural protection against sunburn" would be clearer than the Panel's recommended labeling.

Another comment contended that the application density used in the sunscreen testing procedures is often very different from the actual amount of sunscreen applied by a consumer during normal usage. Therefore, the claim "(this sunscreen product) provides x times your natural sun burn protection," where "x" equals the sunscreen's SPF, is usually false because the two preconditions that are necessary to support this claim are rarely met. The comment described the two preconditions as (1) the application density used by the consumer must be the same as that used in the sunscreen testing procedures, and (2) the SPF value of a sunscreen product must be the same whether tested indoors using artificial UV radiation sources or outside using the sun as the UV-radiation source.

In order to resolve this apparent dilemma, the comment suggested that the agency should disallow the claim that a sunscreen "provides x times your natural sunburn protection." The comment added that "Provides up to x times your natural sunburn protection" is a viable alternate claim. The comment maintained that if this claim were eliminated or altered as suggested, the SPF number on a product would continue to provide consumers with a means of comparing sunscreens but would be a relative, rather than an absolute, parameter for evaluating sun protection.

In § 352.50(b)(2) of its recommended monograph, the Panel included several indications that could be used in addition to the indications recommended in § 352.50(b)(1). These additional indications are based upon a product's PCD and include two basic indications that refer indirectly to the product's SPF value. For example, in § 352.50(b)(2)(i)(f), (b)(2)(ii)(e), (b)(2)(iii)(g), and (b)(2)(iv)(e), the Panel recommended that sunscreen products could display the following indication according to their PCD: "Allows you to stay in the sun [two, four, six, or eight] times longer than without sunscreen protection." In § 352.50(b)(2)(i)(g), (b)(2)(ii)(f), (b)(2)(iii)(h), and (b)(2)(iv)(f), the Panel recommended the following: "Provides [two, four, six, or eight] times your natural protection from sunburn." In § 352.50(e)(1), labeling claims for Product Category Designation (PCD), the Panel also recommended that the following labeling statement be placed on the principal display panel of sunscreen drug products in accordance with their PCD's: "** ** (SPF [2, 4, 6, 8, or 15]). Stay in the sun [twice, 4 times, 6 times, 8 times, or 15 times] as long as before without sunburning."

The agency believes that the concept of "up to the actual SPF value of the product" suggested by the comment provides a more accurate estimate of the protection a consumer can expect from a sunscreen product than the statements recommended by the Panel. Therefore, the agency is proposing to use the wording "up to" in applicable indications. In this tentative final monograph, the agency is not proposing the Panel's recommended indications in § 352.50(b)(2)(i)(f), (b)(2)(ii)(e), (b)(2)(iii)(g), (b)(2)(ii)(f), (b)(2)(iii)(h), (b)(2)(iv)(e), and (b)(2)(iv)(f), but is instead proposing the following indications in § 352.52(b)(1)(i) and (b)(1)(iv): "Allows you to stay in the sun up to (insert SPF of product up to 30) times longer than without sunscreen protection," and "Provides up to (insert SPF of product up to 30) times your natural protection from sunburn." The agency is proposing that the product's labeling display its tested SPF value, as determined by using the agency's proposed sunscreen testing procedures (see comment 43).

The agency agrees with the comment that the term "as long as before" used by the Panel in its recommended statements on product performance is vague and does not tell the consumer "before what." Moreover, the agency believes that the intent of the Panel's recommended phrase "stay in the sun [twice, 4 times, 6 times, 8 times, or 15 times] as long as before without sunburning" in the statements on product performance in § 352.50(e)(1)(i) through (e)(1)(iv) is adequately covered in the indications being proposed in

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§ 352.52(b)(1)(iii) and (b)(1)(iv) of this tentative final monograph. Therefore, the agency is not proposing the Panel's recommended phrase "stay in the sun [twice, 4 times, 6 times, 8 times, or 15 times] as long as possible" for sunburning in § 352.52(a)(4) "Statement on product performance" of this tentative final monograph. The indications that were proposed by the Panel in § 352.50(b)(1)(iv) and (b)(1)(iv) of its recommended monograph are being combined, and the combined indication is included in proposed § 352.52(b)(1)(vii). (See comment 58.)

Several comments contended that "tanning" and related terms with no "representation" for prevention of sunburn are not drug claims but are traditional cosmetic claims. The comments maintained that "tanning representations" may not properly be regulated in an OTC drug regulation. Accordingly, these comments suggested deleting all reference to "tanning" from the monograph and revising § 352.50(b), "Indications," to address only labeling regarding the prevention of sunburn.

One comment suggested three alternative means for regulating tanning claims. Its preferred alternative is for FDA to consider tanning claims to be cosmetic claims and to regulate them under section 602(a) of the act (21 U.S.C. 362). The comment contended that the consumer perceives "tanning" to be a cosmetic activity that equals beauty. The comment recommended that manufacturers be permitted the widest latitude in placing tanning claims on the labeling of their products. The comment added that consumers will be better informed regarding the selection of suitable sunscreen products if information regarding skin types and the quality of tan permitted by the product is placed on the labeling. The comment stated that section 602(a) of the act gives the Commissioner authority to act if a cosmetic claim is false or misleading. The comment also contended that this approach avoids regulation where none is needed; if regulation should be needed for tanning claims, it may be implemented by proposing additional cosmetic regulations.

The second alternative suggested by the comment is that tanning claims or "representations" are descriptive of product attributes and should not be regulated as indications. Remarking that indications relate to how an active ingredient functions relative to a disease or potential disease state, the comment stated that tanning is neither a disease nor a potential disease state. The comment contended that a product's permitting of tanning and the degree, depth, or scope of tanning are a function of the amount of sunscreen in the product and of the unique product formulation characteristics. Therefore, tanning is not an indication, but it is a "tanning" attribute. As a third alternative, the comment recommended that if tanning claims are included in the rulemaking as drug indications, then the monograph should be expanded to provide differential tanning information for each PCD group.

Two comments stated that the Panel's recommended additional indications in § 352.50(b)(2)(i) and (b)(2)(ii) do not inform consumers of the degree of tanning that may be expected with minimal and moderate sunscreen products; whereas, on the other hand, the Panel allowed the following labeling for other sunscreen products: for extra sunscreen products, the phrases "limited tanning" and "extra protection;" for maximal sunscreen products, the phrases "maximal tanning" and "maximal protection;" and for ultra sunscreen products, the phrases "prevents tanning" and "ultra protection." The comments added that the knowledge that individuals tan and burn to different degrees mandates that such information be provided to the consumer for all sunscreen products to permit a proper product choice. The comments argued for labeling information regarding sunscreen-containing products' tanning ability and product skin-type use information. The comments contended that without this information consumers seeking a dark, deep, or fast tan may use products that contain no sunscreens but that make claims such as "deep, dark tan."

One comment recommended that § 352.50(b)(2)(i) be expanded to include for minimal sunscreen products the statements "Permits darkest, deepest tan" and "Minimal (maximum) protection against sunburn," and that § 352.50(b)(2)(ii) be expanded to include for moderate sunscreen products the statements "Permits moderate (dark) tanning" and "Moderate protection against sunburn."

The other comment recommended that §§ 352.50(b)(2)(i) and (b)(2)(iii) be modified so that the indications will inform consumers about skin-type information and the product's ability to permit increased tanning. The comment recommended that § 352.50(b)(2)(i) be expanded to include the following: "Permits fastest, darkest (maximum) tan (tanning)." "Minimal (minimum) protection against sunburn for persons who rarely burn and tan profusely;" and "Minimal (minimum) protection for persons who burn minimally and always tan well." The comment further recommended that § 352.50(b)(2)(i) be expanded to include the following: "Permits fast, dark (moderate) tan (tanning)," and "Moderate protection for persons who burn (sunburn) moderately and tan gradually." The comment concluded that these recommendations should only be implemented if the agency determines that tanning claims are drug claims.

Although tanning claims have traditionally been considered to be cosmetic claims, based upon numerous factors discussed below, the agency has now tentatively determined that tanning claims used in conjunction with a sunscreen ingrediant are drug claims. The Panel included tanning claims in its recommended monograph for OTC sunscreen drug products because such claims are very closely related to the sunscreening ability of the products. Both the sunscreen ingredient in the product and the SPF of the product directly influence the amount of tanning that occurs (i.e., the more radiation that a product absorbs, the less tanning that the product permits). A "tanning" product that contains a sunscreen controls a physiological process (melanogenesis), i.e., it affects the function or structure of the body and is, therefore, a drug. Even if the sunscreening activity is not mentioned in the product's labeling, its intent clearly is (1) to prevent a disease (i.e., sunburn), and (2) to affect a function of the body (i.e., melanogenesis). Both of these intended uses are drug activities under section 201(g) of the act (21 U.S.C. 321(g)).

The agency agrees with one of the comments that consumers will be better informed regarding the selection of suitable sunscreen products if information related to skin types and the quality of tan permitted by the product is placed on the labeling. The comment stated that § 352.50(b)(2)(i) be expanded to include for minimal sunscreen products the statements "Permits darkest, deepest tan" and "Minimal (maximum) protection against sunburn," and that § 352.50(b)(2)(ii) be expanded to include for moderate sunscreen products the statements "Permits moderate (dark) tanning" and "Moderate protection against sunburn."

The other comment recommended that §§ 352.50(b)(2)(i) and (b)(2)(ii) be modified so that the indications will inform consumers about skin-type information and the product's ability to permit increased tanning. The comment recommended that § 352.50(b)(2)(i) be expanded to include the following: "Permits fastest, darkest (maximum) tan (tanning)." "Minimal (minimum) protection against sunburn for persons who rarely burn and tan profusely;" and "Minimal (minimum) protection for persons who burn minimally and always tan well." The comment further
Therefore, the agency is proposing the tanning claims that were set out in § 352.50(b)(2)(i)(c), (b)(2)(ii)(e), (b)(2)(iii)(c), (b)(2)(iv)(b), (b)(2)(v)(b), (b)(2)(v)(e), and (b)(2)(v)(f) of the Panel's recommended monograph. These tanning claims are included in § 352.52(b)(2) "Additional indications" of this tentative final monograph and may be used in addition to the required indication in § 352.52(b)(1) if the manufacturer wishes to do so. These claims can be included in the boxed area or under "APPROVED USES" in the labeling of OTC sunscreen drug products in accordance with § 330.1(c).

The other indications recommended by one of the comments, i.e., "Minimal (minimum) protection against sunburn" and "Moderate protection against sunburn," are substantially the same as the following claims recommended by the Panel in § 352.50(b)(2)(ii)(a) and (b)(2)(iii)(a): "Affords minimal protection against sunburn" and "Affords moderate protection against sunburn." The agency believes that the Panel's recommended indications can be revised to accommodate the comment's suggestion by adding the word "minimum" to the Panel's recommended indication in § 352.50(b)(2)(i)(c). In addition, the agency believes that the word "Provides" may be better understood by consumers than the Panel's recommended word "Affords" and that the words "extra" and "maximal" should be revised to "high" and "very high" to reflect the agency's proposed revision of the PCD labeling. (See comment 45.) Therefore, the agency is proposing the following indications in §§ 352.52(b)(2):

(i)(A) [Select one of the following: "Provides minimal," "Provides minimum," "Minimal," or "Minimum") "protection against sunburn."

(ii)(A) [Select one of the following: "Provides moderate" or "Moderate") "protection against sunburn."

(iii)(A) [Select one of the following: "Provides high" or "High") "protection against sunburn."

(iv)(A) [Select one of the following: "Provides very high" or "Very high") "protection against sunburn."

(v)(A) [Select one of the following: "Provides the most" or "The most") "protection against sunburn."

With regard to one comment's concern that skin type information be made available to consumers, the agency is proposing a "Recommended Sunscreen Product Guide" that includes skin type information as part of the required labeling of OTC sunscreen drug products. (See comment 43.)

References


59. One comment objected to the use of indications that would state that a sunscreen drug product can completely prevent tanning. Referring to the Panel’s recommended label and "protection against sunburn." The comment explained that the most effective products (ultra sunscreens) will significantly reduce the tanning response of an individual, but that the tanning ability of individuals varies, and this tanning ability is genetically predetermined. Explaining further, the comment added that an individual with Skin Type I or II will not tan as easily as an individual with Skin Type IV or V. The comment stated that an ultra sunscreen drug product which may not permit tanning in individuals with Skin Types I or II will certainly permit tanning, although at a reduced rate, in individuals with Skin Types IV or V. The comment requested that the statement "permits no tanning" be modified to reflect this fact. The comment suggested that this statement include the information that sunscreens with an SPF of 8 or more may not permit tanning in certain individuals (Skin Types I and II) who burn easily but tan poorly, but may permit some tanning in those individuals (Skin Types IV or V) who burn moderately or minimally. The comment also stated that tanning stimulated by UVA radiation cannot be blocked by the sunscreens that contain only the UVB absorbing active ingredients and that UVA radiation may cause tanning in individuals with a genetic predisposition and Skin Types III or IV.

The agency does not agree with the comments that the Panel’s recommended § 352.50(b)(2)(ii) and (b)(2)(iiii) should be expanded to further inform consumers of the degree of tanning that may be expected from a sunscreen drug product. The statements recommended by the Panel are adequate to inform the consumer that sunscreen drug products that provide minimal and moderate protection also permit tanning. The agency does not believe that additional qualifying phrases or terms are necessary. The quality of tanning depends upon many things including the individual’s genetic predisposition to tanning, as one comment indicated and the Panel noted (43 FR 38206 at 38210), and the length of time that the individual remains in the sun.
from sunburning and permit no suntanning. (43 FR 38206 at 38213). The Panel stated, however, that "The tanning ability of an individual is genetically predetermined and is governed by the individual's capacity to produce melanin pigment within the pigment cells (melanocytes) when stimulated by UVB and UVA." (43 FR 38210).

The agency is proposing the term "ultra high" to describe sunscreen drug products that provide the most protection from UV radiation and is defining such products in §352.3(b)(5) as follows: "Sunscreen products that provide an SPF value of 20 to 30, offer the most protection from sunburning, and permit no suntanning. The agency agrees that sunscreen drug products with the same SPF value may completely inhibit tanning in some individuals while permitting other individuals to tan. However, the labeling of the sunscreen drug products must not necessarily describe all possibilities without becoming cumbersome. The agency believes that the Panel's recommended labeling that refers to the different degrees of tanning permitted by various products is appropriate to inform the consumer regarding the protective qualities of that product. Therefore, the agency is including the labeling recommended by the Panel in §352.5(b)(2)(v)(b) of its monograph in proposed §352.52(b)(2)(v)(b).

The agency is combining the labeling recommended by the Panel in §352.50(b)(2)(e) and (b)(2)(f) of its monograph and is including the revised additional indication in proposed §352.52(b)(2)(v)(E) as follows: "Provides the highest degree of" (select one of the following: "sunburn" or "sunscreen") "protection and permits no tanning."

60. One comment objected to the Panel's definition of a "sunscreen opaque sunblock" in §352.3(c) as "An opaque sunscreen active ingredient that reflects or scatters all light in the UV and visible range * * * and thereby prevents or minimizes sunburn." The comment argued that the definition of the term "sunblock" need not be limited to opaque substances and that this definition does not reflect what the comment felt to be consumer comprehension of a sunblock as a physical or chemical substance that prevents or minimizes sunburn. The comment stated that the Panel's definition is "unacceptable because the term "sunblock" need not be limited to opaque substances and that this definition does not reflect what the comment felt to be consumer comprehension of a sunblock as a physical or chemical substance that prevents or minimizes sunburn. The comment stated that the Panel's recommendation additional indication for sunblock ingredient so long as the final product provides an SPF of 20 to 30. A product with a high SPF may also contain an opaque sunblock ingredient or a sunscreen ingredient that is not an opaque sunblock ingredient so long as the final product provides an SPF of 12 to 20. (For a discussion of SPF values as they relate to PCD's, see comment 45.) High and ultra high sunscreen products that contain a sunscreen opaque sunblock ingredient may display the indication in §352.52(b)(3) for products containing the active ingredient identified in §352.10(e)(5) that provide an SPF of 12 to 30, the following labeling statement may be used: "Reflects the burning rays of the sun."

The agency does not agree with the comment's recommendation that "sunblock" be included as an additional indication for ultra high sunscreen drug products because the term "sunblock" is not an indication for use. Rather, it is a term that is descriptive of product performance or the name of a type of ingredient that may be used in a sunscreen drug product. The agency agrees with the comment that the descriptive term "sunblock" would be informative to users of OTC sunscreen drug products. The agency believes that the term "sunblock" may be used as an additional statement of product performance on sunscreen products that contain the ingredient titanium dioxide and provide an SPF of 12 or higher. Therefore, the agency is proposing the following additional statement in §352.52(e)(5) for products containing the active ingredient identified in §352.10(e)(5) that provide an SPF of 12 to 30, the following labeling statement may be used: "Sunblock."

J. Comments on Warnings for Sunscreen Drug Products

61. Two comments urged that the Panel's recommended warnings in §352.50(c)(2) (i) and (ii) be deleted. The warning in §352.50(c)(2)(i) states that sunscreen products providing an SPF value of 2 to under 4 should be used on children under 2 years of age only with the advice of a physician. The warning in §352.50(c)(2)(ii) states that sunscreen products providing an SPF value of 4 or greater should be used on children under 6 months of age only with the advice of a physician. Both comments stated that these warnings would dissuade the use of sunscreens on children, with one comment adding that children are in need of greater protection from the sun than adults. One comment contended that these warnings could communicate to the parent that it is better to expose the child to the sun with no protection then to protect the child with a sunscreen product. The comment also stated that the Panel may have recommended these warnings because of its concern about the permeability of children's skin. The comment added that in 1976 Maibach had presented data to the Panel showing that within days after birth a child's skin behaves much the same as adult skin regarding permeability (Ref. 1).

According to the comment, the greater
permeability of a child's skin as compared to an adult's skin has not been established. Consequently, the comment contended that "the risks attendant to inclusion of the warning far outweigh the benefits achieved by the deletion of the warnings."

A third comment disagreed with the Panel's conclusion at 43 FR 38217 that sunscreen products should not be used on children under 6 months of age. The comment strongly recommended that sunscreen products with high SPF values be used on babies if they are exposed to direct or indirect sunlight but added that direct exposure should be avoided.

The literature and data concerning sunscreens that the Panel reviewed included information on the percutaneous penetration of drugs and chemicals in infants and young children. The Panel did not find any convincing evidence that sunscreen active ingredients are safe for use on children under the age of 6 months and recommended that sunscreen products should not be used on children under 6 months of age. The Panel also recommended that sunscreen products with an SPF value of 2 to under 4 should not be used on children under 2 years of age (43 FR 38217).

In other words, only sunscreen products providing a minimum SPF of 4 should be used on children between the ages of 6 months and 2 years. All sunscreen products, regardless of their SPF value, may be used on children 2 years of age and older.

The agency believes that sunscreen products may help to protect a child under the age of 6 months from the damaging effects of sunlight. However, the possible adverse effects of sunscreen active ingredients on a child of that age also must be considered. The agency, like the Panel (43 FR 38217), is concerned that biological systems that metabolize and excrete drugs absorbed through the skin may not be fully developed in children under the age of 6 months.

The agency agrees that children between 6 months and 2 years of age need sunscreen protection. Based on this need, the agency is proposing that only sunscreens that have a minimum SPF value of 4 or more be used on children in this age group. The agency does not believe that a sunscreen with an SPF value less than 4 provides enough protection for children in this age range. The agency also believes that children under 6 months of age should not be in the sun for prolonged periods of time. Therefore, they have little or no need for sunscreens. If, by chance, an infant under 6 months of age should need a sunscreen, the parent should ask a doctor which sunscreen to use.

Therefore, the agency concurs with the Panel's age limitation recommendations for sunscreen drug products. The agency notes, however, that in the Panel's recommended monographs, the age limitations in the recommended warnings in §352.50(c)(2)(ii) and (c)(2)(iii) were also included in the directions in §352.50(d)(1)(i) and (d)(1)(iii) (43 FR 38268). In other recently published tentative final monographs, the agency has been including age limitation information in the directions for use. Therefore, the agency is deleting the Panel's recommended warnings in §352.50(c)(2)(i) and (c)(2)(ii), but the content of the warnings, with some minor format changes, is being proposed in the directions included in §352.52(d). (See comment 66.)

Reference

(1) Transcript of the 27th Meeting of the Topical Antiglare Panel, November 18, 1976, pp. 4 to 44, in OTC Vol. 06ATFM, Docket No. 78N-0048, Dockets Management Branch.

62. One comment objected to the Panel's recommended warning in §352.50(c)(1)(i), "Avoid contact with the eyes." The comment contended that this warning might discourage consumers from using sunscreen products on the face. The comment asserted that such use of sunscreen products should be encouraged because the face is the part of the human body most often exposed to UV rays and skin cancer occurs more frequently on the face than on other parts of the body. The comment suggested the following warning instead, which, it stated, would not be so general as to discourage use of sunscreens in the eye area and would tell the consumer what to do if the product did enter the eye: "If contact with eyes occurs, flush eyes with tepid water." The comment stated that according to the Panel (43 FR 38206 at 38244), padimate O is not a primary irritant to the cornea or iris at concentrations of 2 and 5 percent; therefore, an eye-contact warning should not be required for products containing this ingredient. Adding that certain products such as lip balms with sunscreens are not indicated for use near the eyes, the comment requested that lip balms be exempt from any eye warning requirement.

The agency believes that the warning "Avoid contact with the eyes" should appear in the labeling of all sunscreen-containing products except for those products that are not intended for use around or near the eyes, such as lip balms and lipsticks. (See comment 52.) The agency considers this warning to be necessary because most sunscreen products are used on the face and can accidentally get into the eyes. Moreover, the agency believes that a warning statement similar to that suggested by the comment would be additional useful information to a consumer because any sunscreen used on a consumer's face could get into the eyes. Similar warnings (e.g., "Avoid contact with eyes. In case of contact, flush eyes with water" and "Avoid contact with eyes, eyelids and mouth. If contact occurs, rinse thoroughly with water") currently appear on some OTC sunscreen drug products (Ref. 1). The agency notes that the comment has included the word "tepid" in the warning to describe the type of water that should be used to rinse the eyes. However, the comment did not provide any reason for this change. The agency is not aware of any reason to specify that "tepid" water must be used. Accordingly, the agency is proposing to amend the Panel's recommended warning in §352.50(c)(1)(i) as follows: "Avoid contact with the eyes. If contact occurs, rinse eyes thoroughly with water," and to include the revised warning in proposed §352.52(c)(1)(i).

The agency disagrees with the comment that products containing padimate O should not be required to bear the eye-contact warning. The Panel stated that 2 and 5 percent padimate O in mineral oil was not a primary irritant to the cornea and iris of test animals. The Panel noted that, in one study, 2 percent padimate O was at the upper limit of the mild primary irritant range in regard to its effect on this conjunctiva, as hyperemia was observed. In other eye irritation studies, 5 percent padimate O produced slight redness of the conjunctiva of each test animal on the first and second days following treatment (43 FR 38244). The Panel did not review all possible sunscreen drug product formulations. The agency believes that vehicles used to formulate the various sunscreen products may have different effects on the eye(s) and might also cause irritation. Therefore, if padimate O is included in the final monograph (see preamble discussion of padimate O above), products containing this active ingredient would not be exempted from the eye-contact warning.

Reference

(1) Labeling contained in OTC Vol. 06ATFM, Docket No. 78N-0038, Dockets Management Branch.

63. Several comments described adverse reactions resulting from the use of sunscreen drug products containing aminobenzoic acid. One comment
reported experiencing swelling of the face, swelling of the eyes causing them to close, and an allergic skin reaction after using a sunscreen drug product containing aminobenzoic acid in a cream formulation. The comment recommended that the labels of sunscreen drug products containing this ingredient display a prominent warning for the benefit of consumers with allergies. A second comment reported that several trials had shown aminobenzoic acid to sting and burn. (No supporting data or literature references were submitted.) The comment stated that only 3 percent aminobenzoic acid is allowed in Europe and that no European company uses aminobenzoic acid. The comment submitted an abstract of a presentation by Hodges, et al. (Ref. 1) regarding the sensitizing effect of aminobenzoic acid in a test on Escherichia coli (E. coli). A third comment expressed concern that the warning on a sunscreen drug product containing aminobenzoic acid was not strong enough. The comment, from a consumer who once had skin cancer, reported experiencing a rash after using the product on a substantial area of the body. The comment added that many people who will use these sunscreens have had skin cancer or very sensitive skin. A fourth comment recommended that FDA publicize safety guidelines for sunscreen ingredients and, if hazards are present, weigh these hazards against the hazards of overexposure for sun-sensitive people. 

One comment requested that the agency consider labeling sunscreen drug products in clear, bold letters as either "PABA SUNSCREEN" or "NON-PABA SUNSCREEN." The comment stated that products appropriately labeled will enable consumers to choose the proper sunscreen. Two other comments disagreed with this comment. One comment stated that because PABA (i.e., aminobenzoic acid) and its derivatives are active sunscreen ingredients, they must already be listed in the labeling of OTC sunscreen drug products. The comment maintained that consumers who are concerned about the presence of these ingredients need only check the active ingredient list to ascertain their presence in the sunscreen drug product. The comment added that requiring a statement in "bold letters" is unnecessary and urged the agency not to adopt this recommendation. The other comment stated that there is no reason to treat aminobenzoic acid differently from other sunscreen active ingredients. The agency is aware that some individuals can have moderate or acute adverse reactions to active ingredients which cause no reactions in most people. The Panel, in reviewing the submitted literature on the safety of aminobenzoic acid, determined that the incidence of allergy to aminobenzoic acid was low and individual intolerance was rare (43 FR 38206 at 38220). In the submitted abstract (Ref. 1), Hodges, et al. report on the survival levels of a repair deficient strain of E. coli following exposure to 313 nm UV radiation and to varying concentrations of aminobenzoic acid up to a maximum of 0.1 percent. The abstract states that the survival level of the bacteria decreases with increasing concentrations of aminobenzoic acid. The abstract does not explain how the effect of aminobenzoic acid on the survival level of a repair resistant strain of E. coli can be extrapolated to humans. 

The agency has reviewed its adverse reaction files for the years 1979 to 1989; 14 cases of adverse reactions associated with the use of sunscreen products containing aminobenzoic acid were reported to FDA (Ref. 2). The reports show that allergic reaction, rash, pruritus, dermal exfoliation, and a few other problems occurred. However, only one report showed a serious reaction that might be attributed to aminobenzoic acid. Because the reported adverse reactions were mostly dermal problems, the agency agrees with the Panel that the appropriate warning for sunscreen products containing aminobenzoic acid would be "Discontinue use if signs of irritation or rash appear." However, the agency is proposing to add to the Panel's recommended warning additional guidance to the consumer, i.e., "If irritation or rash persists, consult a doctor." This addition to the warning is proposed in § 352.52(c)(1)(iiii). The agency believes that these proposed warning statements are sufficient to alert consumers to the possibility of an allergic reaction to aminobenzoic acid or any other sunscreen active ingredient. Therefore, it is unnecessary for a product to be labeled as either a "PABA SUNSCREEN" or a "NON-PABA SUNSCREEN." In addition, the agency notes that the official name for PABA is aminobenzoic acid and that is the name that should be used in labeling (see comment 30).

References


(2) Department of Health and Human Services, Food and Drug Administration, Adverse Reaction Summary Listings for the years 1979 to 1989, OTC Vol. 06ATFM, Docket No. 78N-0038, Dockets Management Branch.

64. In response to the January 26, 1988 public meeting at which sunscreens with SPF values above 15 and sunscreen testing methods were discussed, one comment suggested that sunscreens with SPF values of 15 or above should include ingredients that offer UVA protection or prominently state that the product does not provide UVA protection. The comment indicated that the consumer is entitled to know if a high SPF product does or does not provide substantial protection against UVA because the scientific literature suggests that UVA is just as likely as UVB to contribute to photoaging and skin cancer and, in cases of prolonged exposure, erythema.

Another comment also indicated that the consumer is entitled to know if a high SPF product does or does not offer substantial broad spectrum protection. The comment contended that consumers purchasing high SPF products are as much interested in the antiaging and anticancer benefits of the products as they are in the erythema protection benefits. Moreover, the comment added, the proposed monograph encourages consumers to focus on photoaging and skin cancer concerns in that it permits manufacturers to claim that sunscreen drug products offer such protection. Because both UVA and UVB spectra contribute to photoaging and skin cancer, as well as erythema, the comment recommended that the agency consider requiring manufacturers to disclose the absence of UVA protection in high SPF products.

One comment was concerned that subjects taking part in the testing of high SPF sunscreen drug products will receive very high doses of intermediate and long-wave UVA radiation unless the product under test contains an agent that blocks out these wavelengths, or the solar simulator is appropriately filtered. The comment added that similar concerns apply, to some extent, to the use by consumers of products that do not include an appropriate UVA blocking agent. Another comment stated that for sunscreens with SPF values higher than 10, the amount of unfiltered UVA is such that aggression of tegument tissues is important. The comment added that this type of aggression is not detected by erythema, which is the recommended and available end point for the sunscreen testing procedures.

As stated in comment 53, the agency is aware that UV radiation contributes to both acute and chronic skin damage.
such as erythema, melanogenesis, carcinogenesis, drug-induced photosensitivity, and photosaging. Sunscreens with higher SPF values allow consumers to remain in the sun for long periods of time without burning, thus increasing UVA exposure. The agency believes that protection against UVA radiation may be as important to a consumer’s well-being as protection against UVB radiation. Therefore, the agency is proposing in this tentative final monograph conditions under which an OTC sunscreen drug product may identify itself as a “broad spectrum” sunscreen. Such a product would be able to include UVA protection claims in its labeling as discussed in comment 53.

Regarding the comments’ recommendation that manufacturers be required to disclose in labeling the absence of UVA protection in some high SPF products, the agency believes there is some merit to this recommendation. Persons using such products have a tendency to remain in the sun for long periods of time, with increased exposure to UVA radiation. The agency is proposing in this tentative final monograph that sunscreen drug products that provide both UVA and UVB protection be allowed to state that they are a “broad spectrum” sunscreen and that they provide protection against UVA radiation. FDA believes that the message that the comments have recommended (i.e., does not provide UVA protection) would be useful to consumers, and the agency wants to develop language that would be meaningful to consumers. (Normally, the labeling of OTC drug products does not contain “negative” statements—i.e., that the product does not do a certain thing. Some manufacturers have done so for ingredients voluntarily, e.g., “Contains no caffeine.”) Possible language that could be used in this situation includes “does not provide UVA protection” or “does not provide broad spectrum protection.” The agency invites further comment as to whether such information should appear only in the labeling of sunscreen drug products with an SPF value of 15 or above, or should appear in the labeling of any sunscreen drug product not providing such protection regardless of its SPF value. The agency will address this issue further in a future issue of the Federal Register after evaluating the comments received.

65. One comment stated that care must be taken in recommending sunscreens for chronic use because they suppress cutaneous vitamin D₃ synthesis. To support its contention, the comment cited a recent paper by Matsuoka, et al. (Ref. 1) in which a single application of an amino benzonic acid-containing sunscreen (SPF 8) interfered with the cutaneous synthesis of vitamin D₃.

Although exposure of the skin to UVB radiation produces a variety of pathological effects such as sunburn, immunological changes, and skin cancer, UVB radiation is essential for the endogenous production of vitamin D₃. The relationship of sunshine to vitamin D₃ and the normal growth and development of the skeleton is well known (Ref. 2). The agency is aware that there is evidence that vitamin D₃ synthesis is inhibited by the use of sunscreen drug products. However, Matsuoka, et al. (Ref. 1) stated that the effect of sunscreen drug products to limit or prevent the cutaneous production of vitamin D₃ is probably of little consequence for children and young adults who obtain adequate vitamin D nutrition from their diet and frequent exposure to sunlight. They added that the elderly, who are more prone to developing vitamin D deficiency, could increase their risk of vitamin D deficiency if they consistently apply a sunscreen before going outdoors. The agency further suggested that elderly chronic users of sunscreens should be routinely investigated for vitamin D deficiency. A 1989 NIH consensus development conference basically agreed that, in the United States, sunscreen inhibition of vitamin D₃ synthesis does not present a health hazard for the pediatric population, although deficiencies may exist in elderly populations (Ref. 2). Matsuoka, et al. (Ref. 1) recommended that elderly persons who might be at risk from constant use of a sunscreen may be advised to take supplemental vitamin D₃ or to omit sunscreen use and expose their skin only to suberythemal doses of sunlight. In the case of prolonged outdoor activities, a topical sunscreen may be applied immediately after the initial exposure.

The comment did not distinguish between the use of sunscreens by any age group. The agency does not believe that there should be a warning on sunscreen drug products regarding vitamin D₃ suppression, because such a warning might discourage the use of sunscreens, especially in children. Both Matsuoka, et al. (Ref. 1), and the NIH consensus development conference (Ref. 2) stated that the inhibition of vitamin D₃ synthesis by sunscreens does not present a health hazard for the pediatric population. Further, the agency considers the use of sunscreens in children to be especially important because much of the skin damage that appears in adulthood is a cumulative result of sun exposure in childhood (Ref. 3). The NIH consensus development conference stated that it is important for the public health that sunscreen drug products be used frequently and properly (Ref. 2). The agency concurs and is proposing labeling that it hopes will meet these objectives. The agency invites public comment on whether any of the above information related to the use of sunscreens by elderly persons should appear in the labeling of sunscreen drug products.

References


K. Comments on Directions for Sunscreen Drug Products

66. Referring to the “Directions for use” in § 352.50(d), in which the Panel recommended that all sunscreen products be applied liberally, one comment contended that liberal or heavy application is not required for some formulations to be effective and, in some cases, may decrease efficacy. The comment stated that because certain vehicles “crack, peel or pill” when applied too heavily, these products require an even application to dry skin. The comment argued that, because sunscreen products are available in a variety of forms (oils, lotions, creams, sprays, etc.), the monograph should allow manufacturers to develop specific application

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instructions based on clinical experience with the formulation. The agency has reviewed the
suggested changes and agrees with the comment that the proper use of some
formulations does not require liberal or heavy application for the reasons stated by the
comment. Therefore, to allow for variations in the application of different
product formulations, the agency believes that the Panel’s recommended
directions in §352.50(d)(1) and (2) may not be adequate for all types of
sunscreen drug products.

To accommodate the various dosage forms of sunscreen drug products that are
available, the agency is including in proposed §352.52(d) only brief,
required directions for sunscreen drug products. The monograph will also
provide that manufacturers can voluntarily expand and supplement these
required directions with more detailed instructions applicable to a
particular product formulation and dosage form. In addition, as discussed in
comment 105, the agency is
proposing that manufacturers determine the waiting period (the time between
applying a sunscreen drug product and exposing the test site to water, if
applicable) for water resistant and very
water resistant sunscreen drug products and include this information in the
labeling. Accordingly, the agency is
proposing the following directions in
§352.52(d):

(d) Directions. The labeling of the product
forms in the following information under the heading
"Directions". More detailed instructions applicable to a particular product
formulation (e.g., cream, gel, lotion, oil, spray, etc.) may also be included.

(1) For products containing any
ingredient in §352.10 that do not satisfy the water resistant or very water
resistant testing procedures in §352.76.

"Adults and children 6 months of age and
older: Apply [select one or more of the
following, as applicable: “liberally,”
“generously,” “smoothly,” or “evenly”]
“before sun exposure. Reapply after
swimming or excessive” (select one of the following:
“sweating,” or “perspiring,”) “or
anytime after towel drying. Children
under 2 years of age should use
sunscreen products with a minimum
SPF of 4. Children under 6 months of
age: consult a doctor.”

67. Referring to the directions for
water resistant sunscreen drug products
recommended by the Panel in
§352.50(d)(2)(i), one comment objected to the requirement for reaplication
after 40 minutes in the water. Because
a product must retain its original PCD
after 40 minutes of swimming in order
to qualify as water resistant, the
comment found the requirement to
reapply the product after this time
period to be contradictory. The
comment requested that the monograph
be revised to allow manufacturers the
option of testing to determine the
minimum immersion period that would
cause a reduction in the product’s PCD
value and then labeling the product
with the reaplication instructions
based on these test results.

Alternatively, the comment stated that
those manufacturers not wanting to
conduct further tests would be required
to use the 40-minute reaplication time.
The comment added that these options
should also apply to the directions for
waterproof and sweat resistant products.
(The agency is substituting the term
“very water resistant” in place of the
term “waterproof” in this tentative final
monograph. See comment 50.)

Another comment stated that the
Australian standard, AS2604-1986,
allows only the claim “water resistant,”
but gives reasonable scope in that the
label claim can include how long
consumers can stay in the water before
 reaplication is necessary. For example,
the comment noted that several
products are now claiming “water
resistant for up to two hours.”

The agency disagrees with the
comment’s suggestion that the
monograph be revised to allow
manufacturers to test for the minimum
immersion period that would cause a
reduction in the product’s PCD and to
include this time for reaplication of
the product in the directions for use.
The directions to reapply a water resistant
sunscreen drug product after 40 minutes
in water are based on the testing
guidelines for establishing that the
product is water resistant. In order to be
labeled as a water resistant sunscreen
drug product, the SPF value of the
product after water immersion testing
must remain within the PCD range into
which the product was originally
categorized. This time is included in the
monograph directions applicable to
such a product because it ensures a safe
lower limit of the effectiveness of the
product.

The agency believes that permitting a
proliferation of reaplication times,
based upon the actual time period a
product can retain its PCD while
undergoing water immersion testing
would lead to consumer confusion and
may be unsafe. In general, sunscreen
drug products should be reapplied
frequently in order to be most effective.
The agency believes that consumers
should be encouraged to reapply water
resistant or very water resistant
sunscreen drug products at minimal
time intervals. A water resistant or very
water resistant sunscreen drug product
should enable an individual to maintain
a certain level of protection from the
harmful rays of the sun. This is
especially important for individuals
with a high risk of wash-off such as
children who may be constantly in and
out of the water and who may remain in
a beach/pool environment for long
periods of time. The agency considers
two designations (i.e., water resistant
for 40 minutes and very water resistant
for 80 minutes) to be adequate as to the
number of categories and times
appropriate for the safe and effective use
of such products. The agency believes
that requiring the labeling to state that
the product should be reapplied after 40
minutes for water resistant or after 80
minutes for very water resistant
sunscreen drug products helps to ensure
that consumers receive maximum
protection from sunlight both when in
and out of water.

Regarding the comment’s statement
that the options it suggested for water
resistant products should also apply to
very water resistant sunscreen drug products, the agency
agrees with the reaplication times
included in the Panel’s recommended
directions in §352.50(d)(2)(ii) for very
water resistant sunscreen drug products.
If the product maintains its PCD after 80
minutes of water immersion, it can be
labeled “very water resistant” and
contain directions for reaplication after
80 minutes. The agency is not including
the Panel’s recommended “sweat
resistant” test or directions for use of
products that satisfy the sweat
resistance test in this tentative final
monograph. A product that passes the
water resistant or very water resistant
tests is also permitted to make “sweat
resistant” claims. (See comment 100.)

The agency believes that consumers
should be directed to reapply water
resistant and very water resistant sunscreen drug products after 40 or 80 minutes, as appropriate. Therefore, the agency is including the Panel's recommended times for reapplication of water resistant and very water resistant sunscreen drug products in the directions for use of these products in proposed § 352.52(d)(2).

68. One comment recommended that labeling directions include the following statement in block letters: "FOR INFORMATION, ASK A PHARMACIST." The comment contended that consumers, especially the young, do not read directions and that a grading system for sunscreens would be confusing. The comment added that pharmacists could put up informative posters or displays and distribute leaflets prepared in English and Spanish at no cost to the government.

As discussed in comment 44, the grading system is clearly explained in the labeling recommended by the Panel and proposed in § 352.52(e). Therefore, the agency sees no need to require the labeling statement requested by the comment. The agency has stated many times that the pharmacist is a valuable source of health care information. Pharmacists are available to provide information about the grading system for sunscreens to consumers who require assistance.

L. Comments on Professional Labeling for Sunscreen Drug Products

69. Several comments requested labeling that includes indications for the use of sunscreens for pathological conditions. Some of these comments requested professional labeling, while others requested consumer labeling.

One comment stated that the Panel should have included a discussion of special types of sunscreens useful for patients with polymorphic photodermatitis, drug photosensitivity, and other types of photodermatitis. A reply comment agreed with the comment and suggested that a section for professional labeling be incorporated into the tentative final monograph to include an indication for patients with solar urticaria, polymorphic light eruptions, drug photosensitivity, and other types of photodermatitis where sunscreen therapy is indicated. The reply comment felt that the Panel recognized that some sunscreens containing a titanium dioxide, also provide broad-spectrum protection. This comment stated that it "would support indications for products with an appropriate absorption spectrum for the prevention of, or decrease exacerbation of, diseased states effected by the specific spectra screened by the screening products."

One comment from a person who has systemic lupus erythematosus (SLE) stated that this condition is exacerbated by exposure to sun, fluorescent lights, X-rays, etc. The comment added that people with this condition need accurate information on sunscreen preparations, such as how often to reapply the product, ability to protect, etc. The comment expressed support for appropriate labeling of a sunscreen product that might help persons with SLE to avoid flareups of fever and pain caused by the sun's rays.

One comment stated that there was a need in the proposed labeling system for "one more category" that would be for persons with reactions such as a rash on exposure to sunlight. The comment requested labeling information that would allow persons who develop a rash on exposure to sunlight to choose an effective sunscreen product without consulting a doctor. Although many photodermatoses have been described, the exact etiology of most of these light-related skin diseases is not known (Ref. 1). The agency does not believe that the labeling for OTC sunscreen drug products should include indications for the use of sunscreens to protect against photodermatoses. In order to prescribe the appropriate sunscreen drug product for a particular photodermatosis, it is necessary to know the action spectrum (i.e., limits of the wavelength region) that causes a particular photodermatosis (Ref. 2) because that portion of the spectrum must be blocked in order to protect against the photodermatosis. Pathak, et al. (Ref. 2) have identified various action spectra for responses of human skin to solar radiation. The condition of variegate porphyria can be caused by a range of wavelengths between 390 and 600 nm with a maximum effect between 390 and 420 nm. Drug photosensitivity reactions can be caused by wavelengths between 300 and 400 nm with a maximum reaction between 320 and 380 nm. The range of effective wavelengths implicated in certain solar urticaria is 290 to 380 nm with a maximum reaction between 290 and 320 nm (Ref. 2). In order to successfully protect against a photodermatosis with a sunscreen drug product, the agency believes that a clinical diagnosis is necessary. Sun protection measures in persons with photodermatoses must be individualized to reflect the nature of the disorder, the causative wavelengths of sunlight, the individual's exposure habits, and the severity of the disease. The recommended measures for individuals with photodermatoses vary from disease to disease and may be very different from the recommendations for individuals without such conditions (Ref. 3). Because such determinations cannot be made by the consumer, the agency concludes that indications for the use of sunscreen drug products for protection against photodermatoses should only be made in a professional context.

Regarding professional labeling specific to photodermatoses, the comments suggested indications for special types of sunscreen products that may be useful for persons with photodermatitis. However, the comments did not provide any data to establish appropriate indications for such use. Therefore, the agency has no basis at this time for including professional or consumer labeling in the tentative final monograph. Nevertheless, the agency invites the submission of data that would establish appropriate professional labeling for sunscreen drug products for persons with photodermatitis and the other conditions described by the comments. (See comment 33.) Any data submitted on specific claims for specific sunscreen ingredients will be reviewed by the agency and addressed in the final monograph.

The agency notes that many of the conditions described by the comments may be caused by or exacerbated by exposure to UVA radiation (Ref. 2). If a Category I sunscreen ingredient is shown to have an absorption spectrum that extends to 360 nm or above in the UVA range, and a product containing that ingredient can demonstrate UVA protection using appropriate testing procedures that the agency is proposing to be developed, that product may include UVA protection claims in its labeling. (See comment 53.) Such a claim would imply nonspecific protection against UVA induced photodermatoses.

References

The agency has reviewed the data submitted by the comment, which include UV and IR spectroscopy curves that were originally submitted to the Panel, and other chemical, clinical, and safety data (Ref. 1). The agency concludes that the chemical data are insufficient to demonstrate clearly that allantoin and aminobenzoic acid form a discrete chemical entity whose properties are different from those exhibited by the individual substances described by the comment. From the data, it is not possible to conclude that a complex is formed that exhibits chemical and physical properties not shown by a mixture of the components. In addition, the data do not address the effectiveness of allantoin combined with aminobenzoic acid as a sunscreen agent. Therefore, the agency is proposing that allantoin combined with aminobenzoic acid remain in Category III in the tentative final monograph when labeled only as a sunscreen. The agency's detailed comments and evaluation of the data are on file in the Dockets Management Branch (Refs. 2 and 3). The agency notes, however, that 0.5 to 2 percent allantoin is proposed as a Category I skin protectant active ingredient (see the tentative final monograph for OTC skin protectant drug products published in the Federal Register of February 15, 1983; 48 FR 6832) and that Category I sunscreen active ingredients may be combined with Category I skin protectants. (See comment 71.) Therefore, aminobenzoic acid, a Category I sunscreen, may be combined with allantoin, a Category I skin protectant, provided the combination is labeled as both a sunscreen and a skin protectant.

References

(1) Comment No. C00040, Docket No. 78N-0038, Dockets Management Branch.
(2) Letter from W.E. Gilbertson, FDA, to S.B. Mecca, Schuylkill Chemical Co., coded ANS 81/01/09 to C00040, Docket No. 78N-0038, Dockets Management Branch.
(3) Letter from W.E. Gilbertson, FDA, to S.B. Mecca, Schuylkill Chemical Co., coded C000731ANS, Docket No. 78N-0038, Dockets Management Branch.

71. One comment stated that the Panel discussed its desire to permit combinations of sunscreen and nonsunscreen active ingredients, but failed to provide for these combinations in its recommended monograph. To remedy this oversight, the comment recommended that the following section be established in the monograph:

"§ 352.30 Combination of sunscreen and nonsunscreen active ingredients. Two or more sunscreen active ingredients may be combined with other active ingredients provided that the ingredients are generally recognized as safe and effective."

Although the Panel concluded that "sunscreen active ingredients may be combined with other active ingredients, e.g., skin protectants, provided that the ingredients are generally recognized as safe and effective, i.e., Category I active ingredients" (43 FR 38206 at 38217), it did not include any such combinations in its recommended monograph nor did the comment provide any information on specific combinations. The agency's combination policy for OTC drugs in § 330.10(a)(4)(iv) provides for the combination of two or more safe and effective active ingredients when each ingredient makes a contribution to the claimed effect(s); when combining of the active ingredients does not decrease the safety or effectiveness of any of the individual active ingredients; and when the combination, when used under adequate directions for use and warnings against unsafe use, provides rational concurrent therapy for a significant proportion of the target population. In addition to the above requirements, the agency's "General Guidelines for OTC Drug Combination Products" (Ref. 1) provide that Category I active ingredients from different therapeutic categories may be combined to treat different symptoms concurrently only if each ingredient is present within its established safe and effective dosage range and the combination meets the OTC combination policy in all other respects.

In some cases, the agency believes that combination drug products containing Category I sunscreens and active ingredients from other therapeutic categories may be rational. In situations where the skin is subjected to the combined effects of the sun and wind that could result in irritating and potentially harmful effects such as chafing, cracking, and windburn as well as sunburn, the agency believes that a combination drug product containing a sunscreen and a skin protectant is a rational combination. Certain skin protectant ingredients (i.e., allantoin, cocoa butter, dimethicone, glycerin, petrolatum, shark liver oil, and white petrolatum) are used to help prevent and temporarily protect chafed, chapped, cracked, or windburned skin and lips. (See § 347.50(b)(2) of the tentative final monograph for OTC skin protectant drug products (February 15, 1983; 48 FR 6820 at 6832).) The agency notes that several products submitted to the Topical Analgesic Panel contained ingredients such as lanolin, cocoa butter, allantoin, glycerin, or petrolatum in combination with sunscreen ingredients. In addition to sunscreens, the comment argued that testing in over 500 subjects demonstrates that allantoin and aminobenzoic acid in concentrations from 2 to 6 percent with an SPF value from 6 to 15 (Ref. 1). As mentioned by the comment, the Panel determined that allantoin combined with aminobenzoic acid is safe, but concluded that the data are insufficient to demonstrate effectiveness. The Panel recognized that allantoin-aminobenzoic acid in combination has shown sunscreensing activity equivalent to aminobenzoic acid alone. However, the submitted studies did not show that the combination of allantoin and aminobenzoic acid possesses any greater sunscreen potential than aminobenzoic acid alone (43 FR 38256). In addition, data submitted to the Panel referred to allantoin combined with aminobenzoic acid as a complex; however, the studies did not show that there was complexation involved between allantoin and aminobenzoic acid or that any modification had resulted which would alter in any way the individual characteristics of the parent compounds (43 FR 38206 at 38256 to 38257).
claims, these products displayed skin protectant labeling claims such as “Protects from drying by sun, wind, water,” and “Moisturizes skin to help protect against dryness and chapping due to exposure to sun and wind.” (Refs. 2, 3, and 4). The agency believes that the data submitted to the Topical Analgesic Panel (Refs. 2 and 3) support the safety and effectiveness of such products. Moreover, because the pharmacological action of Category I sunscreens is similar (i.e., the ingredients screen or scatter the UV radiation from the sun) and because the pharmacological action of certain skin protectants is similar (i.e., the ingredients are chemically inert compounds that form a barrier on the skin and protect it against drying and other irritations), the agency concludes that any Category I sunscreen active ingredient can be safely and effectively combined with the following Category I skin protectant active ingredients: allantoin, cocoa butter, dimethicone, glycerin, petrolatum, shark liver oil, and white petrolatum. Accordingly, the agency is proposing to include new paragraphs (b) (1) and (2) in § 352.20, to read as follows: “(b)(1) Any single sunscreen active ingredient when used in the concentration established in § 352.10 may be combined with one or more skin protectant active ingredients identified in § 347.10 (a), (d), (e), (f), (h), (i), and (j) of this chapter, provided the finished product has a minimum SPF value of not less than 2 as measured by the testing procedures established in subpart D of this part and provided the product is labeled according to § 352.60.” “(b)(2). Two or more sunscreen active ingredients when used in the concentrations established in § 352.20(a)(2) may be combined with one or more skin protectant active ingredients identified in § 347.10 (a), (d), (e), (f), (h), (i), and (j) of this chapter, provided the finished product has a minimum SPF value of not less than 2 as measured by the testing procedures established in subpart D of this part and provided the product is labeled according to § 352.60.” (See comment 37 for a discussion of minimum dosage limits for combination sunscreen drug products.)

The agency does not consider all skin protectant active ingredients to be appropriate for combining with a sunscreen. Certain skin protectant ingredients (i.e., aluminum hydroxide, calamine, kaolin, zinc acetate, zinc carbonate, and white petrolatum) are indicated only for drying the oozing and weeping of poison ivy, poison oak, and poison sumac. There does not appear to be any need to combine these ingredients with sunscreen ingredients, nor is the agency aware of any products currently being marketed. Accordingly, such combinations are not being proposed in this tentative final monograph. However, the agency invites comment on this proposal.

The agency has determined that appropriate labeling for combination products containing sunscreen and skin protectant active ingredients would be any applicable sunscreen indication proposed in § 352.52(b) along with the skin protectant indication proposed in § 347.50(b)(2). Because consumers use a sunscreen-skin protectant drug product primarily as a sunscreen and because proper application is important to the safe and effective use of a sunscreen drug product, the combination product should be labeled with the sunscreen directions for use in § 352.52(d) of this tentative final monograph that are appropriate to the indication used on the product, the dosage form, and the substantivity of the product (e.g., a lipstick that contains a sunscreen and displays the indication “Filters out the sun’s rays,” should bear the following directions: “Apply liberally as often as necessary.”). (See comments 52 and 66 for further discussion of these directions.)

The agency does not believe that any special labeling is necessary for the warnings required on sunscreen-skin protectant drug products. The warnings for each ingredient as established in the warning sections of the respective OTC drug monographs are appropriate, except the agency does not find the general warning proposed in § 347.50(c)(3) for OTC skin protectant drug products. The warnings for each ingredient as established in the warning sections of the respective OTC drug monographs are appropriate at this time. The agency believes that labeling for such a combination in the final monograph for OTC skin protectant drug products so that interested parties will know where to find the pertinent information about those products.

Similarly, a combination of a sunscreen and hydroquinone, a skin bleaching active ingredient, may be included in the final monograph for OTC skin bleaching drug products to be published in a future issue of the Federal Register. That combination product is primarily for skin bleaching, and its labeling is included in § 358.50 of the skin bleaching tentative final monograph. For informational purposes, the agency is proposing to include a cross-reference to that combination in § 352.20(c) of this tentative final monograph to read as follows: “For sunscreen and skin bleaching combinations. See § 358.50 of this chapter.”

The agency does not find any other combination products containing sunscreen and nonsunscreen active ingredients appropriate at this time. The agency invites further comments and supporting data on such combination drug products.

References
(2) OTC Vol. 060002.
(3) OTC Vol. 060065.
(4) OTC Vol. 060076.
N. General Comments on Testing Procedures for Sunscreen Drug Products

72. Several comments agreed that testing is necessary to ensure that OTC sunscreen drug products meet the standards set forth in the monograph. However, these comments argued that testing procedures should be in the form of guidelines that outline a currently acceptable method of evaluating OTC...
sunscreen drug products and should not be included in the monograph. Two comments stated that the agency had proposed this approach in other OTC drug monographs such as the monograph for OTC antiperspirant drug products. Another comment stated that such an approach would be highly desirable for SPF measurement in view of the international character of the sunscreen drug products market, where many identical formulations are sold in various countries around the world.

One comment added that maintaining the testing procedures for OTC sunscreen drug products in the form of guidelines would allow a company to use either the method specified in the guidelines or any other properly validated method that can be shown to assess performance at least as accurately as the guideline method. One comment stated that once alternative methods were validated, they would enjoy the same status as the proposed guidelines without the need to be submitted and approved through a rulemaking procedure. Another comment stated that the agency should explicitly state that other validated methods, or validated modifications of the methods proposed, are acceptable provided they are shown to evaluate performance consistently with and at least as accurately as the guideline method.

Some comments argued that establishing the testing procedures for sunscreen drug products as guidelines would build flexibility into the system and allow for easier handling of advances and improvements to the testing methodology. One comment maintained that mandating specific test protocols that must be followed to substantiate efficacy tends to stifle scientific and technological investigations in these areas. The comment contended that parties affected by the rules are often unwilling to support additional research because any changes proposed would have to go through a lengthy rulemaking procedure before being accepted. The comment added that other advances would be likely to cause the whole procedure to be repeated again and again. One comment stated that it is essential to have the best data available on which to base regulatory decisions and that the best way to have current data available is to provide for new and improved testing methods to be used.

The agency does not agree with the comments that testing procedures should be guidelines rather than be included in the monograph. The agency notes that the seriousness of the consequences that may result if a consumer relies upon an inaccurately labeled sunscreen (e.g., one that promises more protection than it actually affords) mandates that the final formulation of OTC sunscreen drug products be tested using standardized and validated testing procedures. Labeled SPF values should be based on testing conducted under the most carefully controlled conditions so that results are as accurate as possible. The outcome of an accurate and reproducible testing procedure ensures that competitive products on the market with the same SPF value provide essentially the same degree of protection. The agency believes that this can be accomplished best by requiring all manufacturers to use fully evaluated and validated testing procedures for testing the final formulation of OTC sunscreen drug products. The data from this testing need not be submitted to FDA by the manufacturer. The agency intends to use the testing procedures set forth in the final monograph for any necessary compliance testing of these products. The agency concludes that these testing procedures should be codified in the Code of Federal Regulations (CFR).

The agency agrees that it is essential to have the best data available on which to base regulatory decisions and encourages the development of new methods for testing sunscreen drug products. (See comment 53.) Properly validated, alternate methods for determining the SPF value of OTC sunscreen drug products would be acceptable so long as they have been evaluated and accepted by the agency. Such methods must be submitted to the agency as a petition under the rules established in § 10.30 of this chapter. The petition should contain data to support the modification or data demonstrating that an alternative testing procedure provides results of equivalent accuracy. All information submitted will be subject to the disclosure rules in Part 20 of this chapter. If acceptable, these alternative methods could be included in the monograph. The petition process is included in § 352.77 of this tentative final monograph.

Regarding one comment's statement that the agency had agreed to permit testing guidelines in the case of antiperspirant drug products, the agency notes that the consequences of a consumer using an ineffective antiperspirant drug product are not as serious as those that might be expected should a consumer use an ineffective sunscreen drug product. For further discussion of the adverse effects of sunlight and the serious consequences that may occur if a consumer uses an ineffective sunscreen, see comments 27, 53, and 56.)

Final formulation testing procedures are included in the monographs for OTC antacid drug products in 21 CFR part 331 and for OTC first aid antibiotic drug products in 21 CFR part 333. Such testing procedures are also included in the tentative final monograph for first aid antiseptic drug products published in the Federal Register of July 22, 1991 (56 FR 33644). The agency points out that several revisions to the antibiotic testing procedures have been accomplished in a timely fashion by using the normal OTC drug review rulemaking procedures. Accordingly, the agency finds no valid reasons not to include the testing procedures for OTC sunscreen drug products in this tentative final monograph.

O. Comments on Testing Procedures for UVA Sunscreen Drug Products

73. In response to the January 26, 1988 public meeting at which sunscreen testing methods were discussed, several comments addressed testing methodologies for sunscreens that absorb UVA radiation. One comment stated that increasing concern over the long-term effects of UVA radiation has generated a new interest in the development of UVA sunscreens. Despite this concern, the comment noted that the agency had not proposed any methodology for assessing the photoprotective properties of such sunscreens. Another comment noted that there have been significant discussion and some publications regarding the appropriate way of claiming a protection factor against UVA radiation. The comment recognized that protection against UVA radiation is important for reducing the harmful effects of UVA radiation on the skin as well as for reducing the risks of photosensitization in susceptible individuals. The comment mentioned the difficulty in evaluating the direct effects of UVA radiation in nonphotosensitized individuals (a large dose of UVA radiation is needed to produce a measurable endpoint). The comment suggested the use of topical 8-methoxypsoralen (8-MOP) plus UVA radiation as one way of determining a phototoxic protection factor (PPF) for UVA protective sunscreens. (8-MOP is one of several photosensitizing chemicals which when applied topically or taken orally causes the skin to become abnormally sensitive to certain wavelengths, usually in the UVA range.)

One comment stated that the determination of a UVA radiation-induced MED value ratio with and
without topical application of sunscreen is appropriate for assessing UVA absorbing sunscreens. However, the comment maintained that methods involving the determination of a minimum phototoxic dose ratio in the presence of a topically applied 0.1 percent solution of 8-MOP and subsequent UVA irradiation in the presence and absence of UVA absorbing sunscreens have limited value. Although the comment did not submit an alternative approach, it did assure the agency that the Photobiology Task Force of the AAD would cooperate in developing a test for evaluating UVA sunscreens.

Another comment stated that many currently marketed sunscreen products contain a UVA absorbing active ingredient. However, a universally acceptable quantitative measure of the UVA protection afforded by such products has not been established. Therefore, the comment considered it necessary for the agency to provide manufacturers with guidelines for a testing methodology for UVA absorbing sunscreens. The comment stated that published results for benzophenone-3 and Parsol 1789 demonstrate UVA protection factors ranging from slightly more than 1 to almost 5. Maintaining that the techniques used for obtaining those results involve human evaluations that include (1) measurements of UVA or anthracene phototoxicity, (2) delayed erythema, (3) immediate tanning, and (4) delayed tanning, the comment added that all but the latter produce a clearly defined end-point in Type I and Type II individuals. The comment stated that although phototoxicity studies give higher protection factors than the other techniques, the erythemal effectiveness spectrum for sensitized skin is different from that for normal skin, and the results obtained from phototoxicity studies cannot be extrapolated to a "normal" situation. The comment stated that, for the above reasons, delayed erythema in unsensitized subjects is the most meaningful parameter for evaluating UVA protection. The comment maintained that a UVA protection factor expressed in terms of protection against delayed erythema would be analogous to the SPF and would have similar advantages and disadvantages. The advantage is that sunburn or delayed erythema is a measurable end-point, and sunburn protection is needed. A disadvantage is that the relevance of sunburn protection to protection from skin cancer and photaging are not known, particularly in the case of UVA radiation. The comment acknowledged that the dose requirements for UVA erythema are high and require prohibitively long exposures. However, it maintained that this problem could be solved by using a modified solar simulator with a quartz lens that concentrates the UVA energy within a small area.

One comment claimed that the additional UVA protection afforded by higher SPF's has been advanced as the main reason to allow unlimited SPF label claims. The comment stated that if the primary benefit of SPF's over 30 is protection from UVA radiation, then a methodology should be devised to measure and quantify the amount of this protection. The comment maintained that merely raising the SPF number, which is an indication of UVB protection, is a misdirected effort toward accomplishing this goal. Another comment also recommended that the agency develop appropriate terminology for the protection factor of UVA absorbing sunscreens. Stating that the term "sun protection factor" or "SPF" is well accepted for UVB absorbing sunscreens, the comment maintained that the term "SPF" should not be applied to UVA protection.

The agency believes that including UVA protection information in the labeling of those OTC sunscreen formulations that provide such protection is important in order to fully inform the consumer. However, currently there is no generally acceptable method for determining a meaningful UVA protection factor that is analogous to the SPF. Several methods have been used with varying degrees of success. In one study (Ref. 1), photoprotection against UVA radiation by three sunscreens was evaluated in humans, with delayed erythema, immediate pigmentation, or delayed melanogenesis used as endpoints in normal skin, in skin sensitized with 8-MOP, and in skin sensitized with anthracene. The individual protection factor for each of these endpoints was calculated as the ratio of the threshold dose in the protected skin to that in unprotected skin. UVA protection factors were found to be significantly higher in sensitized skin compared with normal skin. However, the investigators concluded that UVA protection factors obtained in sensitized skin are probably not relevant to normal skin and that pigmentation, either immediate or delayed, is a reproducible and useful endpoint for the routine assessment of photoprotection of normal skin against UVA.

In another study (Ref. 2), the UVA erythema-protective effectiveness of a sunscreen containing an investigational new drug, butyl methoxydibenzoylmethane in combination with a Category I OTC sunscreen containing O, was evaluated using subjects sensitized with 8-MOP. One portion of the study was done outdoors using natural sunlight, and the other portion was done indoors using a solar simulator. A PPF was derived from the ratio of the minimal phototoxic dose of UVA that produced delayed erythema (22 hours) on sunscreen-protected and unprotected skin. The study demonstrated that the combination of 3 percent butyl methoxydibenzoylmethane and 7 percent padimate O provided significantly greater protection than the other sunscreen formulations and that the PPF values determined indoors and outdoors were comparable. The investigator noted that this method has a number of advantages. First, it avoids the long exposure times and larger doses of UVA radiation required to produce erythema in nonsensitized skin. Second, it minimizes a potential source of error by reducing the thermal component of UVA erythema that is a consequence of long exposures with high intensity UVA sources. Third, the use of topical 8-MOP rather than oral 8-MOP to sensitize small areas of skin reduces the time of UVA exposure, the need for ocular protection, and the risk of other adverse reactions associated with systemic 8-MOP. Fourth, shorter UVA exposure times make the study more practical for both the investigator and the subject and reduce the erythemogenic effects of any contaminating UVB radiation to insignificant levels. However, the investigator also pointed out that the PPF values achieved by this method are applicable to subjects sensitized with 8-MOP and are not necessarily applicable to normal individuals.

In 1985, at the agency's request, the Dermatologic Drugs Advisory Committee evaluated a study (Ref. 3) similar to the one described above (Ref. 2) except that some of the subjects were sensitized with orally-ingested 8-MOP and others were sensitized with topically-applied 8-MOP. PPF values were derived from erythema reactions at 48 and 72 hours. Melanogenic protection factors (MPF) were derived from pigmentation responses at 12 to 14 days. The Committee agreed that the use of 8-MOP to accelerate the subject's response to UVA radiation is an acceptable method to qualitatively determine UVA protection. It was also concluded that PPF values derived from 48- and 72-hour erythema reactions and MPF values derived at 12 to 14 days are appropriate endpoints.
The agency believes that a testing method similar to the one described by Lowe, et al. (Ref. 2) could be used to demonstrate that an ingredient provides protection against UVA radiation. However, at this time, the agency does not have enough information or data to propose a method for determining UVA protection in this tentative final monograph. A method should be developed and validated in the same manner as was the sunscreen testing procedure for protection against UVB radiation that is being proposed in this tentative final monograph. Any such method should clearly demonstrate that a particular product provides significant protection against UVA radiation. It should include the use of a control sunscreen preparation that absorbs UVA radiation and that can be used to assure the reliability of the testing procedure and equipment. Even though it may not result in a meaningful PPF or UVA protection factor, a standardized UVA testing method should demonstrate that a sunscreen ingredient either does or does not protect against UVA radiation. Therefore, the agency is requesting comments and data regarding an appropriate testing methodology for OTC sunscreen drug products that afford UVA protection.

At this time, the agency does not believe that it is appropriate for an OTC sunscreen preparation to display a PPF value in its labeling because a PPF value is obtained with methods that use chemically photosensitized skin and is not necessarily relevant to the protection of normal skin. Other UVA testing methods that use normal skin are not sufficiently developed or standardized to produce valid UVA protection factors. If a testing method is developed that results in a meaningful PPF or UVA protection factor, the agency will consider allowing that factor to be included in OTC sunscreen labeling. The agency’s comments on the data are on file in the Dockets Management Branch (Ref. 4).

References


(3) Summary Minutes of the 26th Meeting of the Dermatologic Drugs Advisory Committee, Food and Drug Administration, November 18, 1985, OTC Vol. 06/ATPM, Docket No. 78N-0028, Dockets Management Branch.


P. Comments on the Standard Preparation for the Testing Procedures for Sunscreen Drug Products

74. Referring to the Panel’s discussion of a standard homosalate-containing sunscreen used in the method for determining SPF values (43 FR 38206 at 38259), one comment stated that the formula for this standard was prepared and evaluated by a collaborative industry group consisting of several independent industrial photobiology laboratories and investigators. The validity of the testing methodology and confirmation of an SPF value of 4 for the standard homosalate sunscreen were submitted to the Panel (Ref. 1). After the submission of these data, however, it was observed during routine shelf-life evaluations of the standard that the stability of this formulation was not adequate for use as a standard. Thus, a revised formulation with improved stability characteristics was prepared and again evaluated by five independent laboratories and investigators. Subsequently, the agency submitted the results of this testing to the agency and concluded that the “revised” formulation is more appropriate for validating the test methodology at the SPF 4 level (Ref. 2). The comment recommended that § 352.40 of the Panel’s report be amended to include the revised formulation and its manufacturing directions.

The agency has determined that the improved stability characteristics of the revised 8-percent homosalate standard formulation make it more appropriate for use as a sunscreen standard than the standard preparation originally submitted to the Panel. The agency notes that the SPF of the revised preparation is 4.47 with a standard deviation of 1.279, while the SPF of the standard reviewed by the Panel was 4.24 with a standard deviation of 1.14. However, the results of the collaborative study performed on the revised formulation (Ref. 2) indicate that general agreement between laboratories performing SPF testing can be achieved using this revised standard formulation. In addition, the results from SPF testing recently submitted to the agency (Refs. 3 and 4) demonstrate the reliability of the revised 8-percent homosalate preparation. (See comment 75.) The agency is aware that the revised 8-percent homosalate formulation is currently being used by most manufacturers of OTC sunscreen drug products as a reference control for their sunscreen testing procedures (Ref. 5).

Therefore, the agency is including the revised formulation and its manufacturing directions in proposed § 352.70(a) and (b) as follows:

“(a) Laboratory validation. A standard sunscreen shall be used concomitantly in the testing procedures for determining the SPF value of a sunscreen product to ensure the uniform evaluation of sunscreen products. The standard sunscreen shall be an 8-percent homosalate preparation with a mean SPF value of 4.47 (standard deviation = 1.279). In order for the SPF determination of a test product to be considered valid, the SPF of the standard sunscreen must fall within the standard deviation range of the expected SPF (i.e., 4.47 ± 1.279), and the 95-percent confidence interval for the mean SPF must contain the value 4.

(b) Preparation of the standard homosalate sunscreen. The standard homosalate sunscreen is prepared from two different preparations (preparation A and preparation B) with the following compositions:

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Percent by weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lanolin</td>
<td>5.00</td>
</tr>
<tr>
<td>Homosalate</td>
<td>8.00</td>
</tr>
<tr>
<td>White petrolatum</td>
<td>2.50</td>
</tr>
<tr>
<td>Stearic acid</td>
<td>4.00</td>
</tr>
<tr>
<td>Propylparaben</td>
<td>0.05</td>
</tr>
<tr>
<td>Preparation B:</td>
<td></td>
</tr>
<tr>
<td>Methylparaben</td>
<td>0.10</td>
</tr>
<tr>
<td>Edetate disodium</td>
<td>0.05</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>5.00</td>
</tr>
<tr>
<td>Triethanolamine</td>
<td>1.00</td>
</tr>
<tr>
<td>Purified water U.S.P</td>
<td>74.30</td>
</tr>
</tbody>
</table>

Preparation A and preparation B are heated separately to 77 to 82 °C, with constant stirring, until the contents of each part are solubilized. Add preparation A slowly to preparation B while stirring. Continue stirring until the emulsion formed is cooled to room temperature (15 to 30 °C). Add sufficient purified water to obtain 100 grams of standard sunscreen preparation.

The agency’s comments on the data are on file in the Dockets Management Branch (Ref. 6).

References

(1) OTC Vol. 06/0169.

(2) "Comparative Study on a New Standard Sunscreen Formula," Comment No. C00046,
Docket No. 78N-0038, Dockets Management Branch.
(3) Comment No. 00080, Docket No. 78N-0038, Dockets Management Branch.
(4) Comment No. 00083, Docket No. 78N-0038, Dockets Management Branch.
(6) Letter from W.E. Gilberston, FDA, to J.D. Cope, Nonprescription Drug Manufacturers Association, coded LET40, Docket No. 78N-0038, Dockets Management Branch.

75. The agency's initial evaluation of the Panel's report and of the comments received raised some questions regarding the use of the 8-percent homosalate formulation as the standard for the validation of sunscreen drug product testing. Results from two collaborative studies submitted to the agency (Refs. 1 and 2) were inconsistent and produced SPF values that placed the 8-percent homosalate standard formulation in different PCD's. From this information, the agency concluded that the SPF and PCD of the 8-percent homosalate formulation had not been precisely established. Therefore, in the notice announcing a public meeting to discuss sunscreen testing procedures (52 FR 33598 at 33600), the agency reopened the administrative record. The agency asked whether new data had become available since the 8-percent homosalate standard formulation was originally tested that would provide additional information regarding the reliability of that formulation.

In response, the agency received several comments favoring retention of a revised 8-percent homosalate preparation as the standard for validation of sunscreen testing procedures (Ref. 2). (For a discussion of the revised homosalate formulation that was submitted to the agency in response to the Panel's report, see comment 74.) Two comments stated that the homosalate preparation is not a standard in the normal meaning of the word. The comments asserted that the formulation actually is a reference control to ensure that the testing facility and the equipment being used to conduct the SPF evaluations provide results within an acceptable range of variation. One comment added that use of the reference control ensures that the SPF calculated for a test product is valid and reproducible. Another comment referred to the results of interlaboratory testing of the 8-percent homosalate formulation that placed it in two different PCD's. The comment maintained that such results are not unexpected because the nominal SPF value of the preparation is on the PCD boundary. Thus, according to the comment, these results are not in themselves an indication of excessive variation.

The comment further suggested that the sunscreen monograph contain guidelines as to how testing laboratories should use the results obtained from the testing of the "control" formulation. For example, the comment asked if all the test results should be invalidated if the "control" SPF is outside the 90-percent confidence interval expected for the control. The comment also stated that the control should be as well characterized as possible, including its physical and chemical stability.

Another comment stated that currently there is no mandatory rejection of data based upon the results of the control. Testing facilities are not required to test the 8-percent homosalate control along with each product test. The comment suggested that, for each test panel, an appropriate control sunscreen should also be tested, and the validity of the test should depend upon the results of the testing of the control sunscreen. If the results of the control sunscreen are found to be significantly different from the "nominal" value, then the sample sunscreen test should be invalid. The comment believed that such a requirement would ensure compliance by various testing laboratories to a common reference system. Another comment stated that the collaborative studies submitted previously to the Panel and the agency (Refs. 1 and 2) established consistent results among laboratories for the 8-percent homosalate standard and established its PCD as "Moderate Sun Protection" and its SPF value as 4. The comment maintained that after 12 years of consistent use of the 8-percent homosalate preparation, it was satisfied that the preparation has adequately fulfilled its purpose as a reference control. The comment added that the current 8-percent homosalate standard is the revised formulation that was previously submitted to the agency (Ref. 2). The comment was not aware of any new comparative testing done on this formulation, and stated that there was no particular need to change the current standard. The comment noted, however, that any changes regarding testing methodology, especially those affecting statistics or application density, will also affect the SPF and PCD of the 8-percent homosalate standard or any other standard that might be chosen.

Stating that it had used the 8-percent homosalate standard for the past 9 years or more, one comment stated that it had evaluated the SPF value of this formulation in nearly 500 volunteers. The testing occurred both under indoor conditions using UV radiation from a solar simulator equipped with a xenon-arc lamp and under outdoor conditions using natural sunlight. The comment maintained that if the formulation is correctly manufactured and used within 3 to 6 months of preparation, it provides an SPF of 4.0 ± 0.5 when a solar simulator is used as the source of UV radiation. However, under outdoor conditions, the comment added that the 8-percent homosalate preparation provides an SPF of 2.5 to 3.0. Maintaining that the homosalate formulation is useful, adequate, and acceptable for use as an internal standard for testing sunscreen formulations having SPF values in the range of 4 to 8, the comment recommended that the agency retain this internal standard.

The CTFA stated in 1987 that over the past 10 years, the industry has developed a massive block of test data that substantiates the validity of the 8-percent homosalate preparation. CTFA submitted new data from sunscreen testing conducted by four laboratories during 1985 through 1987 (Ref. 3) and contended that the results show a consistent response for the homosalate control both within and between laboratories. The comment stated that these data substantiate the reliability of the 8-percent homosalate control for sunscreen testing of products over the entire range of SPF's currently marketed. Another comment also submitted recent data and stated that these data confirm that the formula is predictable and reliable as used in its testing facilities (Ref. 4).

The agency believes that the new data (Refs. 3 and 4) that have been submitted support the reliability of the revised 8-percent homosalate standard preparation for testing sunscreens with SPF values of 15 or below. The data submitted by CTFA (Ref. 3) include information accumulated on over 1,700 subjects over 2 to 3 years by four different laboratories. These data indicate a mean SPF value equal to approximately 4, with a standard deviation around 0.7 for the 8-percent homosalate standard. The other data submission (Ref. 4) contains results from 100 subjects, with a mean SPF value of 4.35 and a standard deviation of 0.61. These data are consistent with the results of the CTFA submission (Ref. 3). The agency notes that these new data (Refs. 3 and 4) are consistent with the initial test results of the revised formulation of the 8-percent homosalate
preparation, which indicate a mean SPF of 4.47 with a standard deviation of 1.279 (Ref. 2). (See comment 74.)

The agency notes that one comment suggested that the homosalate standard is appropriate for testing sunscreens with SPF values of 4 to 8. Another comment believed that the homosalate control should be used to validate the testing procedures for products with SPF's up to and including 15. However, there is currently not enough information available for the agency to determine that the use of this standard is valid for testing sunscreens with SPF values above 15. (See comments 77 and 78.)

The agency considers the 8-percent homosalate formulation not to be a standard within the normal meaning of that word. Rather, it is a control that should be used to validate the testing procedure, equipment, and facilities. As such, it plays no part in the calculation of the SPF value for the test product. However, the agency believes that the homosalate control should be tested at the same time as the test product for every SPF determination. If the SPF of the homosalate preparation is within acceptable limits of variability of the validated mean, then the SPF determined for the test product can be considered valid, if it meets all other requirements for acceptable limits of variability. The 95-percent confidence interval for the mean SPF of the data from the control product should contain the values of the study, the study should be considered invalid. These provisions are included in the sunscreen testing procedures being proposed in this tentative final monograph.

Regarding one comment's statement that the 8-percent homosalate preparation provides an SPF of 2.5 to 3.0 under outdoor conditions, the agency is not including outdoor testing procedures in this monograph. (See comment 79.) The agency's comments on the data are on file with the Dockets Management Branch (Ref. 5).

References

(1) OTC Vol. 060169.
(3) Comment No. 00080, Docket No. 78N-0038, Dockets Management Branch.
(4) Comment No. 00083, Docket No. 78N-0038, Dockets Management Branch.
(5) Letters from W.E. Gilbertson, FDA, to M.B. McTernan, Johnson and Johnson, and E.E. Kavanaugh, Cosmetic, Toiletry and Fragrance Association, coded LET39 and LET57, respectively, Docket No. 78N-0038, Dockets Management Branch.

76. Referring to the Panel's discussion of a standard sunscreen (43 FR 38206 at 38259), one comment contended that the international sunscreen testing experience with a homosalate formulation as a sunscreen standard is rather poor. The comment recommended that 5 percent PABA (aminobenzoic acid) should be used as the standard sunscreen because the international literature mentions it as a widely-known formulation. The comment asserted that in sunscreen testing it is assumed that the sunscreen standard have an SPF value of at least 4 or, preferably, an SPF value of 6.

The comment did not provide any literature references to support its contention that 5 percent aminobenzoic acid is frequently referred to in the international literature. Also, no data were submitted to demonstrate that 5 percent aminobenzoic acid should be preferred over the Panel's proposed 8 percent homosalate formulation as a sunscreen standard. The agency is aware that the Panel reviewed data from a collaborative study involving comparative testing of standard sunscreen products. In this study, two different sunscreen preparations containing either 8 percent homosalate or 4 percent aminobenzoic acid were tested by six laboratories (Ref. 1). The study showed that individual subjects using the 4-percent aminobenzoic acid sunscreen in an alcoholic vehicle had mean SPF values ranging from a low of 6.4 to a high of 9.7. The mean SPF value for the entire group of 60 volunteers was approximately 7, with a standard deviation of 1.61. The SPF values for the 8-percent homosalate formulation were not as scattered or as variable as the SPF values for the 4-percent aminobenzoic acid formulation. The results for the 8-percent homosalate gave an individual mean SPF that ranged from a low value of 3.8 to a maximum value of 6.0. When all the data were compiled for the homosalate formulation, the mean SPF value was 4.24 with a standard deviation of 1.14. The investigators reporting on the comparative testing of aminobenzoic acid and homosalate as sunscreen standards suggested that the 4-percent aminobenzoic acid in alcohol appears to be more difficult to spread uniformly on the test site. This difficulty might have contributed to the wide variation in the test results.

The agency is unaware of any data demonstrating that a 5-percent aminobenzoic acid formulation referred to in the comment is superior to a sunscreen standard to the 8-percent homosalate formulation proposed by the Panel and revised by the agency. Furthermore, additional data supporting the reliability and wide acceptance of the revised 8-percent homosalate standard were submitted to the agency in 1987 (Refs. 2 and 3). (These data are discussed in comments 74 and 75.) The agency tentatively concludes that the revised 8-percent homosalate formulation is suitable to use in the testing procedures to ensure the uniform evaluation of OTC sunscreen drug products. The agency is including the revised formulation for the 8-percent homosalate standard and directions for its manufacture in proposed § 352.70(b). (See comment 74.)

References

(1) OTC Vol. 060169.
(2) Comment No. C00080, Docket No. 78N-0038, Dockets Management Branch.
(3) Comment No. C00083, Docket No. 78N-0038, Dockets Management Branch.

77. In the notice of public meeting to discuss appropriate testing methods for OTC sunscreen drug products (52 FR 33598 at 33602), the agency asked for comment and supporting data on the following question: "Can these higher SPF values be accurately determined using currently available sunscreen testing procedures?" The agency also asked for the submission of appropriate testing methods if the currently recognized sunscreen testing procedures are not considered adequate.

Six comments responded to the agency's question regarding the adequacy of using currently available testing procedures for sunscreen drug products claiming to have SPF values in excess of 15. The comments agreed that the current testing methods are adequate for evaluating such formulations. However, only two comments provided data from actual studies.

One comment (Ref. 1) submitted data on a sunscreen formulation that was tested at two different laboratories which utilized the methods found in the Panel's testing procedures in subpart C of its recommended monograph (43 FR 38206 at 38265). In one laboratory, test results from 21 subjects produced a mean SPF value of 36.88. Results from the 25 subjects tested at the second testing facility produced mean SPF value of 34.1. The comment also submitted data on another sunscreen formulation. The test results from 20 subjects resulted in a mean SPF value of 29.16. Furthermore, the comment claimed that in vitro testing, consisting of optical measurement, yielded SPF values of 32 and 26.5, respectively, for these two formulations. The comment
noted that because no recognized alternate validating methodology is available, it is impossible to answer whether these results are "accurate." However, the comment maintained that the results are reproducible and consistent with optical transmission properties measured in vitro on the skin. The comment added that the principles of testing are the same for both high SPF and low SPF products and that there are no physiological differences in the responses that would necessitate a different testing procedure.

Another comment (Ref. 2) submitted the results of five studies, each involving about 20 subjects. Three of the studies were performed in one laboratory, while the other two were performed in another testing facility. The studies were basically designed according to the Panel's recommended testing procedure. All five studies used test produced including SPF values that exceeded 15. These values ranged from 24.4 to 36. The standard deviation of the results ranged from 1.6 to 5.05, and the standard error percentage of the mean ranged from 0.91 to 2.95.

Regarding the data submitted by the first comment (Ref. 1), the agency believes that the results of tests on the same formulation on humans at two testing laboratories give some indication of reproducibility. Moreover, the results support the use of the Panel's method for evaluating sunscreens with SPF values higher than 15. The in vitro results may also be supportive, but the comment did not submit those data.

It is unclear from the data submitted by the second comment (Ref. 2) whether the test procedure and mean SPF values should have produced the same mean SPF value, or whether they were different products. In addition, it could not be determined whether the 8-percent homosalate control was used in two of the studies (Refs. 3 and 4), and the light source was not well defined in another two studies (Refs. 5 and 6). The agency acknowledges that it is possible to obtain consistent SPF values above 15 in the context of one study. The unresolved problems are whether high SPF values are reproducible among testing laboratories, and whether such values are valid.

The agency notes that the 8-percent homosalate control used in some of these submitted studies has an SPF value of approximately 4. The agency is proposing that one or more standard preparations with SPF values higher than 4 be developed for testing sunscreens with higher SPF values (see comment 78). Also, such standard preparations, when developed and validated, would be used to develop new test procedures to validate existing testing procedures for sunscreen drug products with SPF values higher than 15. At this time, such standards are not available.

The agency has determined that the submitted data are not sufficient to demonstrate that the testing methods currently used to evaluate sunscreen drug products with SPF values up to 15 are equally applicable to evaluating sunscreen drug products with SPF values above 15. The agency believes that collaborative studies using an appropriate control preparation are necessary. The agency invites further comment on this matter. If necessary, the agency will publish an amendment to this tentative final monograph to address any new data submitted regarding testing procedures for sunscreens with high SPF values (above 15), so that the public may comment before a final rule is published.

The agency's comments on the data are on file in the Dockets Management Branch (Ref. 7).

References
(1) Comment No. CO0083, Dockets No. 78N-0038, Dockets Management Branch.
(2) Comment No. CO0080, Dockets No. 78N-0038, Dockets Management Branch.
(7) McTernan, Johnson and Johnson, and E.E. Kavanagh, Cosmetic Industry and Fragrance Association, coded LET38 and LET'74, respectively, in Docket No. 78N-0038, Dockets Management Branch.

78. In the notice of a public meeting to discuss appropriate testing procedures for OTC sunscreen drug products, the agency stated that it was concerned about using a standard preparation that may have a relatively low SPF value of 4 to validate a sunscreen testing procedure that is supposed to determine a wide range of SPF values (currently SPF 2 to SPF 30 and higher) (52 FR 33598 at 33600). The agency asked whether standard formulations with SPF values higher than 4 would make the determination of SPF values higher than 8 and 15 more accurate. The agency stated that it believed that two or three standard preparations should be available having SPF values representing the entire range of possible SPF values (e.g., SPF 8 and SPF 20 or SPF 4, SPF 15, and SPF 25).

The agency also asked if sunscreen preparations were available that would be appropriate for use as standard preparations when testing sunscreen drug products with estimated SPF values greater than 15. If so, the agency requested that data on such preparations be submitted.

Several comments agreed with the agency that additional standard or control preparations with SPF values higher than 4 should be available for sunscreen drug product testing. One comment agreed with the agency on the usefulness of a low and a high SPF control and recommended that the homosalate control be retained for low SPF products. The comment stated that it is aware of prototype control formulations that would fulfill the requirements for a high SPF control. Another comment recommended that the standard preparations with SPF values of 4 and 9 should be available and added that it is essential that a choice be left to the investigator to use either of the standards depending upon the expected SPF testing range. Another comment suggested that standard formulations should have SPF values of 4 and 12.

Some comments recommended that, in addition to the SPF 4 standard control, a standard preparation with an SPF of 15 should be available. One comment stated that one or two additional standards should be available and that one of these standards should have an SPF value of greater than or equal to 15. The comment added that both the level of absorbers and the vehicle (sunscreen base) of the standard preparation must be clearly defined. Another comment stated that for testing sunscreens with SPF values under 15, the 8-percent homosalate standard, as defined and recommended by FDA, or the 2.7 percent cinnamate, as defined and recommended by DIN, should be used. However, for evaluating sunscreen preparations with SPF values higher than 15, the comment recommended that a standard which has an SPF of at least 15 and which does not contain substances known as reflectors should be used. The comment stated that this standard may contain either UVB filters with extended absorption in the UVA
One comment suggested that the sunscreen testing methodology should spell out which control formulation should be used with which range of expected SPF values. For example, the SPF 4 control should be used where the expected SPF of the test product is less than 4, the SPF 15 control should be used where the expected SPF is 8 to 30. Another comment stated that the control standards should be run at least once a year in the laboratory test, but another comment proposed that the standard should be run twice a year.

One comment stated that the use of a high SPF control would improve the accuracy of the testing procedure and provide a benchmark of compliance for testing laboratories. The comment stated that it is willing to provide formulations for use as high SPF (and waterproof) reference standards, but because these formulations are proprietary, they could not be disclosed publicly. The comment stated that it could provide finished products with SPF values of 8⁺ and 20⁺ (both waterproof) to the industry for a fee in line with the costs of producing, and testing, and distributing the materials and submitted data on the SPF testing of these products (Ref.1). One comment noted that it was planning to submit data in support of a control for high SPF testing, but realized that such data could not be submitted before the administrative record closed in April, 1988. The comment stated that it would submit the data as part of a petition to reopen the administrative record to consider these data and requested that the agency give favorable consideration to such a petition. [No such petition has been submitted to date.] The comment stated its willingness to work with the agency to develop and validate an additional control.

The agency believes that the 8- percent homosalate standard preparation proposed in this tentative final monograph is suitable for testing sunscreens with lower estimated SPF values (which may include values up to and including 15). [See comment 75.] However, the agency believes that one or more additional standard preparations with SPF values higher than 4 (e.g., SPF 15, 20, or 25) may be desirable for testing sunscreens with higher SPF values (e.g., SPF values higher than 15). Depending on the SPF values of the additional standard preparations, one of those preparations may be deemed more appropriate to use in testing products with an estimated SPF value of 15. At this time, the agency does not have enough data or information to reach a conclusion regarding the use of other suitable standards or their formulations. Only one comment submitted data on higher SPF standard preparations, one with an SPF of 8⁺ and one with an SPF of 20⁺ (Ref. 1). These data are not sufficient to verify the reliability of these preparations. For the preparation with an SPF of 8⁺, the comment submitted data on 120 subjects, but for the preparation with an SPF of 20, it submitted data on only 20 subjects. In both cases, mean SPF values higher than the expected SPF value were obtained. The agency would need more within-laboratory data as well as data from different laboratories before it could determine if these standard preparations were appropriate. In addition, the agency notes that the formula of any standard preparation required by an OTC drug monograph must be in the public domain so that the preparation can be prepared in any laboratory.

<table>
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<td>(1) Comment No. C00893, Docket No. 78N-0036, Dockets Management Branch.</td>
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Q. Comments on Indoor vs. Outdoor Testing Procedures for Sunscreen Drug Products

79. One comment disagreed with what it believed was the Panel’s opinion that determination of the SPF value under laboratory conditions (with artificial light sources) will produce more reliable and reproducible SPF values than those achieved using natural light. Referring to personal experience in testing sunscreen products, the comment stated that artificial light sources have given a higher SPF value than natural sunlight and offered to submit such data if requested. The comment pointed out that the physical properties of sunscreen products always tend to be altered when tested under natural light, and that the combined effects of UVB, UVA, visible, and IR radiations are more pronounced under outdoor conditions. In view of the availability of reliable meters to measure light fluences (amounts of light) and of good facilities to conduct outdoor testing, the comment concluded that the Panel should have insisted that at least one study be conducted under outdoor conditions in order to obtain a true SPF value, adding that the cost of such testing is not an excuse when the principal issue concerns the health of people and when the major objectives are to minimize or prevent skin cancer and wrinkling of the skin. For these reasons, the comment argued that indoor as well as outdoor testing should be mandated by FDA.

A second comment agreed with the Panel’s recommendation that both artificial and natural light can be used in the testing of sunscreens (43 FR 38206 at 38259). However, the comment suggested that final sunscreen formulations should be required to undergo at least one outdoor simulated-use test with natural sunlight. The comment maintained that artificial light sources should be used only in research and development programs to identify formulations that appear to have merit under laboratory conditions and to partially evaluate formulations with very high protective factors, explaining that the SPF of such formulations “might range from 8X to 18X in the laboratory environment, but that range narrows considerably (from 4X to 6X with some formulations) when the products are tested under natural sunlight-simulated-use conditions.” The comment concluded that it would be reasonable to require all sunscreens (even those with protection in the range of 8X or greater) to demonstrate performance under natural sunlight-simulated-use conditions. The comment requested that the tentative final monograph explain the role of artificial and natural light testing in the development of sunscreen drug products, and provide guidelines for natural sunlight testing and recommendations for preferred simulated-use conditions.

One reply comment questioned the validity of the above comments and supported the Panel’s recommendations regarding both solar simulator testing...
and natural sunlight testing. The reply comment stated that it believed laboratory conditions using artificial light can be constructed to parallel outdoor conditions without the variables associated with outdoor testing. It believed that "solar simulator testing provides a means of standardization, a means of assuring reproducible results and ultimately, and most importantly, a means of insuring uniform product labeling." The reply comment contended that the same amount of erythemic energy is required to produce a sunburn using either a xenon arc solar simulator or natural sunlight, and that, as long as other environmental factors are reproduced, the SPF of a sunscreen drug product is reproducible under laboratory conditions using a xenon arc solar simulator. The reply comment submitted a published paper (Ref. 1) and the results of studies, previously submitted to the Panel for review, which it said demonstrated reproducible results in various laboratories, using the xenon arc solar simulator (Ref. 2).

Another comment, responding to the January 26, 1988 public meeting to discuss sunscreen testing procedures, stated that it did not support an outdoor test. The comment maintained that although sunscreens are applied for use in natural sunlight, this source of UV radiation is too variable and too unpredictable for routine use in the assessment of a large number of commercial sunscreen products.

The Panel did not recommend the use of an artificial light source over natural sunlight for determining SPF values. In discussing testing procedures for determining the SPF value of a sunscreen product, the Panel considered the use of artificial light (i.e., a solar simulator) and the use of natural sunlight as light sources (43 FR 38206 at 38259 and 38260). The Panel discussed the advantages and disadvantages of using these light sources for determining SPF values. The Panel described an artificial light source in § 352.41(a) and discussed the use of a natural light source in § 352.41(b) of its recommended monograph. It outlined procedures for determining SPF values using an artificial light source in § 352.43 and for the determination of SPF values using sunlight in § 352.44. However, the Panel did not favor one method over the other. The use of SPF values evolved from research and development efforts involving both natural and artificial light sources. The agency believes that labeled SPF values should be based on testing conducted under the most carefully controlled conditions so that the results are as accurate and reproducible as possible. Accurate and reproducible testing procedures ensure that competitive products with the same SPF values have essentially the same effectiveness.

The agency agrees with the reply comment that indoor testing using a properly filtered and calibrated solar simulator provides an appropriate means of standardizing SPF measurements by providing controls over most of the variables that cannot be controlled in outdoor testing. (For a discussion of solar simulators, see comment 86.) The agency believes that indoor testing ensures reproducible results because it is easier to control significant variables such as temperature and humidity. Outdoor testing of sunscreen products is not reproducible from day to day because of uncontrollable variables such as changing cloud cover, changing radiation intensity with time, changing sun angle to the body surface with time, and variable heat-induced sweating. A solar simulator produces a constant spectrum at a constant angle with a high output in the UV range of 290 to 400 nm (43 FR 38260). It is a more reliable source of UV radiation than the sun whose spectrum changes continuously depending upon angle, altitude, pollution, and the amount of ozone in the atmosphere (Ref. 3). Additionally, although there is not enough sunlight in a day to conduct outdoor testing of sunscreens with high SPF values, testing of these products may be done quickly and efficiently using a high intensity solar simulator.

The agency has reviewed the published paper and the results of a study submitted by the reply comment (Refs. 1 and 2) as well as a later publication not available to the Panel (Ref. 4). The agency tentatively concludes that SPF values determined by indoor testing compare favorably with SPF values determined by outdoor testing. The study by Sayre, et al. (Ref. 1) showed that the MED for unprotected skin induced by a solar simulator was similar to the MED values obtained in outdoor testing using natural sunlight. SPF values obtained for products tested indoors using solar simulators were consistently higher than the SPF values obtained outdoors using natural sunlight. However, the study demonstrated that if certain critical environmental conditions, such as temperature, are controlled, the SPF value of a sunscreen product determined with an artificial light source is similar to that obtained using natural sunlight. A subsequent study by Sayre, et al. (Ref. 4) suggests that when testing sunscreens for substantivity (resistance to water wash-off), varying environmental conditions are not considered because the substantiveness of the sunscreen formulation negates the effects of heat and humidity on the SPF determination. The data in this study demonstrate good correlation between indoor and outdoor testing results of substantive sunscreen formulations.

The agency believes solar simulator testing is a more accurate method of determining SPF values for product labeling than outdoor testing. Carefully controlled solar simulator testing provides a convenient means of standardization among laboratories and is not affected by variable outdoor environmental conditions. Therefore, the agency is proposing only general testing procedures in § 352.72 that use an artificial light source, as specified in § 352.71, for determining SPF values. Accordingly, the agency is not including the Panel's recommended § 352.41(b) "Natural light source (sunlight)" and § 352.44 "Determination of SPF value using natural light source (sunlight)" in this tentative final monograph. In addition, the Panel's reference to natural sunlight testing in § 352.42(b) "Response criteria" is not being proposed.

References:
(2) Comment No. SUP002, Docket No. 78N-0036, Dockets Management Branch.

80. One comment suggested that a conversion factor of 0.7 be used to correct for the observation that the calculated SPF of sunscreen drug products is higher when tested indoors using an artificial UV light source than when tested outdoors using natural sunlight. The comment maintained that this approach would also provide for retaining the 2 milligram/centimeter squared (mg/cm²) application density in the sunscreen testing procedures. At the same time, it would result in an SPF value that would better reflect the actual sunscreen protection the consumer would experience in natural sunlight.

The agency does not believe that the testing procedures should include a conversion factor of 0.7 to adjust a calculated SPF that has been determined using an artificial light...
source. The proposed sunscreen testing method using an artificial light source is reasonably, but not absolutely, comparable to sun exposure conditions. As discussed in comment 79, there are inherent variables in sunscreen testing done under outdoor conditions. The agency believes that indoor testing with an artificial light source is a more accurate method of determining SPF values than is outdoor testing. Furthermore, the comment did not submit data to demonstrate a constant relationship between SPF values determined using an artificial light source and SPF values determined under natural sunlight conditions. Nor were data provided to support the suggested conversion factor. Therefore, the agency is not including a conversion factor in the proposed sunscreen testing methods.

81. Referring to the Panel’s discussion of environmental conditions for testing sunscreen products in sunlight (43 FR 38206 at 38260 and 38266), one comment provided possible specifications for the testing of the standard sunscreen formulations in natural sunlight. To circumvent environmental variables, the comment suggested that following possible specifications for weather (and environmental) conditions: no intermittent clouds (less than 2 percent), ambient temperature of 84 °F to 88 °F, haze (minimal), and humidity of 50 to 70 percent. Among other environmental variables affecting the testing of standard formulations, the comment listed wind, air quality index, and other exposure conditions, such as latitude and the time of the year. The comment did not suggest specifications for these conditions. The comment predicted that test failures would result if cloudiness became excessive. Therefore, the comment urged the agency to place very strict limits on weather variations during the testing of standard formulations.

The Panel discussed the effect of atmospheric conditions and geographic latitude on the development of the MED in fair-skinned people (43 FR 38206 at 38210). Atmospheric conditions alter the solar erythmic intensity and, depending upon the latitude, also affect the exposure time required to induce one MED. Although testing of sunscreen products in natural sunlight provides useful information, such testing is associated with many variables, such as those mentioned by the comment. Accordingly, the agency is not proposing natural sunlight testing as a regulatory standard. For a discussion on the determination of SPF values using an artificial light source, see comment 79.

82. Noting the subject selection procedures in § 352.42(a), one comment stated that the selection of subjects with Skin Types I, II, and III seems appropriate for evaluations using artificial light. For natural sunlight testing, however, the comment contended that subject selection should be restricted to test subjects with moderate skin pigmentation. The comment argued that restricting the skin type for natural sunlight tests should decrease subject variation in evaluating the test and control formulations. The comment added that the conditions of simulated use during natural sunlight testing of sunscreens should be specified. It cited “no swimming” and “schedule of exercise” as examples of conditions that should be specified.

As described in comment 79, natural sunlight testing of sunscreen drug products provides SPF values that vary too greatly to be useful in assigning PCD claims. Therefore, the agency is proposing only artificial light testing procedures. Thus, it is not necessary to specify conditions for natural sunlight testing of sunscreens.

R. Comments on Artificial Light Sources

83. One comment disagreed with the Panel’s statement that solar simulators of 150 Watts (W) usually produce 10 or 12 solar constants (43 FR 38206 at 38260). The comment explained that solar simulators “based on the principle reported by Berger, where the radiation is reflected from visible light and an IR reflecting dichroic mirror, produce the equivalent of ten to twelve times the amount of UV radiation contained in mid-latitude noon sunlight.” The comment added that if most of the visible light and IR radiation were not removed from the beam, severe burns would result. Therefore, the comment felt that the Panel’s statement is too broad and incorrect. For similar reasons, the comment also objected to the Panel’s statement concerning solar simulators producing 40 solar constants (43 FR 38260) and contended that because not all solar simulators are built on the Berger principle, they will emit a variety of intensities of UV radiation depending on their design and construction.

The Panel defined a solar constant as “the total amount of energy at all wavelengths per square meter, available from the sun, at the earth’s surface” (43 FR 38260); however, as the comment stated, solar simulators recommended for sunscreen testing emit only UV wavelengths of radiation. A true solar constant also includes energy from visible light and IR radiation. The agency believes that the Panel’s report would have been more precise had it read “solar constants of UV radiation.” Concerning the comment’s objection that solar simulators will emit a variety of intensities of UV radiation depending on their design, the Panel stated that the “more powerful instruments can produce up to 40 solar constants.” The Panel recognized that solar simulators may emit a variety of intensities of UV radiation when it qualified its statement by saying “up to” 40 solar constants.

84. One comment questioned the Panel’s statement, in its discussion of light sources and monitoring (43 FR 38206 at 38260), that the UV intensity of a solar simulator will be reported in J/m². The comment stated that if the J/m² refers to “the total output of a solar simulator without specifying spectrum, the results in terms of numbers will be most misleading.” Further, the comment claimed that the statement is technically incorrect because joules represent the energy output of a solar simulator. Therefore, the comment added that the dose of radiation should be expressed as “erythema effective joules/m²,” and the intensity of radiation should be expressed as “erythema effective Watts/m².” The comment stated that a number of action spectra for skin erythema have been published and that it is of particular importance for the sunscreen ruling that “the FDA specify one action spectrum which will then be used for appropriate integrations.” The comment added that because the majority of the sun’s energy output is in the visible and IR range, and the UV radiation component rarely exceeds a few percent of the total and changes rapidly with time, measurement of the sun’s intensity without making the corrections suggested above will produce useless results. Therefore, the comment felt that radiometers for measuring the sun’s intensity should also be calibrated in “erythema effective joules/m²,” if a dose is being measured, or in “erythema effective Watts/m²,” if intensity is being measured.

A second comment felt that, although the monograph appropriately does not specify the scale to be used in measuring the output of solar simulators, the Panel’s report is confusing regarding the units in which radiometers should be calibrated. The comment cited the following statements from the Panel’s report (43 FR 38260):
The output of a solar simulator is measured in units of Joules. The UV light intensity of a solar simulator will be reported in J/m². The comment stated that this requirement would restrict the use of monitoring devices (such as the widely used Roberton-Berger (R-B) meter) that meet all other Panel-recommended requirements for radiometers but that provide output in terms of sunburn units/hour. The comment suggested that the Commissioner clarify that the agency believes that the Panel's SPF calculation as follows:

\[
Watts, \text{ and } \text{"radiant energy," which has simulators. The agency believes that the Commissioner clarify that the comments suggested that this requirement provide output in terms of sunburn all other Panel-recommended units/hour. The comment suggested that the SPF calculation as follows:

The output of a solar simulator is "erythema effective exposure" in place of the term "intensity" instead of "dose" in its discussion of solar simulators. The agency believes that the proper nomenclature should be the currently accepted CIE definitions of units applicable to all radiation (Refs. 1, 2, and 3). The acceptable quantities are "radiant power," which has units of Watts, and "radiant energy," which has units of Joules. "Irradiance" is the radiant power incident upon a surface per unit area of the surface and is expressed in W/m². "Radiant exposure" is the energy equivalent of irradiance and is expressed in J/m². Additionally, the term "spectral irradiance" refers to the irradiance of the source restricted to a narrow wavelength band of the spectrum, and is expressed in terms of Watts per square meter per nanometer (W/m²-nm).

In § 352.43, "Determination of SPF value using artificial light source," the Panel defined UV radiation exposure in units of time. The agency believes that it is more accurate to express dose as the "erythema effective exposure," in units that define the total amount of erythema effective energy applied to the testing substrate, i.e., as J/m². Thus, in order to determine the erythema effective exposure, the measured output from the solar simulator (spectral irradiance, W/m²-nm) must be weighted using an agreed-upon erythema action spectrum. And this spectrum must have weighting factors that have a different effectiveness for producing erythema with different wavelengths of UV radiation.

The agency is aware that although various erythema action spectra have been published, none have been universally adopted (Ref. 4). The agency agrees with the first comment that an action spectrum for erythema should be agreed upon. The CIE has proposed a reference action spectrum based upon a statistical analysis of the results of several published studies carried out since 1964 (Ref. 4). The agency believes that the CIE's proposed reference action spectrum is appropriate for use in the testing procedures for OTC sunscreen drug products. The following equations describe the proposed reference spectrum:

\[
V_i(\lambda) = 1.0(250 < \lambda < 298 \text{ nm})
\]

\[
V_i(\lambda) = 10^{0.094(298 - \lambda)}(298 < \lambda < 328 \text{ nm})
\]

\[
V_i(\lambda) = 10^{0.015(139 - \lambda)}(328 < \lambda < 400 \text{ nm})
\]

The data contained in the action spectrum are to be used as spectral weighting factors to calculate the erythema effective exposure of a solar simulator as follows:

\[
E = \sum_{\lambda} \frac{V_i(\lambda)*I(\lambda)}{250}
\]

where:

\(E\) = Erythema Effective Exposure (dose)

\(V_i\) = Weighting Factor (Erythema Action Spectrum)

\(I\) = Spectral Irradiance (W/m²-nm)

The agency believes that adoption of this erythema action spectrum would represent a significant step forward in the development of standardized equipment for the testing of sunscreen drug products. Therefore, the agency is proposing to modify § 352.43 of the Panel's recommended monograph to include this action spectrum and the proposed calculation to determine the erythema effective exposure. This information appears in proposed § 352.73(a), (b), and (c). The agency is using the term "erythema effective exposure" in place of the term "erythema time interval" in the SPF calculation as follows:

SPF value = the ratio of erythema effective exposure (J/m²) to the erythema effective exposure (J/m²) (MED (US)) The agency invites comments on this proposal.

The agency agrees with the second comment that the Panel's report is confusing regarding the units in which radiometers should be calibrated. The agency does not agree, however, that the radiation of solar simulators need not be measured in terms of Joules. The agency believes that the CIE units mentioned above should be used in all sunscreen testing, including the calibration of equipment. The agency acknowledges that requiring the output of a solar simulator to be measured in Joules means that the "widely used" R-B meter cannot be used to measure the output of solar simulators. However, radiometers, including the R-B meter, have limited value for measuring the output of simulators. Considering present technology, the agency recommends the use of multipliers or similar spectrally sensitive devices for measuring the radiant energy output from solar simulators (Refs. 5 and 6). (See comment 88.)

Because natural sunlight is not being proposed as a testing light source in this tentative final monograph, the agency is not addressing the requirements for radiometers to measure natural sunlight. However, any specifications for instruments to be used for measuring solar simulators may also be used for measuring natural sunlight.

References


85. Referring to the Panel's statement that approximately 6x10⁶ J/m², as measured by a recording radiometer, will evoke 1 MED in Skin Types I and II (43 FR 36206 at 36262), one comment stated that the number is meaningless and that such a dose can be obtained from the sun without any UVB being
The agency has proposed an action spectrum for erythema and discussed the 
appropriate units for measuring radiant energy elsewhere in this document. (See 
comment 84.)

86. One comment stated that the 
artificial light source used in testing to 
determine SPF values should not be 
restricted to xenon lamps. The comment 
referred to the SPF values determined 
that the xenon arc solar simulator is the 
preferred artificial light source (43 FR 
38206 at 38259 and 38260). The 
comment suggested that, in the tentative 
final monograph, the agency should 
defocus the use of the xenon arc 
lamp over other artificial light sources 
unless it can be demonstrated to be 
superior through corroboration testing.

The comment argued that the 
Westinghouse FS 40 sunlamps provide a 
useful laboratory source for UVB 
radiation and have two advantages over 
the xenon arc lamp: (1) the absence of 
discomfort to the subject during the 
challenge to UV radiation, and (2) an 
area of coverage of over 20 times greater 
than that of a 150 W xenon arc lamp. 
The comment argued that the FS 40 
sunlamp results in greater effectiveness 
in laboratory studies because the 
exposure of one subject and a 
150 W xenon arc lamp would take about 1½ hours. 
A second comment stated that 
experience with xenon arc solar 
simulators is insufficient to determine 
whether a correlation exists between 
SPF values determined using them as 
the light source and SPF values 
determined using natural sunlight. The 
comment suggested that the Panel's 
testing procedures also allow for the use 
of other light sources, such as the 
Weinsberger Solarium or Osram Vitalux.

A reply comment contended that the 
light sources suggested by the above 
comments, e.g., the FS series of 
fluorescent sunlamps and the filtered 
intermediate pressure mercury vapor 
sunlamp (such as the Osram Vitalux) do 
not adhere to the Panel's 
recommendations for an appropriate 
light source and could cause 
misvaluation of the sunscreen product. 
The comment stated that these two 
types of light sources emit radiation 
shorter than 290 nm and, as a result, 
may produce erythematous responses to nonsolar radiation. The comment added 
that the Osram lamp also emits a line 
spectrum that is not continuous. 

Therefore, the lamp deviates from 
natural sunlight and from the Panel's 
recommendations for an appropriate 
light source. The comment supported 
the Panel's recommendation to use solar 
simulator light sources that emit a 
continuous UVB spectrum of 290 to 320 
nm with not more than 1 percent of the 
emitted radiation shorter than 290 nm.

In the notice of public meeting to 
discuss sunscreen testing procedures 
(52 FR 33598 at 33599), the agency 
questioned the variability of the data 
submitted to the Panel in support of the 
recommended testing methods and 
proposed several possible modifications 
to these testing methods in an effort to 
improve them. In response to the 
publication and the subsequent meeting 
held on January 26, 1988, the agency 
received several comments that 
addressed the solar simulator as a 
possible source of error in the sunscreen 
testing procedures.

Four of these comments suggested 
that light sources other than the xenon 
arc solar simulator were appropriate for 
use in sunscreen testing. Stating that 
the light source is one of the remaining 
variables in the existing methods for 
SPF determination, one comment 
submitted testing results obtained in 
France (Ref. 1). This comment 
maintained that these data suggest that 
the use of different light sources now 
specified by existing methods is 
unlikely to affect results significantly. 
Another comment stated that a frequent 
problem of the xenon arc solar 
simulators is that their spectral 
characteristics can change following 
alteration or damage to the filtration 
system used with these machines. 
Noting that there are alternative UV 
sources that are utilized for sunscreen 
testing, the comment stated that four 
Osram lamps are used in the DIN 
methods. The comment added that high 
pressure mercury halide sources have 
also been used. The comment 
maintained that even though these 
Sources are not as solar simulating as a 
perfectly filtered xenon arc source, their 
spectral characteristics remain constant. 
The comment subsequently presented 
data purporting to show that similar 
SPF values are derived when using 
either an appropriately filtered xenon 
arc solar simulator or a high pressure 
mercury halide lamp even though the 
high pressure mercury halide lamp 
emits a discontinuous spectrum (Ref. 2). 

Stating that both instruments have 
advantages, the comment noted that the 
advantages of the mercury halide source 
include ease of use and stable spectral 
output reliability. The comment 
suggested that alternative UV sources be 
permitted providing that they possess 
appropriate quantities of UVA and UVB as 
terrestrial sunlight. The comment 
also suggested that nonxenon arc 
sources be tested with SPF assays and
compared to xenon arc simulators prior to acceptance of an allowed UV radiation source.

Two comments cited a recent publication (Ref. 3) to support a contention that, for testing sunscreen products with an SPF under 15, either a xenon arc or a mercury halide lamp can be used with similar results. However, both comments claimed that for sunscreens with an SPF over 15, a xenon arc solar simulator should be used. Another comment maintained that the testing of sunscreen drug products with an SPF of 15 or higher is best achieved by using high-intensity xenon arc lamps of 1 kilowatt (kw) or greater and that the Panel-recommended 150 W xenon arc lamp is inadequate for this purpose. One comment noted that an Ultravitalex lamp, which is a "line source mercury arc," has very little emission in the UVA range. This comment stated that when UVA absorbers are added to sunscreen formulations, the Ultravitalex lamp will overestimate the efficacy of protection against a solar source.

Five comments maintained that the solar simulator should be the light source of choice for sunscreen drug product testing. Three comments suggested that the sunscreen monograph should include specifications for acceptable light sources for testing sunscreens. One comment initially suggested that the solar simulator should be filtered to match the spectrum of the sun at a 60° angle; however, the comment subsequently recommended that the light source should be filtered to match the spectrum of the sun at 75° above the horizon. Another comment recommended that because the sun angle rarely exceeds 80° elevation, except in the tropics, a spectrum similar to an 80° elevation should be used and should give adequate safety factors. One of the comments stated that the xenon arc light source should be filtered with "WG 320, 1 mm thickness."

One comment explained that because the biological effectiveness of UV radiation wavelengths from 295 to 400 nm drops rapidly by a factor of over 1,000, the emission spectrum (i.e., spectral power distribution) of the UV radiation source will greatly influence SPF values. The comment stated that:

1. The sun emits a polychromatic continuous spectrum of different wave lengths;
2. Low pressure fluorescent sun lamps emit a continuous spectrum mainly in the UVB, or primarily in the UVA range;
3. High pressure mercury arcs provide discontinuous line spectra; and
4. High intensity solar simulators, based on xenon, xenon-mercury, or doped tungsten may mimic solar UV radiation, but they require special filtration to shape the UVB spectrum and to remove intense visible and IR radiation. The comment added that the age of the lamp, temperature of the bulb or arc, and the age of the filters will influence both spectral power distribution and irradiance.

The comment recommended that for purposes of SPF testing, light sources with a spectral power distribution closely representing that of sunlight should be used and that the light source should not emit radiation below 290 nm. Stating that the power consumption (i.e., 150 W, 2500 W, etc.) is immaterial, the comment maintained that only the spectral power distribution counts. Adding that accurate spectroradiometry methods are now available, the comment stressed that it is important that the spectral power distribution of the light source be known exactly and that equipment be monitored regularly. According to the comment, spectral power distribution and irradiance of filtered light sources vary in the first minutes of operation. For that reason, testing should not begin until 30 minutes after the equipment has been turned on to allow all systems to come to operating temperature and spectrum. This practice is particularly important when new lamps or filters are installed, in which case the solar output of the light source should be monitored frequently during the early times of operation.

The agency points out that the Panel (43 FR 38206 at 38265) did not restrict the artificial light source for sunscreen drug product testing to xenon arc solar simulators; they were recommended as the preferred artificial light source (43 FR 38260). The agency believes that the Panel recommended xenon arc solar simulators as the preferred light source because it had more information and more experience with these light sources than with other light sources.

The agency does not consider the data submitted by two of the comments (Refs. 1 and 2) sufficient to demonstrate that light sources with emission spectra different from that of sunlight can produce results equivalent to those obtained using a xenon arc lamp. In one study (Ref. 1), the investigators determined the SPF of the standard preparation used in the DIN sunscreen testing procedure using a modified DIN testing procedure in which a xenon arc solar simulator replaced the solar simulator normally used. Using 22 subjects and the modified DIN method, they determined that the geometric mean of the SPF was 3.53 and concluded that this result compared favorably with the SPF of 3.7 obtained when the DIN standard preparation is evaluated using the normal DIN testing procedures. However, for a true comparison, the same batch of sunscreen standard should have been evaluated by both methods on the same 22 subjects. The agency also notes that these data merely indicate that the light source may have no effect on the determination of a low SPF. There are no data showing that the light source will not affect the determination of a high SPF such as 15.

The second set of data (Ref. 2) consists of two SPF values for each of five sunscreens. One SPF was determined using a metal halide light source, and the other was obtained using a xenon arc source. No other information or data were included. These data are not adequate to demonstrate the comparability of light sources for sunscreen testing procedures.

At this time, the agency agrees with the Panel that xenon arc solar simulators are the preferred light source for sunscreen testing because they emit a continuous spectrum that can be filtered to match sunlight. However, the agency acknowledges that other light sources may be used providing that they meet the specifications being proposed in § 352.71. (See comment 87.)

The agency believes that the light source is a significant factor that can affect the outcome of sunscreen testing. It is important, therefore, that the sunscreen monograph include adequate specifications describing an appropriate light source. The Panel defined an appropriate solar simulator for sunscreen testing as a light source having: (1) A continuous emission spectrum in the UVB (290 to 320 nm); (2) Less than 1 percent of its total energy contributed by nonsolar wavelengths (wavelengths shorter than 290 nm); and (3) No more than 5 percent of its erythemally effective energy contributed by nonsolar wavelengths.” (45 FR 38259 and 28260). The Panel provided these specifications for a solar simulator in § 352.41(a) of its recommended monograph, but did not identify any specific light source which would meet these criteria.

The knowledge regarding solar simulators, the erythema action spectrum, and the role of UVA in the production of skin damage has increased greatly since the Panel's report was published in 1978. The agency believes that the specifications for a solar simulator recommended by the Panel for sunscreen testing should be revised based on new information. Although the Panel recommended that the solar simulator...
used for sunscreen testing should emit a continuous UV spectrum from 290 to 320 nm (UVB radiation), the agency now believes that the solar simulator used to determine the SPF value of a sunscreen product should mimic the harmful spectrum of the sun as closely as possible and should include both the UVB and UVA spectra. The agency notes that the Panel's recommendation for sunscreen testing is to use a xenon arc lamp which is used for UVA, are most responsible for UVA induced photaging (Ref. 6). UVA radiation can also augment the acute and chronic effects of UVB radiation (Refs. 7 through 11). In addition, the agency notes that some of the Category I sunscreens protect against UVA radiation as well as UVB radiation. The agency, therefore, concludes that the solar simulator used for sunscreen testing should emit a continuous UV spectrum from 290 to 400 nm (UVB and UVA radiation), similar to that of the sun at sea level. (For a discussion of sunscreens that protect against UVA radiation and UVA labeling claims, see comment 53.)

Regarding which sunlight spectrum should be used as the model that a solar simulator should mimic, the agency notes that one comment recommended matching sunlight at an 80° solar elevation. Another comment initially recommended matching sunlight at a 60° solar elevation but later recommended a 75° solar elevation. There are two ways of describing the position of the sun in the sky. The comments' method uses the angle of the solar elevation above the horizon to describe the position of the sun. The other method uses the angle of the sun measured from the sun's zenith. A solar elevation of 80° equals a zenith angle of 10°. In this rulemaking, the agency is using the zenith angle to describe the position of the sun in the sky.

The agency is aware that the spectral quality of the sun is not constant and is dependent upon the effective thickness of the atmosphere through which the radiation must pass. The effective thickness of the atmosphere is dependent upon various factors including the latitude and altitude of the observer and the zenith angle of the sun (Ref. 12). The agency realizes that it is important to specify which sunlight spectrum should be used for testing sunscreen drug products and believes that a zenith angle of 10° represents a reasonable angle to specify in the testing procedures. Therefore, the agency is proposing that the solar simulator used for sunscreen testing should have a spectrum similar to sunlight at sea level from the sun's zenith angle of 10°. The agency invites comment on this proposal.

Regarding one comment's recommendation that the xenon arc light source should be filtered with "WG 320, 1 mm thickness," the agency is not including specific filters in its specifications for solar simulators. The agency is not restricting the light source for sunscreen testing to xenon arc lamps, but is including specifications that the light source used for sunscreen testing must meet. In order to fulfill these specifications, light sources must be appropriately filtered. However, the filters necessary to obtain the proper spectrum depend upon the unfiltered output of the light source. Therefore, it would be inappropriate for the monograph to specify specific filters. However, the agency is proposing that a solar simulator be properly filtered so that its output simulates sunlight at sea level from the sun at a 10° zenith angle between 290 and 400 nm.

The agency is aware that, due to fluctuations in electrical supply and ambient temperature, the spectral output of solar simulators can change significantly during the period of time immediately after being switched on (Ref. 13). This is more pronounced when optical filters are used. Thus, the agency is proposing in § 352.71 that a solar simulator should not have significant time-related fluctuations in radiation emissions after an appropriate warm-up period. The investigator should carefully evaluate the solar simulator being used in order to determine the time period required for warm-up. Because a uniform exposure is important to the outcome of sunscreen testing, the agency is also proposing that the solar simulator have good beam uniformity (within 10 percent) in the exposure plane. The agency is also proposing that a solar simulator be measured periodically with an accurately calibrated spectroradiometer system or equivalent instrument. (See comment 87.)

The Panel recommended that a solar simulator should have less than 1 percent of its total energy output contributed by nonsolar wavelengths shorter than 290 nm and not more than 5 percent of its total energy output contributed by wavelengths longer than 400 nm (43 FR 38206 at 38259). However, the Panel's reasons for choosing these limits are not clear. Ideally, a solar simulator used for testing sunscreen drug products should emit only solar UV radiation. Extrinsic radiation only adds to the error of the testing method. Although the Panel's recommended limits are adequate and are being proposed in this document, the agency believes that these limits could be more narrowly defined because the design of solar simulators is better today than when the Panel report was published. For example, it is possible that a solar simulator could have less than 0.1 percent of its total energy output contributed by nonsolar wavelengths shorter than 290 nm and not more than 1 percent of its total energy output contributed by wavelengths longer than 400 nm. Therefore, the agency is requesting comments on the amount of extraneous radiation that should be allowed in the output of a solar simulator.

The agency is revising the specifications proposed by the Panel in § 352.41(a) of its monograph to reflect these changes and is including new specifications in proposed § 352.71 to read as follows:

A solar simulator used for determining the SPF of a sunscreen drug product should be filtered so that it provides a continuous emission spectrum from 290 to 400 nanometers similar to sunlight at sea level from the sun at a zenith angle of 10°; it has less than 1 percent of its total energy output contributed by wavelengths shorter than 290 nanometers; and it has not more than 5 percent of its total energy output contributed by wavelengths longer than 400 nanometers. In addition, a solar simulator should have no significant time-related fluctuations in radiation emissions after an appropriate warm-up period, and it should have good beam uniformity (within 10 percent) in the exposure plane. To ensure that a solar simulator delivers the proper spectrum of UV radiation, it must be measured periodically with an accurately calibrated spectroradiometer system or equivalent instrument. The agency invites further comment on these proposed specifications.

References
(1) Comment No. C00076, Docket No. 78N−0038, Dockets Management Branch.
(2) Comment No. C00089, Docket No. 78N−0038, Dockets Management Branch.
Therefore, the comment stated xenon
lamps will emit a variety of intensities of UV radiation, depending on their
design and construction. A reply
comment questioned the validity of the objections by the first comment and
stated that at least two highly reputable
and respected manufacturers currently
produce xenon arc lamps under
sufficiently controlled procedures to
effectively eliminate concerns about the
standardization of these light sources
between manufacturers.

The agency agrees with the Panel that
a properly filtered xenon arc solar
simulator is the preferred artificial
radiation source. The xenon arc solar
simulator was first described in 1969 by
Bergen (Ref. 1), and solar simulators
have been widely used in
photobiological research since then.
According to Sayre (Ref. 2), the design
of these instruments has changed little.
According to Diffey (Ref. 3), the
technology of optical radiation sources
is well established, and the factors that
can affect the stability and the life of
these lamps is well documented.

Currently, a number of xenon arc solar
simulators systems are commercially
available to provide solar simulated
radiation. While one type of xenon arc
simulator may produce a slightly
different spectrum than another, and
different models may also emit
different spectra as the lamp ages,
solar simulators are commercially
available to provide solar simulated
radiation, depending on their
specifications. These
differences are useful in measuring
UV, not simply in reproducing sunlight,
but also for eliminating IR radiation that is
important not only for monitoring the
interactions of UV radiation, but
also for eliminating IR radiation that is
significantly present in the xenon arc
emission.

The agency agrees with the intent of
the comment. However, considering
present technology, the agency believes
that spectroradiometry (measurement of
wavelengths in the form of spectra), or
similar spectrally sensitive techniques,
should be used to characterize the
output from a solar simulator (Ref. 1).
Although the Panel recommended the
use of calibrated thermopiles to measure
the output of solar simulators (43 FR
38260 at 38260), the agency believes that
the thermopile is not an appropriate
instrument for performing
measurements of solar simulators. For
measuring the output from a solar
simulator, a radiometer must have
accurate sensitivity in the UV spectral
region and be equipped with an
appropriate mechanism to filter out any
visible light or IR radiation that may be
emitted by the solar simulator.
properly calibrated radiometer, if unfiltered, will measure the total energy output of the light source regardless of the wavelengths present or the intensities of those wavelengths. As a solar simulator ages, it frequently emits progressively less UV radiation although its emissions in the visible and the IR spectrum continue to remain relatively constant. An unfiltered radiometer may not detect these changes.

There are several ways to determine radiometric values which, when correctly used, yield the same physical values. The agency is not requiring a specific method. The following suggestions are offered to establish the important parameters; physically equivalent alternatives are also acceptable.

Measurements should be performed using generally accepted radiometric principles and techniques. The quantity to be measured should be reported in spectral irradiance values which have units of W/cm²-nm. For solar simulators, all measurements should be made on the complete device consisting of the light source and any related housing, filtration, or attachments manufactured or assembled for use with the device. Although filtered radiometers may be used to measure the output of solar simulators, the agency believes that such meters have limited value because they do not measure the spectral distribution of the light source. Accordingly, the agency recommends that spectroradiometers, or similar spectrally-sensitive instruments, be used. Spectroradiometry is the most fundamental method for measuring the radiant energy output (Refs. 2 and 3). Sophisticated instruments for the measurement of spectral irradiance should be used to adjust for spectral output distribution changes caused by such factors as filtration, distance from the source, warm-up time, and lamp age. Additionally, in order to use biological weighting functions, the spectral distribution of the source must be determined.

The spectroradiometric measurements on the solar simulator should be made at the same distance from the lamp that will be used for the sunscreen testing exposures. The measurements on the continuum part of the spectrum should be made at intervals of no more than 10 nm in the UV wavelength region below 400 nm. In addition, the spectral lines in the emission should be measured with a sufficiently narrow spectral bandwidth so as to adequately measure the level of radiation being emitted in those lines.

The measurements should be made with instruments calibrated against standards of spectral irradiance. These standards should have been calibrated either by the U.S. National Institute for Standards and Technology (NIST) (formerly the National Bureau of Standards (NBS)) or by another laboratory against standards calibrated by NIST using NIST-recommended or generally accepted techniques. The instruments should be calibrated on a regular basis, sufficient to document the integrity of the data.

The use of other types of radiometers may be of limited value if properly calibrated and used. There have been attempts to develop radiometers with spectral responses incorporating biological weighting functions. Because biological weighting functions change dramatically with wavelength in the UV spectral region, it is imperative that radiometers be carefully designed for useful results. There are radiometers that measure the photopic (spectral response similar to what the human eye sees) functions well, but this is not the case for other weighting functions (Ref. 3). The principal problem is measuring UV radiation while rejecting all visible light and IR radiation. In addition, because the agency’s proposed erythema action spectrum (see comment 64) covers the entire solar UV spectral region from 290 to 405 nm, a radiometer that measures the entire UV spectrum is needed.

As stated above, a spectroradiometer system or equivalent instrument is preferred for measuring the output of a solar simulator. The agency is specifying in § 352.71 that an “accurately calibrated spectroradiometer system or equivalent instrument” be used. (See comment 87.)

References

89. One comment suggested that, in addition to the R-B meter, the Panel should have recommended other UV measuring instruments that are reliable, well calibrated, give radiant energy in Watt-seconds per square centimeter, and have continuous measurement capability. Arguing that the R-B meter is an expensive research instrument that is not readily available, the comment described another, less expensive instrument that it had found to be very reliable for both the indoor and outdoor measurement of UV radiation. Another comment stated that specific references to the R-B meter should be deleted from § 352.44. The comment stated that, if proper control formulations are used to validate test results and calculate the SPF value, the monitoring device becomes secondary to the control formulation. The comment mentioned that the R-B meter is available from only one commercial source, and this limitation could place unnecessary restraints on natural sunlight-simulated use testing. The comment recommended that § 352.44 either be expanded to be more representative of the available instrumentation or be generalized with no reference to specific instrumentation. Another comment stated that the wording of § 352.44 should be changed because it provides that radiometers other than the R-B meter may be used. Another comment stated that the R-B meter is widely used and widely available.

The Panel discussed the use of the R-B meter for monitoring the amount of exposure to natural sunlight during the testing of a sunscreen drug product (43 FR 38260). Citing a compilation of data from various radiation studies (Ref. 1), the Panel stated that the R-B meter has proved to be successful in monitoring and reproducing solar erythemic exposures. The Panel also stated that other recording radiometers are in use that perform a similar function. The Panel did not limit its recommendation for radiometric instruments to the R-B meter only. Concerning the comment’s recommendation that the agency delete references to the R-B meter in § 352.44 and expand this section to include other types of radiometric instrumentation, the agency is not including the Panel’s recommended § 352.44 in this tentative final monograph. (See comment 79.)

The agency earlier discussed the R-B meter as a monitor of the output of solar simulators used in sunscreen drug product testing. (See comment 84.) The R-B meter is only one of the recording radiometers that can be useful, and the agency is not mandating any specific instrument for monitoring solar simulators.

Reference
90. One comment stated that a major factor that affects the erythema response of individuals and the resulting SPF and
PCD determinations is the xenon arc lamp solar simulator and its four major components: the quartz bulb, dichroic mirror, W. G. cut-off filters used at the UV radiation exit site, and the line voltage. The comment stated that the first three of these components become coated with dust particles, smoke, and laboratory-derived gaseous films from acids, ammonia, etc. To minimize variations in UV intensity, the comment recommended that the light box be kept covered with a black cloth when not in use, and that variations in line voltage be minimized by a voltage stabilizer.

The comment's recommendations appear reasonable in the absence of any contrary evidence. Parties who conduct tests on OTC sunscreen drug products should consider these recommendations as part of their test procedures.

S. Comments on the Design of the Testing Procedures for Sunscreen Drug Products

91. Referring to the agency's public meeting on sunscreen testing procedures and statistical methods held on January 26, 1988, one comment recommended that the testing procedures specify product "blinding." The comment stated that many laboratories already include "blinding" as part of their testing procedures but felt that this procedure should be mandatory to eliminate any product bias during subjective evaluation of the MED.

In a supplementary submission (Ref. 1), the comment maintained that potential investigator bias in clinical studies involving SPF determinations can be eliminated or reduced in several ways. Stating that sunscreen formulations (e.g., lotions, creams, gels, and solutions) can be packaged in identical appearing containers prior to testing, the comment maintained that such a blinding procedure is essential when the person applying the products is also evaluating the erythema on the test sites 16 to 24 hours later. However, the comment added that this blinding procedure can only be completely successful if all the formulations are identical in consistency and color. Moreover, the comment pointed out that the major disadvantage with this procedure is the need to retest repackaged units to ensure that the concentration of the active ingredients has not changed during repackaging. The comment added that this procedure does not contribute much to the study of blinding if a mixture of sunscreen formulations (e.g., gel and cream) are evaluated in the same study or if sunscreens of different SPF estimates are used.

According to the comment, a second way to eliminate investigator bias is to randomize the application of sunscreen formulations to the test sites. Such randomization (generated from computer or random number tables) eliminates investigator bias with respect to evaluation of erythematous scores on a specific test site or sites. An untreated test site may be included in the randomization if necessary. Because the erythema score on the untreated irradiated area is used in the SPF calculation of all sunscreens evaluated, the comment stated that any investigator bias in reading the erythema scores on the untreated, irradiated area will be constant for all formulations.

In order to eliminate bias, the comment stated that it is imperative to blind the erythema evaluator with respect to the application of the products to the treatment sites and, if possible, to the times of UV irradiation. The comment maintained that prior knowledge of these variables may easily influence the reading of the MED by the evaluator, which would ultimately affect the calculated SPF.

The Panel did not require "blinding" in its recommended testing procedures for sunscreen drug products. However, the agency agrees with the comment that blinding would be a desirable part of the sunscreen testing procedures. The agency believes that the person who applies the sunscreen to the test site and administers the doses of UV radiation should not evaluate the erythema end points after the waiting period. In addition, if two or more sunscreens are being tested at the same time, they should be applied to the testing subsites in a randomized manner. If only one sunscreen drug product is being tested, the testing subsites should be exposed to the varying doses of UV radiation in a randomized manner. The agency is also proposing revisions in the Panel's recommended § 352.42(e), Application of test materials. The following sentences are being added to the end of paragraph (e): "If two or more sunscreen drug products are being evaluated at the same time, the test products and the standard sunscreen, as specified in § 352.70, should be applied in a blinded, randomized manner. If only one sunscreen drug product is being tested, the testing subsites should be exposed to the varying doses of UV radiation." The agency is including these revisions in proposed § 352.72(e) and § 352.72(h), respectively.

Reference

92. One comment, submitted in response to the Panel's report, suggested that the testing of sunscreen agents with the solar simulator should also be performed on skin areas below the belt line, where no sun has typically changed skin color. The comment asserted that most people have tanned skin areas on the back of the neck to the belt line. Another comment referring to the subject selection procedures for testing sunscreen drug products was submitted in response to the public meeting held on January 26, 1988. At that meeting and in the notice

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announcing the meeting (52 FR 33598 at 33599), the agency expressed concern regarding the apparent variability of data generated by the testing procedures recommended by the Panel. The comment stated that guidelines for the selection of subjects are not rigidly defined in the Panel’s recommended monograph. The comment suggested that deviations in SPF determinations may result from the enrollment of subjects that do not meet the necessary criteria. Stating that volunteers of Skin Types I, II, and III are essential for evaluating the SPF value of the test product, the comment added that these subjects must not have undergone sunbathing or been exposed at a tanning salon for at least 30 days prior to enrollment as a test volunteer. The comment stated that the site for product application must be clearly defined, and products should not be tested on the habitually sun-exposed areas of the upper back (suprascapular region) or on the anterior forearms. The comment considered any fair-skinned subject who claims to be Skin Type I, II, or III, but who has a tanned back or who exhibits an intense immediate pigment darkening (IPD) reaction, as contributing to significant deviations in the determination of SPF values. The comment recommended that such subjects be dropped from the study after MED tests have been performed on day one of the test. The comment emphasized that fair-skinned individuals with untanned backs of Skin Types I, II, and III should be selected for the evaluation of sunscreen test products; individuals with tanned backs or those who have recently been exposed to the sun should be excluded. The comment added that the MED values of different regions of any test subject vary (e.g., the MED of the upper back [suprascapular] is always higher than the MED of the lower or central back [infraescapular]). The comment maintained that the MED near the anterior cubital region of the upper arm is less than the MED of the volar antibrachial region of the lower arm due to the variations in the thickness of the stratum corneum and pigment content of the epidermis. The comment stated that such variations significantly influence the SPF determination. The comment concluded that to achieve uniformity in test results, the site for evaluation of sunscreen formulations should be specified, and it should preferably be the back area involving the infrascapular region.

The agency agrees with the second comment. Procedures for the selection of test subjects should be clearly defined, and the site for product application should be the carefully inspected back between the beltline and the shoulder blades (scapulae) lateral to the midline. The Panel’s recommended sunscreen testing procedures clearly define the criteria for the selection of test subjects and test sites. In §352.42 of the Panel’s recommended monograph, only fair-skinned volunteers with Skin Types I, II, and III are to be selected for enrollment in testing a sunscreen product. If a test subject has areas on the back that are unsuitable for testing a sunscreen product, then that subject should not be included in the study. In discussing the procedure for inspecting the test site of a potential test subject, the Panel recommended that a physical examination should determine the presence of sunburn, suntan, scars, active dermal lesions, and uneven skin tones on the areas of the back to be tested (43 FR 38208 at 38265).

The Panel also considered the areas of the body that are suitable for sunscreen testing and recommended the area of the back between the beltline and the shoulder blade, and lateral to the midline (43 FR 38265). The Panel stated that the back offers a large surface area which is best suited for testing and comparing a number of sunscreen samples. Also, the back has been traditionally used by manufacturers for testing new sunscreen agents. It is important to use the same skin site on the body for testing because comparisons must be made between treated and untreated areas, and areas treated with different ingredients. Using the same skin site helps to minimize testing result differences that are due to variations in skin sites rather than to actual differences between ingredients. The first comment did not specify particular areas below the belt line that would be suitable for sunscreen testing, nor did it submit data that would demonstrate that the use of such areas will provide consistent test results that allow accurate comparisons between treated and untreated areas. Therefore, the agency accepts the Panel’s recommendation that the area to be tested shall be the back between the beltline and the shoulder blade (scapulae) and lateral to the midline and is proposing this requirement in §352.72(d).

The second comment did not provide any data to demonstrate that test subjects who exhibit an intense IPD reaction contribute to erroneous test results. In §352.42(h), the Panel recommended that all immediate responses, including “immediate darkening or tanning” be recorded. The Panel did not, however, recommend that subjects who displayed immediate reactions be excluded from testing. The agency is not now proposing to revise the Panel’s recommendation. However, if adequate data are submitted demonstrating that an intense IPD reaction contributes to the variability of sunscreen test results, the agency will consider excluding such subjects by modifying §352.72(h) concerning response criteria and/or §352.72(i) concerning rejection of test data.

In its notice of a public meeting to discuss appropriate testing procedures for OTC sunscreen drug products (52 FR 33598 at 33601), the agency questioned the amount of test sunscreen and standard sunscreen that should be applied to the test subject. The agency noted that the Panel had recommended a test application of 2 mg/cm² (the application density). An independent sunscreen testing expert had suggested to the agency that 1 mg/cm² may be a more appropriate amount of sunscreen to use in the testing procedure because 1 mg/cm² more accurately reflects the amount of product normally used by a consumer. The agency commented that use of 1 mg/cm² would undoubtedly produce lower SPF values and suggested that this may be a way to accommodate the new higher SPF values because using this amount of the product may produce SPF values that more closely approximate the time a product will provide protection.

The agency received 24 comments in response to its question. The majority of the comments, including two manufacturer associations in the United States, advocated continuing the use of an application density of 2 mg/cm². Nine comments, including one from a European manufacturer’s association, suggested or recommended that the standard density of sunscreen product per application should be in the range of 1 to 1.5 mg/cm².

Comments advocating an application density of 1.5 mg/cm² stated that this particular issue is one which goes far beyond the simple question of how much sunscreen a consumer may typically apply. These comments stated that the published data on the application rates of sunscreens seem to be confusing because they vary over a wide range. One comment stated that, based on published studies and unpublished communications (Ref. 1), there is not a “universal” application amount which will be appropriate in all cases. The product type, its viscosity, the product container, consumer use habits, and the areas of the body to which the sunscreen is being applied are among the factors which determine
how much product a consumer may typically apply. Therefore, the comment noted, it should not be surprising that the application density amounts found in the literature vary from about 0.6 mg/cm$^2$ to 20 mg/cm$^2$. The comment stated that, although at first glance it may appear not to make any difference which amount one chooses to use for the test conditions, it is important that the testing procedure result in SPF values which reflect actual consumer protection.

The comment stated that several studies and comments have demonstrated that most products tested according to the current United States procedure (using 2 mg/cm$^2$) have sun protection values which promise a higher protection than is usually experienced by a typical consumer under actual use conditions in natural sunlight (Ref. 1). The comment added that the test procedure should result in SPF values which are, in the majority of cases, reflective of actual consumer protection in natural sunlight. Otherwise, according to the comment, currently allowable label claims such as "Stay in the sun X-times as long as before without sunburning" are misleading and incorrect for the majority of consumers. The comment stated that using a smaller application amount, such as 1.5 mg/cm$^2$, will result in SPF values which more accurately reflect the actual protection a typical consumer will enjoy in natural sunlight. The comment continued that the DIN method for evaluating sunscreens, which uses an application amount of 1.5 mg/cm$^2\pm 10$ percent, results in SPF values more clearly reflecting actual consumer protection in natural sunlight. The comment felt that reducing the application amount to 1 mg/cm$^2$ may result in SPF numbers that are too low. The comment concluded that an application density of 1.5 mg/cm$^2$ would be the most appropriate to use for determining SPF values. According to the comment, use of this density would be a significant step towards a uniform, worldwide testing procedure that would ensure a certain level of protection from a product regardless of where in the world it was purchased.

A majority of comments, however, strongly advocated retention of 2 mg/cm$^2$ as the standard application density. Acknowledging that an international reference system of SPF values is a desirable goal, one comment stated that until all other details of the testing protocol are also identical (e.g., the light source used for testing), a change in the application density to a common level will not accomplish that end. The comment added that a review of the literature supports the use of 2 mg/cm$^2$ as a meaningful test density that has been in use for 10 years.

Another comment noted that no other countries' standards use an amount as low as 1 mg/cm$^2$. The Australian standard is 2 mg/cm$^2$, and Japan and Britain generally follow the proposed FDA guidelines. Germany uses an application density of 1.5 mg/cm$^2\pm 10$ percent. Another comment stated that insofar as international uniformity is sought, 2 mg/cm$^2$ is a more appropriate figure than 1.5 mg/cm$^2$. The comment maintained that climate, geography, latitude, population diversity and size, and the multitudes of lifestyles that include year-round sunbathing make the United States a more reliable international model upon which to base sun exposure standards than Germany.

One comment noted that there are many published studies which discuss the average use level of lotions or sunscreen drug products. It cited a study by Schlagel and Sanborn (Ref. 2) which demonstrated that ointments or creams were applied to skin at a use rate of 2.4 mg/cm$^2$ when used to cover the whole body. The comment also mentioned a study by Hoppe (Ref. 3) in which the average use rate for sunscreen drug products was determined to be 4.0 mg/cm$^2$ for creams, 2.1 mg/cm$^2$ for lotions, and 0.75 mg/cm$^2$ for oils. The comment concluded that, for two of the three categories of sunscreen drug products, the use rate was greater than 2 mg/cm$^2$. The comment added that the results of a study by Lynfield and Schechter (Ref. 4), in which they investigated how vehicles were applied, demonstrated that application rates varied among individuals up to 100 percent, confirming that sunscreen application is a highly subjective exercise. The comment stated that this study found usage of a sunscreen lotion to be 1.3 mg/cm$^2\pm 1.3$ mg/cm$^2$. The comment maintained that it is especially interesting that 1.3 mg$^2$ was the average application density when the subject was instructed to apply "thinly," whereas in the United States, the labeling of sunscreen products generally encourages "liberal" application.

The comment also discussed a study by Stenberg and Larko (Ref. 5) which indicated that the actual application of sunscreen preparations by individuals results in a layer thickness closer to 1 mg/cm$^2$ than 2 mg/cm$^2$. It stated that a publication of the Skin Cancer Foundation (Ref. 6) interpreted the study (Ref. 5) to mean that some individuals may be using "inadequate" amounts of sunscreen for achieving proper sun protection and emphasized the need to use enough sunscreen to protect against sunburn and long-term skin damage. The comment noted that the Skin Cancer Foundation reiterated its support of the 2 mg/cm$^2$ level "recommended by dermatologists" (Ref. 6). The comment concluded that it is in the public interest to encourage liberal use of sunscreens than it is to change the application density of SPF testing.

The comment further stated that, in over 10 years of testing sunscreens by the proposed FDA guidelines, it has become apparent that 2 mg/cm$^2$ is an amount which can be uniformly applied to the test site. The comment stated that use of a smaller amount makes uniform application much more difficult, and that some dosage forms cannot be uniformly applied at lower levels. The comment mentioned the wealth of preclinical information in the scientific literature regarding the effects of sunscreens in preventing skin cancer and premature aging. The comment stated that such tests have generally been conducted using the 2 mg/cm$^2$ sunscreen application rate. The comment expressed concern that a change in the application density will make past scientific studies difficult to interpret for comparative purposes. As a result, the comment contended that the scientific community would lose 10 years of valuable historical data that are the basis of much of the educational position of the AAD and the Skin Cancer Foundation. The comments emphasized that there is no scientific support indicating that any other application amount, including 1 mg/cm$^2$ or 1.5 mg/cm$^2$, is better, more accurate, or more reflective of consumer use.

Another comment stated that a change in the application density ought to be considered by the agency only when the results are necessary for adequate protection of the public health.

Several comments noted that consumers have learned by experience what level of labeled SPF they need individually to help prevent sunburn. These comments asserted that radically altering the system for determining SPF values would lead to confusion and inappropriate choices of sunscreen products. One comment stated that consumers in the United States now buy products with SPF numbers based on tests conducted using the 2 mg/cm$^2$ application rate. They have become familiar with the benefits provided by these SPF's based on that testing, and they purchase products on the basis of that familiarity. The comment maintained that lowering the application density in the SPF determination would, in many cases, alter the SPF value, leading to industry-
wide relabeling and/or reformulation of most sunscreen drug products. The comment felt that, from the consumer’s point of view, such a change would require a complete revision in his or her sunscreen buying habits. Noting that an individual who burns moderately and tans gradually typically wants and uses an SPF 4, the comment contended that a product with an SPF of 4 based on a 1 mg/cm² application density would provide more protection than he or she expects or wants. The comment felt that it is not sound public policy for FDA to disturb an established labeling scheme when the change will confuse consumers and the agency has no information that the change will provide any real benefits.

Another comment agreed with the comment above and strongly recommended retention of the 2 mg/cm² application density. Noting that its sunscreen products are labeled with a toll free number to allow consumers to readily report their concerns or complaints, the comment stated that during the past 2 years, data from this consumer contact line, along with all other correspondence, indicate that only 10 reports of sunburning are received per one million units of sunscreen product distributed. The comment contended that these data suggest that consumers are not being misled by SPF claims and are choosing the products appropriate to their skin type and sun exposure habits. The comment added that its sunscreen products include the instructions to apply “liberally” or “generously.” The comment asserted that from the low incidence of reported sunburn it can be inferred that these instructions are being followed. The comment concluded that consumers are adequately choosing and applying sunscreen products with the proper SPF and that the current testing methodology is using the appropriate amount of sunscreen for determining SPF values.

The agency agrees with the majority of the comments. Changing the amount of sunscreen used in the sunscreen testing procedures from 2 mg/cm² to 1.5 or 1 mg/cm² would negatively affect consumers and the scientific community.

The agency agrees with one comment that using 2 mg/cm² of sunscreen product in the testing procedure ensures a more uniform application over the test area and thus contributes to a more accurate method of determining SPF values for product labeling. According to published literature (Refs. 2 through 5), actual application density of sunscreen drug products by consumers varies greatly, ranging from a high amount of 4.0 mg/cm² to a low amount of 0.75 mg/cm² (Ref. 3). Because of the thickness and viscosity of some sunscreen formulations, amounts smaller than 2 mg/cm² may be difficult to apply uniformly. If the application density is not uniform across all the testing sites, the resultant MED’s are not indicative of the true protection provided by the test product. The SPF calculated from those MED’s would be meaningless. Labeled SPF values should be based on testing conducted under the most carefully controlled conditions, so that the results are as accurate and reproducible as possible. The outcome of an accurate and reproducible testing procedure ensures that competitive products with the same SPF values provide essentially the same degree of protection.

Most consumers accept and understand the currently used SPF system. This system effectively communicates to consumers the amount of protection that can be expected from the product. The agency believes that changing this aspect of the SPF system would result in unnecessary consumer confusion and would not be in the public interest.

The agency points out that the SPF value is not an absolute predictor of sunscreen protection. There are many variables involved in sunscreen use (e.g., skin type, latitude, altitude, whether the consumer is at the beach or in a city, and spreading characteristics of the product). The value of the SPF is that it is derived by strictly standardized testing procedures and, therefore, provides a convenient means of product-to-product comparison. The SPF provides consumers a means to evaluate and compare sunscreen drug products based upon the consumer’s previous experience in the sun and previous use of sunscreen with an identified SPF value. The agency believes that currently there is no scientific need to change the sunscreen testing procedures to include an application density lower than 2 mg/cm².

Based on the above discussion, the agency is proposing that 2 mg/cm² be the amount of sunscreen used in the testing procedures in §352.72(e).

References

(1) Comment No. APE003, Docket No. 78N-0038, Dockets Management Branch.
require the rejection of data and the subsequent addition of subjects to the test panel: (1) When the exposure series of a given subject fails to elicit an MED response on either the treated or unprotected skin sites, and (2) when responses on the treated sites are randomly absent. The comment also suggested that if a subject withdraws from the test due to illness, schedule or work conflicts, etc., it should be permissible to replace such subjects on an "as-needed" basis because over-recruitment for a study in anticipation of such withdrawals is expensive, inefficient, and unnecessary.

One comment agreed that the agency should allow a limited number of subjects (e.g., 3 to 5) to be added to a test panel if the criteria for PCD are not met due to deviations resulting from inconclusive results. Another comment recommended that the total number of "replaceable" test panel members be limited to 5; if this number is exceeded, the entire test should be repeated. The comment added that the requirement that "the standard error shall not exceed 5 per cent of the mean" is an arbitrary and unsubstantiated limitation and should not be applied.

One comment stated that it has been a common practice to use data from a smaller panel for a preliminary SPF determination and to supplement this panel with enough test subjects to bring the total panel size to a minimum of 20 for the final SPF determination. The comment recommended that this concept should be recognized in the final monograph. The comment proposed a method to be revised to read as follows: "Number of subjects. Group of at least 20 subjects shall be used for each test panel. The panel size shall be fixed in advance and additional subjects shall not be added." The agency asked that, if this change is not acceptable, what is the best method for evaluating data to determine if additional subjects are needed to obtain a valid SPF value, and what is the minimum number of subjects required? The agency invited public comment on the possible change.

Most of the comments agreed that (1) test panels should consist of at least 20 subjects, (2) the size of the test panel should be fixed in advance, (3) the limitations that the standard error should be less than ±5 percent should not apply, and (4) the testing procedures should make it clear that the addition of subjects to the test panel to achieve the desired minimum is acceptable under specific conditions. One comment maintained that any SPF value derived from a minimum of 8 subjects per test product would not provide convincing data of SPF values acceptable at 99 percent confidence limits.

Another comment, agreeing that at least 20 subjects are needed to complete a test with acceptable data, recommended that the agency recognize the following specific conditions in advance and the product's SPF is approximated. One comment stated that it could neither concur with nor refute the adequacy of 20 subjects based upon the documentation provided for review.

One comment stated that experience in Australia demonstrates that a panel size of 10 subjects yields results similar to those obtained on the same formulation in the United States when 20 subjects are used. The comment suggested that the upper limit on panel size should be fixed, for example at 25, and that the test data should be rejected if, for example, 20 valid results are not obtained. The comment added that it is appropriate to retain the Panel's proposed limit on the standard error of the mean.

One comment agreed with the agency's position stated in the notice of public meeting (52 FR 33598 at 33600) that substitutions or additions to a panel should not be allowed. The comment maintained that where all sites on the sunscreen protected area show erythema, these data should be incorporated into the estimate of the mean instead of merely rejecting them as indeterminate results. The comment suggested that if any panelist showed all irradiated spots on the sunscreen protected site, statistical analysis should automatically be handled by a nonparametric test, such as the modified median test or the Wilcoxon signed ranks test. The comment stated that the purpose of using such methods is to ensure that detrimental (yet valid) test results be included in the determination of the SPF estimate and not excluded because they were nondetermined. The comment maintained that this method would more conservatively estimate the protection provided by the test sunscreen.

One comment stated that the final monograph should be very specific in outlining criteria that would disqualify a test subject; the monograph should allow for subsequently replacing that individual on the test panel. For example, the comment stated that if a test subject were erythematous on all subsites, one could not calculate an SPF value and using another test subject should be permissible. Likewise, it should be acceptable to replace a test subject because of noncompliance or other reasons unrelated to the test.

Another comment stated that criteria for adding additional subjects are outlined in the Panel's report (43 FR 38206 at 38206) and recommended retaining this procedure. The comment stated that the statistical procedures should provide for the addition of test subjects in the event that the SPF variability precludes
placing the product in the desired PCD. Additional subjects should be limited to the smallest number necessary to classify the mean SPF value with a 5 percent standard error of the mean or to classify the mean SPF with a power coefficient of 0.8.

The agency recognizes the possibility that during the testing of sunscreen drug products some subjects may not produce data suitable for analysis. Additionally, there may be instances where a subject must withdraw from a study and a question may arise about replacing this subject. Nevertheless, once a subject enters a study, the subject should be considered as part of the study. If the subject withdraws before any data are obtained, the subject may be replaced because the person has not really become part of the study. However, once data are obtained on a subject, the person should not be replaced but should be considered as producing nonvalid data for analysis. The reason for this approach is that preliminary data obtained may influence a subject's decision to leave the study and thus may introduce biases. In general, the guiding principle should be that new subjects are not allowed. Therefore, the agency has determined that the appropriate approach is for test panels to start at a fixed number (the agency is proposing that that number not exceed 25), from which at least 20 subjects must produce valid data for analysis. Nonvalid test data should be rejected, but the subjects should not be replaced. If there are more than five nonvalid subjects, the study should be considered a failure.

The agency agrees that the standard error criterion recommended by the Panel in § 352.42(g) is confusing. According to the agency, nonvalid data is not being proposed. Instead, the agency is proposing a one-sided t-test to analyze the data obtained from the sunscreen testing procedures. The analysis of sunscreen testing data is discussed further in comment 97.

Therefore, the agency is proposing the following in § 352.72(i): "Number of subjects. A test panel shall consist of not more than 25 subjects with the number fixed in advance by the investigator. From this panel, at least 20 subjects must produce valid data for analysis." All subjects producing valid data must be used in the analysis. Likewise, any subject producing nonvalid data must be omitted from the analysis. Nonparametric tests, such as the modified mean test or the Wilcoxon signed ranks test, should not be used to analyze indeterminate test results. In § 352.42(i) "Rejection of test data," the Panel recommended the following as valid reasons to reject subject data: (1) The exposure series fails to elicit an MED response on unprotected skin sites; or (2) responses on treated sites are randomly absent, which indicates the product was not spread evenly. The agency agrees with the Panel, but believes that subject noncompliance is an additional reason for rejecting data. Therefore, the agency is proposing to revise the Panel's recommendation by adding the phrase "or if the subject was noncompliant (e.g., subject withdraws from the test due to illness or work conflicts, subject does not shield the exposed testing site from further UV radiation until the MED is read, etc.)."

The information on "Rejection of test data" appears in proposed § 352.72(i).

The agency agrees with one comment's suggestion that it is not necessary or practical to test the entire panel of test subjects at the same time. Testing a limited number of subjects per day over a prolonged period should not compromise the testing so long as the testing is properly controlled (e.g., the light source is calibrated, concomitant testing of the standard preparation is done, the SPF of the standard preparation falls within the range specified in § 352.70, etc.). However, the agency does not believe that it is necessary to include such a stipulation in the monograph.

Reference

(1) Comment No. SUP002, Docket No. 78N-0038, Dockets Management Branch.

95. Several comments presented suggestions and recommendations to clarify the definition and precision of measurement of the "minimal erythemal dose (MED)" recommended by the Panel in §§ 352.42(h) and 352.43 of its testing procedures. Three comments stated that the MED should be defined as the minimal erythema producing uniform redness and sharp borders (or erythema reaching all borders). One comment stated that using "any perceptible change" or "just perceptible change" as the endpoint of erythemal response will result in doubtful determinations. The comment stated that one of the great problems is obtained from a definition of "MED" occurs when high SPF sunscreens are tested with solar simulators, because these sunscreens are very effective in absorbing UVB radiation and very long irradiation times are needed. Therefore, significant amounts of UVA radiation are delivered to the skin, so that erythema at the sunscreen-protected sites is mainly due to UVA radiation. In patients with skin Type II and III, immediate pigmentation is produced, some of which lasts for 24 hours. Consequently, sites will appear faintly tanned with doses well below those producing erythema and the question of "just perceptible change" becomes difficult to answer. The comment also stated that it has been shown that it takes significantly less UVA energy to produce erythema with a high irradiance UVA emitting radiation source than with a less intense one (Ref. 1). Because modern solar simulators are designed to give high irradiance (up to 100 milliwatts/cm² UVA) so as to shorten irradiation times, the comment stated that MED values (determined using "just perceptible erythema" criteria) may vary greatly between investigators depending upon the irradiation source used.

The comments suggested various postexposure (after irradiation) time limits for the evaluation of an erythema reaction to UV radiation: 22 to 24 hours, 22 to 24 hours (±10 percent), and 22 to 24 hours (±10 percent). Maintaining that erythema due to UVA is less well defined than that to UVB, one comment concluded that 22 to 24 hours should be satisfactory for both.

Three of the comments suggested environmental conditions under which MED values should be determined. Two maintained that the MED should be read under a tungsten light source. Another comment suggested that the erythema response of the skin of all test subjects should be evaluated under the same conditions of illumination. If natural light is not available, the comment suggested all test subjects be examined under a 100–W tungsten light bulb. The comment added that fluorescent light should not be used to assess the MED because major deviations in MED values can result if some subjects are examined under a fluorescent light source and others are examined under cool, white fluorescent light. All three comments stated that the posture or body position should be the same for all test subjects. One comment maintained that the visually recognizable erythema response often varies with the posture (e.g., the exposed back when examined in a prone position versus a vertical or standing position). Another comment contended that the MED should be read with the subject in the same position as during irradiation. Two of the comments suggested that the MED readings be done in rooms where the external temperature is between 20 and 25 °C.

In §§ 352.42(h) and 352.43 of its recommended monograph, the Panel defined the MED as the "time of exposure that produces the minimally perceptible erythema at 16 to 24 hours postexposure." The agency believes that
this definition should be clarified and narrowed. The Panel stated that immediate pigmentation fades in 30 to 60 minutes (43 FR 38206 at 38266). However, more recent information indicates that immediate pigmentation or immediate tanning may persist with higher doses of UV radiation for 1/2 to 1 hour, up to 24 hours, or (rarely) for 36 to 48 hours after prolonged exposure (Ref. 2). Therefore, the agency agrees with the comments that immediate pigmentation may interfere with an investigator's perception of minimally perceptible erythema. This is especially true when testing a high SPF sunscreen product, where a large dose of UV radiation is required, or if the MED evaluation is done at 16 hours postexposure. Sunscreen testing results will be more accurate and comparable if the MED is defined as the smallest dose of UV radiation that produces redness reaching the borders of the exposure site, and if the MED is determined at 22 to 24 hours postirradiation rather than 16 to 24 hours postirradiation. This time is consistent with those requested by the comments.

The agency has considered the comments' suggested environmental conditions under which the MED should be determined (i.e., light source, position of the body, and temperature of the room). The Panel did not include such conditions in § 352.42(h) of its recommended monograph. Nonetheless, the agency agrees with the comments that some environmental conditions should be included in the sunscreen testing procedures.

In discussing testing procedures, the Panel stated that when reading the MED, the investigator should use a constant light source such as an incandescent or warm white fluorescent lamp at a fixed distance (43 FR 38206 at 38260). The agency believes that there is little difference between the light emitted from an incandescent (i.e., tungsten) light and a warm white fluorescent light. The illumination level at the site of inspection is more important than the source of illumination. The agency notes that various illumination levels are recommended for other types of critical observations (i.e., 300 lux for medication preparation areas, 500 lux for emergency room treatment areas, and 22,000 lux for the emergency table in an operating room) (Ref. 3). The agency believes that 500 lux is an appropriate illumination level for evaluating the MED. Therefore, the agency is proposing in § 352.72(h) that the source of illumination should be either a tungsten light bulb or a warm white fluorescent light bulb that provides a level of illumination at the test site within the range of 450 to 550 lux.

The agency agrees with the comments that the MED should be assessed with the subject in the same position used when the test site was irradiated. Hawk and Parrish (Ref. 2) state that MED assessments should always be made with the subject in the same position to prevent MED variations. The agency is proposing this requirement in § 352.72(h). However, the agency does not believe it is necessary to specify a particular position.

There is insufficient information to determine whether the temperature of the room in which the MED is assessed has an effect on the MED. Therefore, the agency is not proposing a specific temperature, but is requesting further comment.

Based on the above, the agency is proposing to include in § 352.72(h) the following: "The MED is determined at 22 to 24 hours after exposure. The erythema responses of the test subject should be evaluated under the following conditions: the source of illumination should be either a tungsten light bulb or a warm white fluorescent light bulb that provides a level of illumination at the test site within the range of 450 to 550 lux, and the test subject should be in the same position used when the test site was irradiated. Testing depends upon determining the smallest dose of energy that produces redness reaching the borders of the exposure site at 22 to 24 hours postexposure for each series of exposures."

The agency is also proposing to provide a definition of MED in § 352.3 by adding new paragraph (a) as follows:

"Minimal erythema dose (MED). The smallest dose of ultraviolet (UV) radiation (expressed as joules per meter squared) that produces redness reaching the borders of the exposure site."

Other definitions in § 352.3 are being renumbered to adjust for the addition of new paragraph (a).

References


96. Two comments argued that in the Panel's sunscreen testing procedures smaller increments in exposure time would provide more accuracy in determining SPF values that exceed 15. In § 352.43 of its recommended monograph, the Panel included a geometric series of time intervals represented by (1.25)x, such that each exposure time interval is 25 percent greater than the previous time (43 FR 38260 at 38265 to 38266). One comment requested that § 352.43 be revised to read "The time intervals selected shall be a geometric series represented by (1.25)x wherein each exposure time interval is X percent greater (X must not exceed 25 percent) than the previous time."

In its notice of a public meeting to discuss appropriate sunscreen testing procedures, the agency stated that exposure times are crucial to the accurate determination of SPF values and PCD's (52 FR 33598 at 33601). However, the agency expressed concern over the Panel's recommended time intervals. The agency stated that there may be little justification for geometrically increased exposure intervals because of the appearance on the OTC market of sunscreen drug products with SPF values much higher than 15 (i.e., up to 30). Because the MED can be measured with equal precision across the full range of an arithmetically arranged time increment, the agency stated it was considering using an arithmetical progression of at least 11 time intervals increasing in 4-second increments, beginning with a 10-second exposure and ending with a 50-second exposure (i.e., 10, 14, 18, 22, 26, 30, 34, 38, 42, 46, and 50 seconds).

A number of comments objected to the proposed arithmetic progression. Most of the comments preferred a geometric progression method similar to the one recommended by the Panel in § 352.43. Several comments added that this method has been successfully used
by industry for many years. Some comments contended that the fundamental relationship between SPF values and sunscreen spectral absorptance is logarithmic and, therefore, the correct approach is the use of geometric progressions. Another comment stated that the SPF is a ratio of two independently determined values; statistically, ratio values are treated with geometric techniques in order to control the higher expected variance simply because the value is a ratio of two independently-variable measurements. The comment maintained that the precision of the SPF ratio depends on both variables, i.e., the protected skin MED (numerator) and the unprotected skin MED (denominator), but more critically on the denominator which is the smaller quantity. The comment argued that if the agency's proposed arithmetic progression would, in many instances, use larger exposure intervals for the unprotected irradiated sites than the Panel's recommended 25\% exposure intervals, and would compromise rather than improve precision.

One comment contended that a valid scientific rationale for using geometrically increasing time intervals is to relate the SPF values to the time exposures. The comment stated that available data provided only limited ability to examine the need for geometric time increments. The comment added that careful consideration should be given to the spacing of the geometric progression to ensure that there are not large intervals at the upper end of the range of exposure times, thereby eliminating the heedless overexposure and “UV burn” of a large number of test subjects that results from the occasional overestimation of a product's SPF or from the underestimated substantivity of a “wash-off” sunscreen drug product. One comment recommended that the maximum erythema on the protected skin not be induced by more than twice the MED on the protected skin. Several comments contended that the radiation exposure times specified by the agency in the public meeting notice (52 FR 33598 at 33601) are not applicable to all xenon arc radiation sources, because some xenon arc sources may require longer or shorter time exposures due to higher wattage or radiation intensity.

Another comment considered the use of a geometric or arithmetic progression in determining the relevant exposure times. If a geometric progression series is used, the comment asserted that the important issue is that the “multiplicator factor has to be determined very carefully.”

Several comments suggested various methods of determining the exposure intervals to accommodate OTC sunscreen drug products with SPF values in excess of 15. One comment contended that a better approach would be to use a geometric series of 5 exposure times rather than the agency's proposal for an arithmetic progression of 11 exposure times. The comment suggested that the exposure intervals of the geometric series should be calculated as follows: (1) (1.25)X for products with an estimated SPF less than 8, (2) (1.20)X for products with an estimated SPF from 8 to 15, and (3) (1.15)X for products with an estimated SPF greater than 15. Two comments from a manufacturers' association added that industry should have the option of choosing smaller increments than 25 percent, if desired, in order to achieve greater precision when testing for SPF values. For example, the time intervals selected should be a geometric series represented by (1.X)^n such that each exposure time interval is X percent times greater (X must not exceed 25 percent) than the previous time interval. Another comment recommended a two-tier approach with a cut-off point between SPF 6 and 8. Below SPF 6 or 8, a geometric series based on (1.25)^n would be used. Above SPF 6 or 8, “smaller increments of (1.25)^n corresponding to (1.12)^n” would be used.

One comment strongly recommended that the agency adopt the delivery of UV radiation in terms of mJ/cm², and not in seconds or minutes. Several comments added that the term “light exposure” discussed in the “Exposure times section” of the public meeting notice (52 FR 33598 at 33601) should be expressed in the context of “dose” rather than “time.” According to the comments, the term “dose” would allow for the use of both radiances and time as variables.

The agency agrees with several comments that the expression of radiation exposures be in terms of dose rather than time. The term “dose” is more appropriate because it allows for the use of both radiances and time as variables. Although the Panel defined UV radiation exposure in units of time, the agency believes that it is more accurate to express dose as the “erythema effective exposure,” in units that define the total amount of erythema effective energy applied to the testing subite (J/m²). (The agency is using the term “exposure dose” rather than “exposure time” in this tentative final monograph. See comments 84 and 85.)

The agency agrees with the suggestion that a preliminary range-finding study be performed prior to testing a new sunscreen product on a test panel. The study would prevent unnecessary risks of discomfort, injury, and overexposure to UV radiation to the test subjects.
However, there is insufficient information to establish specific requirements for a preliminary range-finding study at this time. Therefore, the agency is not now proposing such a study in the monograph, but is inviting additional comments and data as to appropriate requirements for such a study.

The agency also agrees that an arithmetic progression of determining exposure doses in the SPF testing for OTC sunscreen drug products is not the method of choice, for the following reasons: the arithmetic progression of exposure doses would: (1) expose the test subjects to higher doses of UV radiation than necessary, particularly at the higher end of the exposure series; (2) provide differences in redness between exposure sites that are too small for the trained eye to distinguish; (3) prolong the time required to deliver exposure doses to the test subjects; and (4) reduce flexibility in exposure doses needed to accommodate different solar simulators.

A geometric progression that is modified to take into account the higher SPF values is more appropriate for determining exposure doses, for the following reasons: (1) it reduces the risk of exposure to UV radiation to the test subjects by decreasing testing time and the number of exposure sites, and (2) a geometric series covers a larger range of exposure doses with fewer exposures.

The agency believes that a geometric series with only five exposure doses may produce overestimations of the true SPF values, thereby producing biased estimates. The possible production of biased estimates is illustrated in the following example: if the MED(PS) is 30 J/m² and the product being tested has an expected SPF of 8, the exposure doses would be 0.69X, 0.83X, 1.0X, 1.2X, and 1.44X, using 1.20 as the base in a geometric series. Here, X is set to yield the estimated SPF, e.g., X=30 J/m² x 8=240 J/m² of exposure doses. The exposures would be 165.6, 199.2, 240, 288, and 345.6 J/m², respectively.

For the above example, a substantial number of MED(PS) would be observed at 240 J/m², as well as 199.2 and 288 J/m². If the same number of subjects are observed at the 199.2 and 288 J/m² exposure doses, the mean SPF would be greater than the expected SPF of 8. For example, if only 20 subjects, 10 MED(PS) were observed at 240 J/m², 5 at 199.2 J/m², and 5 at 288 J/m², the corresponding SPF values for these MED(PS) values are 8.00, 6.64, and 9.6, respectively. In this example, an MED(PS) of 288 produces an SPF of 9.6, which is 1.6 units above the expected SPF value of 8, while an MED(PS) of 199.2 produces an SPF of 6.64, which is only 1.36 units different from the expected value of 8. Because the exposure dose of 288 J/m² is a greater distance from 240 than 199.2 is from 240, each time a MED(PS) greater than 240 is produced, it is assigned an undue extra large value. Ultimately, the effect produces an overestimation of the average SPF value.

The major reason for the overestimation is that the geometric series is implemented in such a way that it has a nonsymmetric assignment of SPF values. When an MED(PS) exceeds the expected MED(PS), it produces a corresponding SPF farther away from the expected SPF value than when the observed MED(PS) is below the expected SPF value.

The agency believes that exposure doses are crucial to the accurate determination of SPF values and PCD's. A geometric series similar to that proposed by the Panel, but modified to include 2 additional exposure doses equally spaced around the expected SPF, would eliminate the overestimation of the true SPF value of a product with a high SPF value. This procedure would also restrict the testing range for products with low SPF values. The doses selected would consist of a geometric series of 5 exposures where the middle exposure is placed to yield the expected SPF plus 2 other exposures, placed symmetrically around the middle exposure.

The agency agrees with one comment that different exposure doses are appropriate for determining different SPF values for greater accuracy. The exposure doses for the geometric series should be calculated as follows:

1. The exposure (oules per meter squared) and the expected SPF of the test product. For products with an expected SPF between 8 and 15, the exposures shall be the MED(US) times 0.64X, 0.80X, 0.90X, 1.00X, 1.10X, 1.25X, and 1.56X, where X equals the expected SPF of the test product. For products with an expected SPF less than 8, the exposures shall be the MED(US) times 0.64X, 0.83X, 0.91X, 1.00X, 1.09X, 1.20X, and 1.44X, where X equals the expected SPF of the test product. The MED is the lowest dose of radiation that produces uniform redness reaching the borders of the exposure site at 22 to 24 hours postexposure. The SPF value of the test sunscreen is then calculated from the dose of UV radiation required to produce the MED of the protected skin and from the dose of UV radiation required to produce the MED of the unprotected skin as follows: SPF value-the ratio of erythema effective exposure (Joules per meter squared) (MED(PS)) to the erythema effective exposure (Joules per meter squared)(MED(US)).

Reference

T. Comments on the Statistical Analysis of Results from the Testing Procedures for Sunscreen Drug Products

97. Many comments questioned aspects of the Panel's recommended testing procedures and statistical methods for determining the SPF and the PCD of sunscreen drug products. The agency discussed these comments in the notice of public meeting to discuss sunscreen testing procedures (52 FR 33598 at 33599 and 33600), and proposed two approaches to analyzing the data generated by sunscreen drug product testing. The first method utilizes the testing procedures proposed by the Panel but adds one step to the determination of the PCD. The added step is equivalent to performing a one-sided t-test at the 0.05 level of significance, where the null hypothesis is that the mean SPF is less than the minimal assigned PCD. The second method concentrates on the boundaries between the PCD's rather than on the actual SPF values of the sunscreen drug product. Following the establishment of a MED for unprotected skin, protected skin is tested at exposure times chosen so that the corresponding SPFs are slightly less than the lower bounds of the intervals defining the various PCD's. This procedure does not distinguish between SPF's in the same PCD but does distinguish between SPF's in different PCD's. The agency requested comments on the Panel's proposed procedure for sunscreen testing as well as the two methods outlined in the notice of public meeting.

The agency received many comments opposing the binomial method. The comments supported the Panel's recommended testing procedure as modified by adding a one-sided t-test to determine SPF values and PCD categories. Several comments stated that the current procedure is a fair and conservative method for categorizing observed SPF measurements into PCD determinations. The comments stated that no rationale was presented by the agency as to why the simple descriptive method currently in use is not adequate and acceptable. One comment maintained that the fact that the current method has been in use for nearly 12 years provides tangible evidence that it is reasonable and appropriate.

Another comment emphasized that an SPF value is not an absolute, but is instead an indication of relative performance. The comment stated that statistical procedures must be adequate for analyzing and classifying sunscreen drug products in a manner that is understandable and meaningful to the consumer. The comment concluded that the system that has been in place for over 10 years accomplishes this purpose. The comment acknowledged that refinements can be accomplished by adopting the one-sided t-test or the Wilcoxon signed ranks test as an acceptable method.

Several comments stated that the modified Panel method allows for the determination of SPF values as well as PCD categories. One comment stated that the PCD is an arbitrarily assigned limit, while the SPF is an experimentally derived value. This comment asserted that it is not necessary to be too stringent in compliance with PCD's so long as the SPF is accurately determined. The comments maintained that a distinct advantage of the t-test is that it encompasses the current procedure for conducting SPF testing; plus, it provides a simple computational procedure for a statistical test that projects the results to the entire population.

One comment suggested that if more precision is needed in assessing the PCD by the "t" test method, the significance level may be set at 0.01 rather than at 0.05 when SPF values are evaluated. Another comment recommended the following modification to make the t-test even more useful. It stated that if the significance level were set at 0.10 rather than 0.05, this would allow for slightly more variability in the SPF range and still allow the product to be placed in the PCD that is appropriate for its mean SPF, without adverse impact on consumers.

Three comments stated that, although preferable to the binomial method, the t-test method has one difficulty: Variability, even from high outlying values, can cause the product being tested to fall below the intended PCD. One comment stated that variability is inherent in the results from this type of testing, particularly with higher SPF products. Two comments stated that such variability can be minimized by allowing for dosing increments smaller than 25 percent, especially when testing products with higher SPF values. One comment added that a minimum of exposures can reduce the chance for variability. Many comments maintained that the binomial procedure proposed by the agency is not appropriate for classifying observed SPF data into PCD categories. Some comments opposed adoption of the binomial method of analysis because it does not provide for the determination of SPF values. One comment cited data from a consumer survey (Ref. 1) that purports to demonstrate that SPF numbers are a major factor that consumers use in selecting an appropriate sunscreen drug product. Another comment added that the binomial method does not distinguish between SPF's in the same PCD category and that products with very similar SPF's may be classified into different PCD's. Two comments stated that the binomial method lacks the sensitivity of the t-test, and it is more difficult to reject the null hypothesis using the binomial analysis than using the t-test.

Some comments pointed out that the binomial method may result in unnecessary UV exposure. Three comments stated that using the set exposure times in this method would expose a panelist to much more UV radiation than necessary and might even cause severe sunburn. One comment stated that the exposure of a panelist to 14.9 X MED(US), when the proposed protection factor for the product is SPF 2 to 4, would result in severe over exposure. The comment added that the fixed exposure schedule would not allow the current flexibility in modifying the exposure schedule to more closely fit the expected SPF of the product. Another comment stated that because the exposure levels proposed in the binomial procedure are not currently used, there is a lack of historical data on this method. The comment contended that predictions on the effects of using this test are difficult to surmise without a historical perspective.

One comment stated that neither of the proposed methods was adequate and that simpler calculations would be preferable. The comment suggested that the variability inherent in the use of sunscreen drug products by consumers is so high that the statistical refinement suggested is unnecessary in calculating SPF values. The comment added, if the proposed method is adopted, manufacturers may be forced to aim for higher mean SPF values to allow inclusion of products in current PCD categories. The comment asserted that this will be an unnecessary cost with no real benefit to the consumer. The comment maintained that consumers have had several years to work out which products are suitable for their use and that a change in labeling now would necessitate a further period of adjustment. The comment added that there are very few complaints that sunscreen drug products fail to provide the expected level of protection. Two other comments stated that the agency should reject each of the methods proposed and accept the Panel's recommendation.
Some comments recommended that any scientifically valid statistical analysis method should be permitted to calculate the results of sunscreen product testing. Some comments suggested the Wilcoxon rank sum test as an equally valid method. According to the comments, this method could be used with the current exposure techniques and still have the benefits of the binomial procedure (i.e., no assumption of a normal distribution and less sensitivity to outlying values). One comment added that the Wilcoxon test takes advantage of the interval nature of the data and, therefore, is more sensitive than the binomial procedure and is close in sensitivity to the t-test procedure. As stated above, another comment mentioned that the Wilcoxon signed ranks test could provide refinements in the existing procedures.

The agency agrees with the majority of the comments that the Panel's recommended method, as modified by the addition of a one-sided t-test, is the preferred method for calculating SPF values and for categorizing sunscreen drug products into PCDs. The statistical procedure used to calculate the relative protection provided by sunscreen drug products should be based upon the determination of SPF values. Consumers understand and depend upon SPF values when choosing a sunscreen. The Panel's recommended method as modified by the one-sided t-test being added to the procedure for calculating SPF values provides an SPF value that can be used to place the product into a PCD for labeling purposes.

The one-sided t-test employs the mean of its observations (i.e., SPF values) as a point estimator, and it incorporates the variability of the data (i.e., the standard deviation). This method classifies a sunscreen drug product into a PCD only where there is statistically significant assurance that the product belongs in the PCD. The agency also points out that this statistical procedure has good power. Further, the modified method is safer than the binomial method because the test subject is exposed to less UV radiation.

The agency is proposing that a sunscreen drug product may display its tested SPF value on its labeling rather than the lowest SPF value in the PCD as the Panel recommended. (See comment 44.) However, a product should only be labeled with a particular SPF if there is sufficient statistical evidence to conclude that the true SPF is at least as high as the label SPF. In order to provide statistical significance to the SPF value that consumers use when choosing products, the agency is proposing that the SPF value permitted in labeling be the largest whole number that is excluded by a 95-percent one-sided confidence interval for the mean SPF.

Regarding the suggestions for making the t-test more useful by setting the significance level at 0.10 or 0.01 rather than 0.05, there is no basis for allowing for more variability in the SPF range with a 0.10 level of significance, or for being more rigid by using a 0.01 level of significance. The agency considers a 0.05 level of statistical significance to be a standard; it should not be charged without compelling reasons.

The agency believes that the Panel's method modified by the addition of the t-test is not the only valid method available. However, it is the best method currently available and is being proposed in §352.73. By knowing in advance the statistical analysis to be used, there will not be an incentive for an investigator to select a method that will produce the desired SPF or PCD for a particular data set. Further, the agency believes it is desirable to have all data for different manufacturer's products analyzed by the same method.

Therefore, the agency is proposing §352.73 to include a one-sided t-test as follows:

(d) Determination of the test product's SPF value and PCD. Use data from at least 20 test subjects with n representing the number of subjects used. First, for each subject, compute the SPF value as stated in §352.73(b) and (c). Second, compute the mean SPF value, x̄, and the standard deviation, s, for these subjects. Third, obtain the upper 5-percent point from the t distribution table with n-1 degrees of freedom. Denote this value by t. Fourth, compute ts/√n. Let this quantity be denoted by A (i.e., A = ts/√n). Fifth, calculate the SPF value to be used in labeling as follows: The label SPF equals the largest whole number less than x̄ - A. Sixth and last, the drug product is classified into a PCD as follows: if 20 + A ≤ x̄ < 30 + A, the PCD is Ultra High; if 12 + A ≤ x̄ < 20 + A, the PCD is Very High; if 8 + A ≤ x̄ < 12 + A, the PCD is High; if 4 + A ≤ x̄ < 8 + A, the PCD is Moderate; if 2 + A ≤ x̄ < 4 + A, the PCD is Minimal; if x̄ ≤ 2 + A, the product shall not be labeled as a sunscreen drug product and may not display an SPF value.

Reference

1 Comment No. C00083, Appendix 3, Docket No. 78N-0036, Dockets Management Branch.

98. Several comments recommended the use of a geometric mean rather than an arithmetic mean when calculating the SPF value. One comment maintained that the geometric mean will dampen the variability of the widely ranging data often present in SPF test data. Another comment stated that the DIN testing procedures use the geometric mean rather than the arithmetic mean.

The agency believes that it is invalid to use the geometric mean in the t-test that is being proposed for use in calculating the SPF. The standard deviation is based on the arithmetic mean, and a "t" ratio of the geometric mean to the standard deviation based on the arithmetic mean is meaningless. Also, an attempt to use the geometric mean in the computation of the standard deviation would produce a meaningless measure of dispersion. Therefore, the agency is proposing to calculate the arithmetic mean of the data to determine the SPF value of the product.

However, it might be useful to modify the statistical analysis procedure further by performing the t-test on logs of the SPF data. Analysis of the logs of the SPF is equivalent to using the geometric mean as a measure of the average for the original data. This procedure might be useful if the data have a very large SPF values which have a detrimental effect on the standard deviation without compelling reasons.

Therefore, the agency is proposing to modify the statistical analysis procedure further by performing the t-test on logs of the SPF data. Analysis of the logs of the SPF is equivalent to using the geometric mean as a measure of the average for the original data. This procedure might be useful if the data have a very large SPF values which have a detrimental effect on the standard deviation without compelling reasons. Therefore, the agency is in favor of modifying the statistical analysis procedure further by performing the t-test on logs of the SPF data. Analysis of the logs of the SPF is equivalent to using the geometric mean as a measure of the average for the original data. This procedure might be useful if the data have a very large SPF values which have a detrimental effect on the standard deviation without compelling reasons.
estimation of the mean SPF value for a sunscreen product.

The comment contended that a product should be labeled on the basis of a 95-percent lower confidence interval for the mean SPF value. The comment stated that a disturbing feature of the lower confidence limits is that most of them exclude a high percentage of the individual SPF values. The comment maintained that confidence intervals provide a lower boundary on the mean SPF value for a product but do not provide limits for individual SPF values. The comment asserted that for a given product the lower confidence interval will exclude a higher percentage of the individual SPF values as the sample size is increased. According to the comment, the SPF values excluded will approach a limit of approximately 50 percent, because the lower limit will approach the true mean SPF value.

The comment maintained that if the intent of SPF labeling is to ensure that individuals users of sunscreen products are provided with the protection indicated on the label of a product, SPF labeling should not be based solely on a lower confidence interval for a product's mean SPF value. The comment added that this recommendation, like the previous one, is equally applicable to the labeling of products by SPF values and by PCD intervals.

The comment stated that if each of the above recommendations were followed, the current methods for product labeling would be discarded. The comment asserted that a statistical tolerance intervals test would ensure that products are adequately labeled to protect consumers. Also, the statistical tolerance intervals test would establish an acceptable measure of the variability of test results in the determination of SPF designations. The comment maintained that a tolerance interval provides a lower bound on the SPF values for individuals, rather than for the mean of a population of individuals as does a confidence interval. The comment added that a tolerance interval is as easy to implement as a confidence interval. The comment stated that the form for a lower tolerance interval for an individual SPF value is \( \text{y - ks < SPF} \), where \( y \) and \( s \) are the average and sample standard deviation of a sample of SPF values, and \( k \) is a factor obtained from statistical tables for tolerance intervals.

The comment maintained that tolerance limits are much lower than the confidence limits and that they generally cover the entire sample of individual SPF values. The comment also stated that the lower tolerance interval is closer to actual data values when the SPF values exhibit small variability. Thus, the comment concluded that the tolerance intervals satisfy the two criteria stated above and lead to a third recommendation that product SPF labeling should be based on a lower tolerance interval for an individual consumer's SPF value.

Stating that this third recommendation has a solid statistical foundation, the comment maintained that it addresses one of the key underlying problems with the implementation of clinical testing of sunscreen products: the incorporation of the variability of test results in the setting of SPF values. The comment stated that, unlike the confidence interval approach, the tolerance intervals incorporate the variability of individual SPF values, not just the variability of the estimate of the mean SPF value. The comment added that the tolerance intervals approach has the seemingly undesirable effect of resulting in lower assigned SPF values for a product. However, the comment stated that, in reality, it is simply an acknowledgement of the variability inherent in the current testing procedures. The comment stated that the tolerance intervals approach, however, does not alleviate the problem of variability, because it would utilize the lower confidence limit for the mean to determine in which interval a product would be placed. Thus, the difficulties with the use of a lower confidence interval discussed above still apply to PCD designations using this proposal.

The comment stated that a product that has an SPF mean around the limit of a PCD could, through the variability associated with the test results, be assigned to one PCD or a bordering PCD almost at random and that this could imply to a consumer that the product has more protection than it actually has. Further, the labeling of SPF values using statistical tolerance intervals eliminates the need for PCD designations. Under this method, tolerance intervals directly address the key problem, protection of the individual consumer, rather than attempting to address a related but clearly not equivalent problem, the variability of average SPF values. The comment stated that the consumer would be protected with tolerance intervals through lower SPF designations when variability is excessive.

The agency agrees with the comment that the use of a 95-percent lower confidence interval for SPF labeling is preferable to the use of only the calculated average SPF in the labeling of sunscreen drug products and is proposing such as the fifth step in § 352.73(d). (See comment 97.) However, the agency does not agree that a statistical tolerance intervals test is an acceptable alternative to the one-sided t-test. The one-sided t-test makes a statement about the mean or average SPF. It does not make inferences about particular individuals. Some individuals will receive less protection than the stated SPF, but others will receive more protection. The tolerance intervals procedure makes a statement about the range of SPF values that most of the population of users would achieve. This inference is not usually made in drug testing, and the agency believes that there is no justification for using this procedure for sunscreen drug products. In addition, the validity of the suggested tolerance intervals procedure depends upon the assumption of normality of the underlying distribution. No justification has been presented for this assumption. Unlike the t-test, which tends to be valid if the underlying distribution is normal, the tolerance intervals procedure depends heavily upon the normality of the underlying distribution for its validity. Therefore, the agency is not including a tolerance intervals statistical analysis method, but instead is proposing that the statistical analysis of sunscreen testing data be done using a one-sided t-test. (See comment 97.)

U. Comments on Water Resistant and Very Water Resistant Testing Procedures for Sunscreen Drug Products

100. Referring to the Panel's statement that a water immersion test is a more severe test of a sunscreen product than a sweat resistance test (43 FR 38206 at 38263), one comment stated that a product that passes the water resistance test should also be permitted to use the term “sweat resistant” and any other claims permitted for products passing the sweat resistance test.

A reply comment disagreed with the above comment and argued that the physical mechanism of removal of the sunscreen product is clearly different in the two tests. The water immersion test recommended by the Panel in § 352.46 requires that the sunscreen product resist removal by water applied “over” the product; the “sweat resistance” test recommended in § 352.45 requires that the sunscreen product resist removal by sweat emerging from “underneath” the product. Contending that there is no assurance that a product that resists removal by one physical action will also resist removal by the opposite physical action, the reply comment pointed out...
that the difference between the chemistry of water and the chemistry of sweat requires different test standards. The reply comment further stated that if §§ 352.45 and 352.46 remain in the monograph, separate tests should be maintained for product performance claims of “water resistance” and “sweat resistance.” Another comment recommended that the determination of the SPF of a product be conducted under the combined stress of sweating and swimming.

The agency agrees with the panel that the “water resistant” test is a more severe test of a sunscreen product than the “sweat resistant” test (43 FR 38206 at 38261). The water resistant tests have a longer time of exposure to water and include a 40- to 80-minute period of moderate activity. The agency disagrees with the reply comment that the difference in the chemistry of water and sweat requires different test standards. The composition of sweat and water differ, but both of them are variable. The composition of sweat varies from subject to subject and the variability in the composition of each is variable. The composition of sweat varies depending on the subject. Sweat is composed predominantly of water (Refs. 1 and 2) and has only traces of lactate, urea, ammonia, sodium chloride, potassium, and other substances (Ref. 3). The Encyclopedia of Biochemistry (Ref. 1) states that the “composition of sweat is about 99 percent water.” White et al. (Ref. 2) states that the sweat glands release virtually pure water. Sweat, which is about 99 percent water with a pH from 5 to 7.5 (Ref. 1), can be considered similar to various types of water. The temperature of variability in the content of treated water, untreated water, or different sources of water can be high. (See comment 104.) In addition, swimming pool and sea water contain different quantities of other minerals and chemicals, and the pH varies depending on the water source.

Therefore, the agency believes that, for the purposes of sunscreen drug product testing, sweat and water are sufficiently similar so as not to require different test standards.

The agency agrees with the reply comment that the physical mechanisms by which a sunscreen product resists removal by sweating and water immersion are different. However, the “wash-off” effects of sweat emerging from under the product can be expected to be less than the “wash-off” effects from water over the product. The requirement for a “water resistant” claim is for the product to retain the original SPF value of the product after 40 minutes of swimming as it had before being exposed to water. If any sunscreen product can withstand 40 minutes of water immersion and retain its original SPF value, the agency and panel agree that the product can also withstand 30 minutes of sweating and retain its SPF value (see the panel’s recommended procedure in § 352.45 for determining sweat resistance). The agency believes that it is appropriate for a product that passes the water resistance and very water resistant tests also to be permitted to make claims that satisfy the sweat resistance test.

The agency agrees that a sunscreen product that passes the “water resistant” test should be permitted to use the claim “sweat resistant.” The agency has reviewed the available information and concludes that for sunscreen drug products that have passed the tests in § 352.76 of this tentative final monograph for water resistant and very water resistant claims, an additional test to support a sweat resistance claim is unnecessary and possibly hazardous.

The agency is concerned that those who serve as subjects for “sweat resistant” testing could be unduly harmed by heat stress. The panel’s recommended procedure in § 352.45 for determining sweat resistance includes exposing the subjects to a temperature of 35 to 38 °C (95 to 100 °F) and 70 to 80 percent humidity, with little air movement. The Panel cautioned that, for safety purposes, older people should not be used and subjects should be fatigued and temperature unshaken for at least 15 minutes. Even with these safeguards, however, the agency believes that this test presents an unnecessary risk when the less-hazardous water resistance testing can be used in support of a sweat resistant claim. Further, the agency is unaware of any sunscreen products that make “sweat resistant” claims but do not also make “water resistant” claims. Accordingly, the agency concludes that the potential benefits of the sweat resistance test do not outweigh the possible risks to the test subject.

The agency disagrees with the recommendation that the SPF value of a product should be done under the combined stress of sweating and swimming. The determination of an SPF value is a test independent of stress. The requirement that the product be labeled with the appropriate SPF value provides sufficient information for consumers to choose the proper sunscreen product for their individual needs.

In summary, the agency is proposing to permit the use of the terms “sweat resistant,” “perspiration resistant,” “resists removal by sweating,” or “resists removal by perspiring” for a sunscreen drug product that qualifies for the claim of “water resistant” or “very water resistant.” The agency is proposing the phrase “sweat resistant” or “perspiration resistant” in § 352.45(e)(2) and (e)(3) and is not proposing §§ 352.50(e)(2)(ii)(C) as recommended by the panel. The agency is not including the panel’s recommended “sweat resistant” test in the testing procedures and is proposing only the procedures for “water resistant” and “very water resistant.”

References


101. Referring to the panel’s recommended procedures for testing water resistance and waterproof claims in § 352.46 (a) and (b), the comment stated that the criteria for these tests are not defined. The comment mentioned that both procedures simply state that “A sunscreen product that can withstand 40 (80) minutes of water immersion may claim to be water resistant (waterproof).” However, the panel’s discussion of these tests (43 FR 38206 at 38263) and the sweat resistance test (§ 352.46) require that the product demonstrate the same PCD before and after water immersion. The comment requested that this standard also be included in the water resistance and waterproof testing procedures.

The agency agrees with the comment that the criteria for passing the panel’s recommended tests in § 352.46 (a) and (b) should be defined and included in the testing procedures. Therefore, the agency is proposing in § 352.76(a) to replace the panel’s recommended sentence “A sunscreen product that can withstand 40 (80) minutes of water immersion may claim to be water resistant (waterproof)” with the following sentence: “If the sunscreen product retains the same PCD after 40 minutes of water immersion as it had before water immersion, the claim of ‘water resistant’ may be made.” In § 352.76(b), the agency is proposing to replace the panel’s recommended sentence “A sunscreen product that can withstand 80 minutes of water immersion may claim to be waterproof” with the following sentence: “If the sunscreen product...”
product retains the same PCD after 80 minutes of water immersion as it had before water immersion, the claim of "very water resistant" may be made."

(See comment 30 regarding use of the term "very water resistant" instead of "waterproof.")"

102. One comment believed that the Panel's recommendations to use an artificial light source for substantiating the claim of sweet resistance (43 FR 38206 at 38262) are ideal but far from being realistic or achievable. If the Panel feels that a sunscreen product should retain the same PCD after the sweat test as before the sweat test, the comment explained, "there will be a tendency on the part of the regulatory agency to disapprove such claims for failure in compliance; because, every sunscreen product, no matter how good it is, will not give the same protection factor value before and after the stress of swimming. The product after the stress of sweating will always give a lowering protection factor value (hence, a lower PCD designation)."

The comment offered the following example: Products with an SPF value of 12 or more (PCD maximal or ultra) tend to show a decreased SPF value after the stress of swimming or sweating, e.g., an SPF of 12 may decrease to an SPF of only 8 (a decrease of nearly 33 percent). The same SPF value cannot be achieved for various reasons (e.g., elution changes due to the partition coefficient, thinning of the applied film, alteration in physical properties, etc.). Another comment also contended that the same SPF value will never be obtained after swimming because 15 to 20 percent of the sunscreen effectiveness will be lost depending on the base (vehicle) used in the product. The first comment concluded that, if the criteria recommended by the Panel are retained, the tendency on the part of the manufacturer will be to claim a low SPF value. Thus, in order to have a claim of "sweet resistance" or "water resistance," the comment argued, a manufacturer could only claim an SPF value of 8.

The comment felt that less effective products (i.e., products with a low SPF value but which retained the original SPF values after a period of sweating) had a marketing advantage because these products could not be denied a claim of sweet resistance. The comment gave the following example: a product with an SPF value of 4 (before and after sweating) could have a claim of sweet resistance, whereas a superior product with an SPF value of 8 or more could not qualify for such a claim because its SPF value decreases to 6 after the stress of sweating. The comment felt this problem could be resolved by allowing the sweet resistance claim if the SPF value differs before and after the stress of sweating are less than 20 percent, provided the initial SPF value is at least 8 or 10.

The agency is not proposing the Panel's recommended testing procedure for a sweet resistance claim in this tentative final monograph (see comment 100). Accordingly only the comments' concerns about the test for water resistance are being addressed. The agency is aware of two studies, conducted since publication of the Panel's report, that determined the water resistance of single-ingredient and combination sunscreen products (Refs. 1 and 2). One study (Ref. 1) used the protocol recommended by the Panel, and the second study (Ref. 2) used a similar protocol involving a 10-minute whirlpool treatment. In both studies, the SPF values for several different sunscreen ingredients alone and for combinations of sunscreen ingredients were determined before and after the water treatment. A decrease in the SPF values occurred for all of the products tested, including sunscreen drug products previously determined to be water resistant. With some products, e.g., 5 percent aminobenzoic acid, the decrease in the SPF values after the water treatment was significant. In other cases, e.g., 8 percent octylmethyl aminobenzoic acid plus 3 percent oxybenzone, the decrease in the SPF value after the water treatment was minimal. Because every product was affected, the agency believes that some allowance for a decrease in SPF values after the water test should be made.

The Panel recommended that a sunscreen drug product must retain the same PCD, not the same SPF value, after the test as it had before the test (43 FR 38263). A product can experience a reduction in SPF value and still remain in the same PCD. For example, a product with a PCD of very high has an SPF value of 12 to under 20. If the product has an SPF value of 20 before the water test, it must have an SPF value of 12 or above after the test in order to retain the same PCD and make the claim for water resistance. The SPF value of the product could decrease by as much as 40 percent and the product would still be classified under the same PCD. Even sunscreen drug products that offer less protection, e.g., products with a moderate PCD, can undergo a reduction in SPF value after exposure to water and still remain in the same PCD. Therefore, the agency believes that the range of SPF values listed for each PCD recommended by the Panel is sufficiently broad to provide for a reduction in the SPF value after the water test. This criterion in the test for water resistant and very water resistant claims is proposed in § 352.76. (See comment 101.)

References


103. One comment referred to the Panel's recommended testing procedure in § 352.46 for determining whether a sunscreen product is water resistant or waterproof. The comment stated that:

(1) The terms "water resistant" and "waterproof" should be defined; (2) the criteria are unrealistic, arbitrary, and scientifically not established; (3) 2 water immersion periods of 20 minutes with moderate activity in water (a total of 40 minutes) are not essential for ascertaining the water resistance of a sunscreen product because the average person rarely remains in water for 40 minutes; and (4) 3 water immersion periods of 20 minutes with moderate activity in water (a total of 60 minutes) are totally unrealistic. A similar comment stated that it is inconsistent that FDA would demand proof that the 8-percent homosalate standard is validated before accepting and promulgating the in vivo sunscreen testing procedures, and at the same time, promulgate in vivo water resistant testing procedures which have not been validated. The comment maintained that the same exacting standards should be required for all in vivo testing procedures that substantiate labeling claims upon which consumers rely.

Another comment added that it would not differentiate between water resistant and waterproof because several studies have shown that the average swimming time is not more than 10 minutes.

The agency believes that the term "waterproof" has a different meaning than from that described by the Panel for a sunscreen product; therefore, the agency is proposing the term "very water resistant" instead of the term "waterproof." (See comment 50.) Although the Panel recommended testing procedures for determining whether sunscreen drug products are "water resistant" or "waterproof" (§ 352.46(a) and (b)), the agency does not agree with the comment that these terms are not defined. A "water resistant" sunscreen resists removal for at least 40 minutes in the water, and a "very water resistant" (waterproof)
sunscreen resists removal for at least 80 minutes in the water. (For a further discussion of these terms, see comment 50.)

The comments did not elaborate on the statement that the testing criteria necessary to establish a claim of water resistant or very water resistant are unrealistic, arbitrary, and scientifically not established. At the time of the Panel’s deliberations there were no adequate standards on which to base water resistant and very water resistant claims. Thus, to establish criteria for testing water resistant and very water resistant sunscreen products (Ref. 2), the Panel proposed a testing method that it considered to be a reasonable and fair representation of swimming habits.

Since the Panel completed its deliberations, there have been new testing procedures that have been tested and found to provide a good measure of the water resistance of sunscreen products. Studies have shown that the substantivity of such products has improved over the years (Ref s. 3 and 4). Kaidbey and Kligman (Ref. 3) evaluated sunscreen products using the Panel’s recommended procedures and found that certain sunscreen products, especially some of the newer products, were more resistant to wash-off than others. Further, such products, after undergoing water treatment, maintained an SPF number closer to the original SPF number. In addition, in a communication with the agency, the Nonprescription Drug Manufacturers Association, a trade association of OTC drug manufacturers, stated that the Panel’s recommended testing methods are frequently used in determining water resistant and waterproof claims (Ref. 5). Thus, the agency disagrees with the comment’s assertions that these procedures are unrealistic, arbitrary, and scientifically not established.

The agency also does not accept one comment’s claim that a total of 40 minutes of moderate activity in water is not essential for ascertaining the water resistance of a sunscreen product because the average person rarely remains in the water for 40 minutes. The comments did not provide any evidence to support their statements that the average person rarely remains in the water for 40 minutes or that the average swimming time is not more than 10 minutes. Likewise, the agency disagrees with one comment’s claim that 60 minutes of moderate activity in water is an unrealistic time period to determine that a sunscreen product is waterproof. The Panel concluded that two 20-minute periods of moderate activity in water (for a total of 40 minutes) is an appropriate test for determining the water resistance of a sunscreen product. Likewise, four 20-minute periods of moderate activity in water (for a total of 80 minutes) was recommended to establish that a product is very water resistant. The Panel chose the 20-minute water immersion periods because unpublished marketing data revealed that a typical population of adults and children under 12 years of age goes into the water 3.6 times for an average duration of 21 minutes per immersion at the beach or pool, and has an average total immersion time of approximately 80 minutes (Ref. 1). Further, the data indicated that 38 percent of users do not reapply a sunscreen product after swimming. By selecting a water immersion period of 40 minutes for a water resistance claim and 80 minutes for a very water resistant claim, the Panel chose reasonable average times that a product should withstand removal by water in order to show effectiveness as a water resistant or very water resistant sunscreen product. The agency considers a sunscreen drug product that can be removed by water in less than 40 minutes as not appropriate as a water resistant or very water resistant sunscreen. A water resistant or very water resistant sunscreen product should enable an individual to maintain a certain level of protection from the harmful rays of the sun after an average period of swimming without the need to reapply the product. For example, children are constantly in and out of the water, and may stay for hours at a time in the beach/pool environment. These individuals are at the greatest risk for “wash-off.” They are also at the greatest risk of subsequent adverse effects if the SPF value of a sunscreen is overstated based on test methods that underestimate the exposure time to water immersion of very active individuals. Therefore, the agency believes that test times must approach the longer times that some consumers will be immersed in water, rather than “average” times which would significantly underestimate immersion times of a high-risk group.

The agency concurs with the Panel’s recommendations concerning testing procedures for water resistant claims in sunscreen drug product labeling; however, as noted above, the agency is proposing to replace the Panel’s recommended term “waterproof” with the term “very water resistant.”

References
(1) OTC Vol. 060168.
(2) Summary Minutes of the Advisory Review Panel on OTC Topical Analgesic, Antihemorrhagic, Otic, Burn, and Sunburn Treatment and Prevention Drug Products, March 4 and 5, 1976, OTC Vol. 06AATFM, Docket No. 78N-0038, Dockets Management Branch.

104. One comment contended that the Panel’s recommended testing procedure, in § 352.46, for determining if a sunscreen is water resistant or waterproof cannot be controlled because of the high degree of variability in the content of fresh water. (The test is to be performed in an indoor fresh water pool.) The comment stated that fresh water has, depending on its source, different pH values and different amounts of minerals and chemicals (such as chlorine and fluoride), which may influence the solubility of the sunscreen ingredient in the product. Because the Panel did not define the term “fresh water,” the comment stated that FDA must provide, in the regulation, specifications for the fresh water in order to standardize the procedures for testing the effectiveness of water resistant and waterproof sunscreen products.

FDA proposes to define “fresh water” for the purpose of this tentative final rule as drinking water that meets the standards established by the United States Environmental Protection Agency (EPA). Tap (piped) water for drinking and domestic use is generally supplied by rivers, lakes, wells, and springs. Water from a public water system is filtered and treated with chemicals in water treatment plants to kill bacteria, soften the water, and improve its taste (if it is to be consumed). The treated water might even go to another reservoir such as a swimming pool or a whirlpool and undergo further treatment if it is used by the public for swimming, in a factory, or a sunscreen testing laboratory, etc.

The EPA is responsible for establishing the minimum standards for all water systems that provide water suitable for human consumption to the public. Service to the public includes factories and private housing developments, communities, camping sites, etc. EPA regulations provide the maximum contaminant levels for organic and inorganic chemicals other than fluoride, for disease-causing microorganisms, etc., in drinking water. (See the National Interim Primary Drinking Water Regulations in 40 CFR...
Accordingly, used for sunscreen testing are necessary. Accordingly, FDA is defining "fresh water" in §352.76 as clean drinking water that meets the standards in 40 CFR Part 141.

One comment stated that the Panel's recommended instructions concerning the waiting period between applying a sunscreen drug product and exposing the test site are inconsistent with the testing procedures for water resistant and waterproof claims in the Panel's report. The general testing procedure in §352.42(f) specifies a waiting period of at least 15 minutes after application of the sunscreen before exposing the test site; whereas, the procedures in §352.46(a)(1) and (b)(1) for testing water resistant and waterproof claims require that application of the sunscreen be followed by the waiting period indicated on the sunscreen drug product's labeling. The comment further noted that a waiting period is not included under the product labeling requirements of the Panel's recommended monograph. The comment suggested that, for uniformity, the individual testing procedures should all reference §352.42. When determining the water resistant and very water resistant claims, the Panel recommended that the waiting period should be that indicated on the product labeling (43 FR 38266 and 38267). The agency agrees with the Panel that the waiting period for each water resistant and very water resistant product should be individually determined by the product's manufacturer. Water resistant and very water resistant sunscreen drug products are specifically formulated to withstand wash-off by water. The degree of water resistance of such products varies and is greatly influenced by the vehicle in which the sunscreen ingredient is incorporated. As stated by the Panel at 43 FR 38218, "the persistence, penetration, and resistance of the active ingredients to abrasion, sweating, and washing often depends upon the vehicle." A waiting period may be necessary for some water resistant products (e.g., to allow the product to dry) in order to provide better resistance to water, and the waiting periods for different sunscreen products may vary. For these reasons, the agency is proposing the Panel's recommendations regarding waiting periods in §§352.72(f) and 352.76(a)(1) and (b)(1).

With regard to the comment's statement that waiting periods are not included in the Panel's recommended monograph labeling, the agency believes that consumers should be informed if a waiting period is necessary for the most effective use of water resistant and very water resistant sunscreen drug products. Therefore, the agency is proposing that the manufacturers determine the waiting periods for the most effective use of their products and include this information in the directions for their product (see comment 66).

106. Four comments addressed the Panel's recommended testing procedure in §352.46 for determining if a sunscreen product is water resistant or waterproof. The agency is using the term "very water resistant" rather than waterproof. See comment 50.) One comment requested that: (1) A whirlpool testing method be included as an alternative testing procedure for water resistant and very water resistant claims; (2) the 20-minute drying periods between immersion periods be deleted; and (3) in analyzing data, the projected slope technique not be excluded from acceptability to product labeling. The comment maintained that such techniques as linear regression and least square techniques require data obtained for different amounts of water exposure, and is not located in the present proposed procedure. The comment contended that the complexity of the Panel's proposed procedure (e.g., the time an investigator must spend with each subject, the number of subjects required, and the requirement for the testing facilities to be close to a swimming pool) makes conducting these tests very expensive in terms of manpower, equipment, and resources. In addition, without access to a close indoor pool, water resistant and very water resistant testing would require the use of an outside swimming pool, which would limit periods of testing to good weather only. Further, if that were to occur, the testing would be subject to many uncontrolled environmental variables such as the weather. The comment added that if the swimming pool was in the same facility as the testing area and solar simulator, transportation of the subjects between the pool and the testing facility would be required, thereby adding further variability in test results between laboratories. The comment concluded that the proposed requirements could eliminate most comparative testing of sunscreen products and stop laboratories from performing such tests.

The comment contended that a testing method using a whirlpool would be more economical and accessible than a method using an indoor swimming pool, provide better standardization of the test environment, and provide better control of environmental variables such as sun exposure, water temperature, and chlorination. In addition, the whirlpool could be located close to the solar simulator testing area. The comment submitted a summary of the results of tests conducted to determine if a sunscreen is water resistant or very water resistant using the procedure proposed in §352.46 and using a whirlpool. The tests compared results obtained in large or small whirlpools to those obtained in a
swimming pool for a number of sunscreen products with various SPF values. All SPF determinations for water resistant and very water resistant were performed with solar simulators in accordance with the Panel's recommended procedures, except that not all studies included 20 test subjects. Based on the results obtained, the comment concluded that under indoor laboratory testing conditions using a whirlpool bath: (1) The environment and the well-being of the volunteers can be more carefully monitored, and indoor heating can be carefully controlled to maintain the volunteer's temperature; (2) the solar simulators can be more rigorously maintained; (3) an acceptable laboratory test using an indoor whirlpool can lead to "a better discussion and treatment of other environmental factors not directly applicable in a swimming pool environment," e.g., the influence of temperature, humidity, and wind; and (4) testing can be performed year-round.

The comment added that its data indicate there is no difference in product effectiveness introduced by inclusion of the Panel's recommended 20-minute drying period between water exposure periods. The comment concluded that this condition appeared to needlessly complicate the testing procedure, and requested that it be deleted. However, the comment did not submit data comparing test results with and without the 20-minute drying period.

A second comment proposed a water resistance test using either a jacuzzi or a swimming pool for sunscreen drug products with an SPF value of 15 or more. The proposed water resistance testing involved the application of the sunscreen product followed by a 15-minute waiting period at room temperature before entering the water. The subject would then bathe in a pool or jacuzzi (temperature between 25 and 30 °C) for 20 minutes. This would be followed by a 20-minute drying period, then by a 10-minute mild shower (temperature between 33 and 37 °C, minimum 2 liters/minute), and then by a 10-minute drying period. The MED of the protected skin would be determined before the procedure for bathing and immediately after the last drying period. The comment stated that the ratio of "bathing/no bathing" of protected sites should be better than 0.8 (i.e., the decrease in SPF should not be more than 20 percent after the test). The comment stated that a product that does not fulfill this water resistance test could not claim to belong to "class I" or to "ultra-sun protection."

A third comment recommended that specific guidelines be provided for water immersion testing. The comment did not provide any guidelines for such testing but did indicate that guidelines for factors such as temperature, method of agitation, and movement should be specified for manufacturers to employ in determining substantivity.

A fourth comment opposed adding a requirement for a very water resistant standard for water resistant testing procedures. The comment stated that the current static standard is adequate to fulfill the purpose of the control and can be used in conjunction with the very water resistant testing without a problem. The comment concluded that nothing would be gained by adding a requirement for a very water resistant standard control.

The comment stated that a whirlpool or jacuzzi is an acceptable alternate to an indoor swimming pool in the testing procedure recommended by the Panel in §352.46. These facilities provide an appropriate means of standardizing water resistant testing among laboratories by providing control over most of the variables. Whirlpools and jacuzzi are similar to an indoor swimming pool in that they provide: (1) Adequate control of environmental factors, e.g., temperature and humidity; (2) proximity to the testing sites; and (3) year-round testing capabilities because testing would not be weather dependent. Additionally, whirlpools and jacuzzi are economical and provide a more rigorous water challenge to test the water resistant properties of the sunscreen drug product. The agency believes that indoor testing helps ensure reproducible results because it is easier to control indoor environmental variables such as temperature and humidity. An accurate and reproducible testing procedure can ensure that competitive products with the same water resistant labeling have essentially the same effectiveness (see comment 79). Therefore, the agency is proposing that the testing procedure (§352.46) be revised to state that an indoor fresh water pool, whirlpool, and/or jacuzzi maintained at 23 to 32 °C shall be used in the testing procedures to determine if a sunscreen drug product is water resistant or very water resistant. This revised testing procedure is in proposed §352.76.

The agency does not agree with one comment's suggestion that a total of only 30 minutes of water immersion is adequate for ascertaining the water resistance of a sunscreen drug product. The Panel concluded that two 20-minute periods of moderate activity for a total of 40 minutes in the water is an appropriate test for determining water resistance (43 FR 38206 at 38263). Likewise, the Panel recommended four 20-minute periods of moderate activity in water (for a total of 80 minutes) to establish that a product is very water resistant. (See discussion in comment 103.) The comment did not provide any test data or other evidence to support its suggestion for moderate activity in water for 30 minutes.

The agency also disagrees with another comment's request to delete the Panel's recommended 20-minute drying period between immersion periods. The Panel reviewed an unpublished consumer marketing survey (Ref. 1) that studied typical water immersion behavior patterns among sun care product users and used these data to establish the 20-minute water immersion periods. Although the survey did not specifically address the amount of time spent out of the water between the immersion periods, the agency considers the Panel's 20-minute drying periods reasonable and a fair representation of the swimming habits of individuals at the beach or swimming pool. The survey indicates that the typical population does spend time out of the water and then reenters the water several times. The agency believes that a water resistant or very water resistant sunscreen drug product should enable an individual to maintain a certain level of protection from the harmful rays of the sun even after an average period of swimming, including time spent out of the water between immersions, without the need to reapply the product. If data are submitted that support deleting the 20-minute drying periods between immersion periods, the agency will consider revising the testing procedure to delete the drying periods.

Regarding specific guidelines for water immersion testing, the agency notes that the Panel required that the water temperature be 23 to 32 °C. Further, the Panel stated that the pool and air temperature and the relative humidity should be recorded. The agency agrees with these Panel recommendations and, in addition, agrees with the comments that more specific guidelines (e.g., water and air temperature, humidity, and minimum size of the whirlpool or jacuzzi) should be included in the testing procedures for sunscreen drug products. However, the comments provided no specific guidelines that might be used for water resistant testing procedures or data concerning the use of such guidelines.

Therefore, the agency is proposing in §352.76 that the water temperature of the indoor pool, whirlpool, or jacuzzi be maintained at 23 to 32 °C and is
requesting comment and data on including other specific environmental guidelines, such as those noted above, that would improve the water resistant testing procedures.

The agency agrees with one comment that an additional control standard for water resistant testing serves no added benefit because the current 8-percent homosalate standard adequately fulfills the purpose of serving as a control for the SPF testing procedure. The Panel stated in its recommended water resistant testing procedures in § 352.46 that “The standard sunscreen is not used in these tests.” The agency is concerned that this statement could imply that the 8-percent homosalate standard is not required for the SPF testing procedure. Therefore, the agency is not proposing this sentence in § 352.76.

Regarding the acceptability of a projected slope technique for the analysis of data for product labeling, the statistical analysis of data from sunscreen drug product testing is addressed in comment 97.

Reference
(1) OTC Vol. 060168, Docket No. 78N–0038, Dockets Management Branch.

V. Comments on In Vitro Testing for Sunscreen Drug Products

107. Referring to the Panel’s recommended testing procedure in § 352.46 for determining if a sunscreen is water resistant or waterproof, one comment recommended that an in vitro substantivity test with isolated specimens of epidermis be used. The comment described the procedures for the in vitro test as follows: (a) Obtain small specimens of skin (5 inches by 2 inches) from postmortem cases; (b) isolate the epidermis by treating the skin specimen at 60 °C for 30 to 60 seconds; (c) measure the transmission spectra of the isolated and untreated epidermis between a spectral range of 200 to 400 nm; (d) apply the sunscreen lotion (2 mg or 2 microliters/cm²), select the minimum and the maximum time for diffusion of the applied sunscreen agent, determine the chemical conjugation of the sunscreen, and measure the transmission spectra after 30- and 60-minute intervals; (e) immerse the specimen in water with constant mechanical stirring for varying periods of time ranging from 10 to 90 minutes; (f) measure the transmission spectra of the specimen after immersion in water for these varying intervals of time; (g) determine the amount of sunscreen agent left on the specimen before and after immersion in water; (h) determine the percent transmission changes in the spectral range of 200 to 400 nm; and (i) calculate the substantivity or water resistance. The comment added that the variables in this test can be controlled.

Another comment submitted in response to the January 1988 public meeting to discuss sunscreen testing methods acknowledged that human testing is the accepted method for determining SPF values. The comment added that in vitro methods are nevertheless being developed and should be encouraged.

The agency agrees that in vitro testing of sunscreen drug products may be useful and encourages the development of such testing methods. The agency has reviewed the in vitro substantivity test suggested by the comment and believes it may be suitable for obtaining an approximate measure of a sunscreen product’s water resistance. However, the agency needs further details about the procedure to properly evaluate it. The protocol offered by the comment is very brief and does not contain enough information for adequate performance of the test and interpretation of the results. While the protocol appears to have merit, it needs to be expanded, developed, and compared to in vivo methods for determining water resistance. Sayre, et al. (Ref. 1) have tested a similar in vitro procedure for determining the water resistance of several sunscreen products using the epidermis of hairless mice in a spectrophotometric assay. The results showed clear differences in substantivity among several sunscreen ingredients using this in vitro method. The results from the in vitro method were reported to be similar to those determined by the in vivo method.

The agency points out that while data from in vitro tests using isolated skin samples may offer some supportive evidence of water resistance, in vivo tests for determining the effectiveness and substantivity of a sunscreen product are still required. Isolated skin specimens do not behave like natural living skin, e.g., they do not sweat, vary in temperature, or develop erythema. Therefore, such in vitro tests alone are not suitable for determining the effectiveness or substantivity of a sunscreen drug product. In addition, comparative evaluations between in vitro and in vivo methods must be performed in order to establish a direct correlation between these methods. Therefore, the agency believes that additional studies with in vitro procedures using isolated skin samples need to be performed and evaluated before these methods can be considered for inclusion in a monograph.

Reference

W. Comment on Safety Testing for Sunscreen Drug Products

108. Stating that the 3 methods of patch testing recommended by the Panel for final products or Category III ingredients are acceptable methods (43 FR 38206 at 38218), one comment requested that a routine patch test method proposed by the International Contact Dermatitis Research Group (ICDRG) also be included as an acceptable method. The comment cited two references in which the ICDRG method is described (Refs. 1 and 2) and added that many sunscreen products have been previously evaluated by this patch test method, which is an accepted method in Europe.

The 3 methods of patch testing recommended by the Panel are part of a general discussion of test methods applicable to human safety testing of Category III ingredients or final-formulated products (43 FR 38218). Because these tests have proven valuable in predicting skin irritancy and potential sensitization, the Panel recommended that these methods be considered for providing adequate data to establish the safety of OTC sunscreen ingredients. The Panel did not recommend that any specific patch test be included in the monograph.

The agency has not addressed specific testing methods for determining the safety of OTC sunscreen drug products in this tentative final monograph; the agency is not, therefore, recommending the use of a particular patch test. Each manufacturer or sponsor should determine which scientifically valid patch test to use to evaluate the safety of its sunscreen drug product. Before utilizing a new patch testing method for sunscreen drug products, the sponsor may want to discuss the use of the method with the agency.

References

### III. The Agency’s Tentative Conclusions and Adoption of the Panel’s Report

#### A. Summary of Ingredient Categories and Testing of Category II and Category III Conditions

1. **Summary of ingredient categories.** The agency has reviewed all claimed active ingredients submitted to the Panel, as well as other data and information available at this time, and is proposing to reclassify padimate A from Category I to Category II for concentrations of 5 percent and higher and to Category III for concentrations less than 5 percent. As a convenience to the reader, the following list is included as a summary of the categorization of sunscreen active ingredients recommended by the Panel and the proposed categorization by the agency.

In this list, sunscreen active ingredients are identified by their current established name. If the current established name is different from that used by the Panel, the Panel’s designation is indicated by footnote.

<table>
<thead>
<tr>
<th>Sunscreen active ingredient</th>
<th>Panel</th>
<th>Agency</th>
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<tbody>
<tr>
<td>Allantoin/aminobenzoic acid complex</td>
<td>II</td>
<td>III</td>
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<tr>
<td>Aminobenzoic acid</td>
<td>I</td>
<td>I</td>
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<tr>
<td>Bomeone</td>
<td>III</td>
<td>III</td>
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<td>Cinoxate</td>
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<td>I</td>
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<td>Diethanolamine</td>
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<td>methoxycinnamate</td>
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<td>I</td>
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<td>Digalloyl trioleate</td>
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<td>Dioxynone</td>
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<td>I</td>
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<td>Dipropylene glycol salicylate</td>
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<td>III</td>
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<tr>
<td>Ethyl 4-bis(hydroxypropyl)aminobenzoate</td>
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<td>II</td>
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<td>2-Ethylhexyl 4-phenoxybenzophenone-2 carboxylic acid</td>
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<td>Gliceryl aminobenzoate</td>
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<td>Homosalate</td>
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<td>Lawson with dihydroxyacetone</td>
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<td>Menthol anthranilate</td>
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<td>II</td>
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<tr>
<td>3-(4-Methylbenzyldiene)-cinnamyl</td>
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<td>II</td>
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<tr>
<td>Octocrylene</td>
<td>II</td>
<td>II</td>
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<td>Octyl methoxycinnamate</td>
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<td>I</td>
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<tr>
<td>Octyl salicylate</td>
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<td>I</td>
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<tr>
<td>Oxybenzone</td>
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<td>II</td>
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<tr>
<td>Padimate A (up to 5 percent)</td>
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<td>III</td>
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<tr>
<td>Padimate A (5 percent or higher)</td>
<td>II</td>
<td>II</td>
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<td>Padimate O</td>
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<td>I</td>
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<tr>
<td>Phenyldizimidazol sulfonylic acid</td>
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<td>II</td>
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<tr>
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<td>Titanium dioxide</td>
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<td>Trolamine salicylate</td>
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2. **Testing of Category II and Category III conditions.**

The Panel recommended testing guidelines for sunscreen drug products (43 FR 38206 at 38258 and 38259). Interested persons may communicate with the agency about the submission of data and information to demonstrate the safety or effectiveness of any sunscreen ingredient or condition included in the review by following the procedures outlined in the agency’s policy statement published in the Federal Register of September 29, 1981 (46 FR 47740) and clarified April 1, 1983 (48 FR 14050). That policy statement includes procedures for the submission and review of proposed protocols, agency meetings with industry or other interested persons, and agency communications on submitted test data and other information.

#### B. Summary of the Agency’s Changes

FDA has considered the comments and other relevant information and concludes that it will tentatively adopt the Panel’s report and recommended monograph with the changes described in FDA’s responses to the comments above and with other changes described in the summary below. A summary of the changes made by the agency follows.

1. The agency is placing the labeling sections of this tentative final monograph in Subpart C. In addition, the agency is renumbering the testing sections, §§ 352.40 through 352.46, of the Panel’s recommended monograph as §§ 352.70 through 352.76 and is placing these sections in Subpart D.

2. Because the term "ultraviolet radiation" is preferred when speaking of the wavelengths between 100 and 400 nm, the agency is using the term "ultraviolet light" instead of "ultraviolet radiation" throughout the tentative final monograph. (See comment 2.)

3. To clarify that the scope of this monograph extends only to drug products and to be consistent with the format of other OTC drug monographs, the word "drug" is being added to § 352.1 to read as follows: "An over-the-counter sunscreen drug product in a form suitable for topical administration."

4. The agency is proposing to provide a definition of MBD in § 352.3 by adding new paragraph (a) as follows: "Minimal erythema dose (MED). The smallest dose of ultraviolet (UV) radiation (expressed as Joules per meter squared) that produces redness reaching the borders of the exposure site."

5. The agency is proposing to provide a definition of SPF in § 352.3 by adding new paragraph (a) as follows: "Sunscreen active ingredient. An active ingredient that absorbs at least 85 percent of the radiation in the UV range at wavelengths from 290 to 320 nanometers, but may or may not transmit radiation at wavelengths longer than 320 nanometers."

6. The agency is proposing to provide a definition of the word "drug" in § 352.3(b) and is including the revised definition in proposed § 352.3(c) as follows:

7. Based upon data showing that padimate A is a weak phototoxic agent, the agency is classifying padimate A at 5 percent and higher concentrations in Category II and in concentrations less than 5 percent in Category III. (See comment 35.)

8. Although the Panel did not include zinc oxide in its report on OTC sunscreen drug products, the agency is proposing in this tentative final monograph to classify zinc oxide in Category III. (See comment 36.)

9. Because a sunscreen active ingredient’s performance is not totally dependent upon the concentration of the active ingredient in the drug product, the agency is proposing only maximum concentrations in § 352.10. However, because the agency is concerned that each ingredient of a combination drug product contributes to the effect of the product, the agency is proposing minimum concentrations for sunscreens used in combination with one another in § 352.20. (See comment 37.)

10. The agency is proposing that any Category I sunscreen active ingredient can be safely and effectively combined with certain Category II skin protectant active ingredients (allantoin, cocoa
11. The agency concludes that OTC sunscreen drug products with SPF values higher than 15 are beneficial to consumers and is proposing in §§352.50 and 352.52 that the upper limit for SPF values be 30. The agency is also proposing that a sunscreen drug product should display its tested SPF value up to 30. The agency believes that SPF values should be displayed on the principal display panel of OTC sunscreen drug products and, therefore, is proposing new §352.50 that requires SPF values to appear on the principal display panel.

The agency is proposing to renumber the Panel’s recommended monograph, the agency is proposing to replace the Panel’s recommended labeling in §§352.50(b)(1)(iv) and (b)(1)(v) with the following statement in §§352.52(e)(6): “SUN ALERT: The sun causes skin damage. Regular use of sunscreens over the years may reduce the chance of skin damage, some types of skin cancer, and other harmful effects due to the sun.”

The agency is also proposing the following in §§352.52(b)(1)(vi): “Any variation of the statement in §352.52(e)(6) that does not relate skin aging or skin cancer as being ‘due to the sun’ will cause the product to be misbranded under section 502 of the act (21 U.S.C. 352).” (See comment 51.)

12. The agency believes that including both a static and a water resistant SPF value in the labeling of water resistant and very water resistant sunscreen drug products will be beneficial to the consumer. Therefore, the agency is proposing such labeling in §§352.50(b)(2). (See comment 51.)

The agency has determined that some of the Panel’s recommended indications can be combined and simplified. In this tentative final monograph, the agency is combining the indications recommended by the Panel in §§352.50(b)(1)(i) and (b)(1)(ii) and is proposing the combined indication in §§352.52(b)(1)(ii) as follows: Select one of the following: “Filters” or “Screens” “out the sun’s” (select one of the following: “burning” or “harsh and often harmful”) “rays to prevent sunburn.” The agency is also combining the additional indications recommended by the Panel in §§352.50(b)(2)(v)(e) and (b)(2)(v)(f) and is proposing the combined indication in §§352.52(b)(2)(vi)(E) as follows: “Provides the highest degree of” (select one of the following: “sunburn” or “sunscreen”) “protection and permits no tanning.”

The agency has determined that sunscreen-containing products that are not indicated for the prevention of sunburn, but only for added protection against the sun are drug products. Because such products are not adequately addressed by the Panel’s recommended monograph, the agency is proposing to include the following new indications in §§352.50(b)(1) as follows: §§352.52(b)(1)(v) (Select one of the following: “Filters” or “Screens” “out the” (select one of the following: “sun’s rays,” “sun’s harsh rays,” or “sun’s harmful rays”) “to help prevent” (select one or more of the following: “lip damage,” “skin damage,” “freckling,” or “uneven coloration”), and §§352.52(b)(1)(vi) (Select one of the following: “Protects from” or “Shields from”) (select one of the following: “the harmful rays of the sun” or “the sun”). (See comment 52.)

13. The agency is proposing to replace the Panel’s recommended labeling in §§352.50(b)(1)(iv) and (b)(1)(v) with the following statement in §§352.52(e)(6): “SUN ALERT: The sun causes skin damage. Regular use of sunscreens over the years may reduce the chance of skin damage, some types of skin cancer, and other harmful effects due to the sun.”

This statement is required on all sunscreen drug products. The agency is also proposing the following in §§352.52(b)(2)(vi): “Any variation of the statement in §§352.52(e)(6) that does not relate skin aging or skin cancer as being ‘due to the sun’ will cause the product to be misbranded under section 502 of the act (21 U.S.C. 352).” (See comment 52.)

14. To accommodate the various dosage forms of sunscreen drug products that are available, the agency is including only brief, required directions that can be expanded with more detailed instructions applicable to a particular product formulation and dosage form. In addition, the agency is...
proposing that manufacturers determine the necessary waiting period between applying a sunscreen drug product and exposing the test site to water, if applicable, for water resistant and very water resistant sunscreen drug products and include this information in the directions for use. Accordingly, the agency is proposing these requirements in the directions in §352.52(d). (See comment 67.)

24. The agency is combining the directions recommended by the Panel in §352.50(d)(1)(i) and (d)(1)(ii) and is proposing the combined directions in §352.52(d)(1). The agency is also combining the directions recommended by the Panel in §352.50(d)(3)(i) and (d)(3)(ii) and is proposing the combined directions in §352.52(d)(3) of this tentative final monograph.

25. The agency is also proposing specific directions for sunscreen-containing drug products such as lip balms, make-up preparations, skin preparations, and lipsticks in §352.52(d) as follows:

"(4) For products containing any ingredient identified in §352.30 labeled with only the indications in §352.52(b)(1)(v) and/or (b)(1)(vi) and formulated as a make-up preparation or lipstick, 'Apply liberally as often as necessary.'"

"(5) For products containing any ingredient identified in §352.10 labeled with only the indications in §352.52(b)(1)(v) and/or (b)(1)(vi) and formulated as a lip balm or skin preparation, 'Adults and children 6 months of age and over: Apply liberally as often as necessary. Children under 2 years of age should use sunscreen products with a minimum SPF of 4. Children under 6 months of age: consult a doctor. '"

26. The agency is proposing to allow manufacturers the option of using the word "perspiration" for "sweat" and the word "perspiring" for "sweating" in §§352.50(b) and (c) and 352.52(d) and (e). (See comment 49.)

27. The agency is not proposing the Panel's recommended term "waterproof" in this tentative final monograph, but is proposing instead the term "very water resistant" in §§352.50(c) and 352.52 (d) and (e). (See comment 50.)

28. The agency is proposing to revise the Panel's recommended PCD labeling in §350.50(e) to more accurately reflect the actual protective values of sunscreen drug products and that PCD labeling claims be optional. The agency is also proposing the terms "minimal," "moderate," "high," "very high," and "ultra high" to identify PCD's. The agency is proposing this revised PCD labeling in §352.52(e). (See comments 44 and 45.)

29. The agency believes that it is appropriate for a sunscreen drug product that passes the water resistance and very water resistance tests to be permitted to make claims regarding sweat resistance in addition to making claims regarding water resistance. Therefore, the agency is proposing to permit the use of the terms "sweat resistant," "perspiration resistant," "resists removal by sweating," or "resists removal by perspiring" for a sunscreen drug product that qualifies for the claim of water resistant or very water resistant. The agency is proposing the phrase "sweat resistant" or "perspiration resistant" in §352.52(e)(2) and (e)(3) and is not proposing §352.50(e)(2)(i)(c) as recommended by the Panel. In addition, the agency is not including the Panel's recommended sweat resistant test in §352.46 in the sunscreen testing procedures. (See comment 100.)

30. The agency is proposing the following additional statement in §352.52(e)(5): "For products containing the active ingredient identified in §352.10(s) that provide an SPF of 12 to 30, the following labeling statement may be used. 'Sunblock.' " (See comment 60.)

31. The agency is proposing to include the following labeling requirements for the indications, warnings, and directions of sunscreen-skin protectant combination products in §352.50(b), (c), and (d), respectively, concerning labeling of combination sunscreen drug products: "For permitted combinations containing a sunscreen and a skin protectant identified in §352.20(b). In addition to any or all of the indications for sunscreens in §352.52(b), the indication for skin protectants in §347.50(b)(2) of this chapter should be used.""For permitted combinations containing a sunscreen and a skin protectant identified in §352.20(b). The warning for skin protectants in §347.50(c)(3) is not required." "For permitted combinations containing a sunscreen and a skin protectant identified in §352.20(b). The directions for sunscreens in §352.52(d) should be used."

The agency is also proposing a new §352.20(c) to include a cross reference to the combination of a sunscreen active ingredient and a skin bleaching active ingredient. Labeling for this combination will be included in the final monograph for OTC skin bleaching drug products. (See comment 71.)

32. Because the Improved Stability characteristics of a revised 8-percent homosalate standard make it more appropriate for use in the testing procedures for sunscreen drug products than the standard originally submitted to the Panel, the agency is proposing the revised formulation and its manufacturing directions in §352.70(a) and (b). In addition, the agency is including in §352.70(a) the following statement: "In order for the SPF of the test product to be considered valid, the SPF of the standard sunscreen must fall within the standard deviation range of the expected SPF (i.e., 4.47 ± 1.279), and the 95-percent confidence interval for the mean SPF must contain the value 4." (See comments 74 and 75.)

33. The agency is not including the Panel's recommended §352.41(b) "Natural light source [sunlight]" and §352.44 "Determination of SPF value using natural light source [sunlight]," in this tentative final monograph. In addition, the Panel's reference to natural sunlight testing in §352.42(h) "Response criteria" is not being included. (See comment 79.)

34. The agency is revising the light source specification proposed by the Panel in §352.41 of its monograph and is proposing new specifications in §352.71. Also in §352.71, the agency is specifying that an "accurately-calibrated spectroradiometer system or equivalent instrument" be used to measure the output of a solar simulator. (See comments 86 and 89.)

35. The agency believes that blinding procedures should be included in the sunscreen testing procedures. Therefore, the agency is proposing blind procedures in §352.72(e) "Application of test materials" and §352.72(h) "Response criteria." (See comment 91.)

36. In this tentative final monograph, the agency is not including the Panel's recommended §352.42(g) but is proposing the following in §352.72(g): "Number of subjects. A test panel shall consist of 25 people, no more than 25 subjects with the number fixed in advance by the investigator. From this panel, at least 20 subjects must produce valid data for analysis." In addition, the agency is proposing to revise the Panel's recommended §352.41(i) "Rejection of data" by adding the phrase "or if the subject was noncompliant (e.g., subject withdraws from the test due to illness or work conflicts, subject does not shield the exposed testing site from further UV radiation until the MED is read, etc.)" and is including the revised section in §352.72(i). (See comment 94.)

37. The agency is proposing that §352.72(h) include the following: ""* * * The MED is determined 22 to 24 hours after exposure. The erythema
responses of the test subject should be evaluated under the following conditions: the source of illumination should be either a tungsten light bulb or a warm white fluorescent light bulb that provides a level of illumination at the test site within the range of 450 to 550 lux, and the test subject should be in the same position used when the test site was irradiated. Testing depends upon determining the smallest dose of energy that produces redness reaching the borders of the exposure site at 22 to 24 hours postexposure for each series of exposures. The agency is also proposing in § 352.73 that the MED is the lowest dose of radiation that produces uniform redness reaching the borders of the exposure site at 22 to 24 hours postexposure. (See comment 95.)

In § 352.73(c) the agency is proposing to revise the Panel’s recommended determination of SPF values in § 352.43 to include a geometric series of 5 exposures plus 2 other exposures placed symmetrically around the middle exposure. In addition, the agency is proposing that the exposure doses for the geometric series shall be calculated as follows: (1) 1.25X for products with an estimated SPF less than 8, (2) 1.20X for products with an estimated SPF from 8 to 15, and (3) 1.15X for products with an estimated SPF greater than 15. (See comment 96.)

The agency is proposing an erythema action spectrum and a proposed calculation to determine the erythema effective exposure in § 352.73. The agency is also proposing to replace the term “exposure time interval” in the SPF calculation in § 352.73 with the term “erythema effective exposure.” (See comments 84 and 85.)

The Panel recommended in § 352.43 that the MED(U) be determined on the day before evaluating the MED(PS) of the test sunscreens and the standard sunscreen. The agency agrees that it is necessary to establish the inherent MED of the test subject prior to evaluating a test sunscreen drug product so that the investigator can select appropriate doses of UV radiation to administer to the test subsites based upon the individual’s predetermined MED(U) and the expected SPF of the test product. The agency is proposing that an MED(US) be determined on a day prior to the testing of the sunscreen drug product and that this previously established MED(US) be used to determine the testing doses of UV radiation. However, the agency also believes that the MED(US) and the MED(PS) that are used in the calculation of the SPF value of a sunscreen drug product should be determined on the same day. Such concomitant testing will eliminate any discrepancies resulting from day to day variations that may exist in the testing environment. Therefore, the agency is proposing in § 352.73 that, in addition to establishing an MED(US) on a day prior to the testing of the sunscreen drug products, a second MED(US) must be established on the same day as the MED(PS). The MED(US) that is established concomitantly with the MED(PS) is to be used in the calculation of the test product’s SPF value.

The agency is including a statistical analysis based on the t-test to be used in analyzing the results of the testing procedures for sunscreen drug products. Therefore, in § 352.73, the agency is proposing to include a sided t-test. The agency is also proposing the use of a 95-percent lower confidence interval to establish a statistically significant SPF value for use in OTC sunscreen drug product labeling. (See comment 85.)

In § 352.76(e) the agency is proposing the following sentence at the end of the section: "If the sunscreen product retains the same PCD after 40 minutes of water immersion as it had before water immersion, the claim of ‘water resistant’ may be made." In § 352.76(b), the agency is proposing the following sentence at the end of the section: "If the sunscreen product retains the same PCD after 80 minutes of water immersion as it had before water immersion, the claim of ‘very water resistant’ may be made." (See comment 101.)

The agency is proposing in § 352.76 of this tentative final monograph a definition of “fresh water” as clean drinking water that meets the standards in 40 CFR Part 141. (See comment 105.)

To clarify that the procedures in “General Testing Procedures” in § 352.72 apply to the individual testing procedures for water resistant and very water resistant claims, the agency is proposing a cross reference in § 352.76 as follows: “The general testing procedures in § 352.72 should be used as part of the following tests, except where modified in this section.” The agency is also deleting the Panel’s recommended statement in § 352.46 that states that “The standard sunscreen is not used in this test,” and requiring that the 8-percent homosalate standard be used in the general testing procedures in § 352.72. (See comments 105 and 106.)

The agency is proposing testing procedures in § 352.76 to state that an indoor fresh water pool, whirlpool, and/ or jacuzzi maintained at 23 to 32 °C shall be used in the water resistant or very water resistant testing procedures. (See comment 106.)

The agency is proposing to amend the cosmetic regulations in 21 CFR Part 700 by adding § 700.35 to state that if a cosmetic product uses the word “sunscreen” anywhere in its labeling, the term “sunscreen” must be qualified by describing the cosmetic benefit provided by the sunscreen. (See comment 27.)

Because the trade correspondence TC-61 will be superseded by the requirements of the final monograph for OTC sunscreen drug products, the agency intends to revoke TC-61 and will publish a notice of revocation and the final monograph for OTC sunscreen drug products concurrently. (See comment 27.)

In an effort to simplify OTC drug labeling, the agency proposed in a number of tentative final monographs to substitute the word “doctor” for “physician” in OTC drug monographs on the basis that the word “doctor” is more commonly used and better understood by consumers. Based on comments received to these proposals, the agency has determined that final monographs and other applicable OTC drug regulations will give manufacturers the option of using either the word “physician” or the word “doctor.” This tentative final monograph proposes that option.

For an active ingredient to be included in an OTC drug final monograph, it is necessary to have publicly available sufficient chemical information that can be used by all manufacturers to determine that the ingredient is appropriate for use in their products. The recent discovery of a nitrosamine contaminant in sunscreens containing padimate O (see discussion above) underscores the importance of requiring that sunscreen ingredients are adequately characterized and that these standards are published in an official compendium. Only a few of the sunscreen active ingredients that the Panel classified as Category I are standardized and characterized for quality and purity and are included in official compendia. Aminobenzoic acid, cinoxate, dioxybenzone, oxybenzone and titanium dioxide are currently
The remaining sunscreen active ingredients, including the homosalate control preparation used in the sunscreen testing procedures, are currently not adequately characterized.

The agency believes that it would be appropriate for interested parties to develop with the United States Pharmacopoeial Convention appropriate standards for the quality and purity of the sunscreen ingredients that are not already included in official compendia. This tentative final monograph diethanolamine methoxybenzilate, diglycol trilate, ethyl 4-[

In this tentative final monograph diethanolamine methoxybenzilate, diglycol trilate, ethyl 4-[bis(hydroxypropyl)]aminobenzoate, glyceryl aminobenzoate, homosalate, lawsone with dihydroxyacetone, menthol anthranilate, octocrylene, octyl methoxybenzilate, octyl salicylate, phenylbenzimidazole sulfonic acid, red petroleum, sulisobenzone, and trolamine procured from the suppliers listed in this monograph. These ingredients are being added to Category I. However, should interested parties fail to provide necessary information so that appropriate standards may be established, these ingredients will not be included in the final monograph. The same standards should also be developed for any Category II or III ingredients for which data are submitted for inclusion in the final monograph.

Reference


51. The agency has determined that the medical literature supports the Panel's conclusion that overexposure to sunlight/UV radiation is related to skin cancer and premature aging of the skin. (See comments 46 and 56.) The Panel recognized the epidemiological evidence that skin cancer and degenerative skin changes (elastotic degeneration), referred to as premature aging of the skin, are related to chronic exposure to the UV radiation from the sun (43 FR 38206 at 38211 and 38212). This damage is cumulative, and many years may pass before skin changes appear.

The agency notes that premature aging of the skin caused by excessive exposure to the sun is a distinct process very different from normal chronologic or intrinsic aging of the skin. Some of the differences observed between photoaged and chronologically aged skin were discussed in a 1986 review article (Ref. 1). For example, photoaged skin displays massive quadrupoles of elastic fibers that degenerate into an amorphous mass while normally aged skin displays a slightly increased, but almost normal, amount of elastic tissue. Although, the dermis of normally aged skin becomes thicker than normal, the dermis of normally aged skin becomes thinner. Photoaged skin contains an increased number of hyperactive fibroblasts, an increased number of mast cells, and a mixed inflammatory infiltrate. In normally aged skin, the fibroblasts are decreased in number and inactive, the mast cells are decreased in number, and there is no inflammation. The agency emphasizes that the use of sunscreens has no effect on the normal process of aging, either aging of the skin or of the entire body.

The Panel noted that dermatologists routinely instruct their patients who have skin cancer on sun-exposed areas to wear long sleeves and a wide-brim hat, to avoid sun exposure between 10 a.m. and 2 p.m., and to use a sunscreen liberally every day (43 FR 38206 at 38212). The reason that most physicians recommend sunscreens for skin cancer patients is to reduce the risk of skin cancer that may not appear for 10 to 20 years, resulting from current exposure to the sun. It is not intended that the use of sunscreens will heal damage resulting from sun exposure that occurred years earlier.

The Panel notes that many consumers could benefit from protection against everyday chronic exposure to UV radiation in addition to obtaining protection against periodic, acute exposure such as is encountered at the beach. For example, daily protection from exposure to UV radiation could be useful for many outdoor workers (e.g., construction workers, traffic police) and other persons involved in long-term outdoor activities. These individuals would require the most frequent sunscreen application. In addition, individuals who jog, play tennis, walk, drive, or garden may also need protection from UV radiation exposure. The AAD notes that 90 percent of all skin cancers occur on parts of the body that are not protected by clothing. Farmers, outdoor workers, sports enthusiasts, and others who by choice or necessity spend numerous hours in the sun are likely candidates for leathery complexions and solar keratoses (Ref. 2). The AAD recommends that for optimal protection against developing skin cancer, people should avoid constant overexposure to the sun from infancy through adulthood. By selecting appropriate clothing and applying the proper sunscreens, persons can enjoy outdoor activities in the sunshine, while still maintaining healthy and attractive skin throughout life.

The agency is unaware of specific data demonstrating a need for protection from UV light in indoor environments such as in an office building. Most scientific sources, including an NIH Consensus Development Conference (Ref. 3), have concluded that daily sun protection is needed for routine outdoor exposure but have not made recommendations regarding the need for protection indoors. A statement issued by the NIH Consensus Development Conference (Ref. 3) recognizes that unshielded fluorescent bulbs used for illumination are a potential source of artificial UV radiation. An unresolved issue is the amount of UVA emitted by such sources and the long-term effects of this exposure. More research on indoor sources of radiation is needed to identify possible problems. In the absence of definitive data, the AAD provides no recommendations on the use of sunscreens indoors. The agency invites comments, data, and information on the usefulness of sunscreens indoors. Because of the documented importance and value of sunscreen drug products for many consumers, the agency concludes that the marketing of sunscreen drug products for daily use is beneficial, provided the products are appropriately labeled. Therefore, in this tentative final monograph, the agency is proposing labeling that is appropriate for daily use (nonbeach products) as well as for products that are intended for occasional use where intense sun exposure is likely to occur (beach products). (See comment 52.)

The Panel's recommended monograph included the following two indications for all sunscreen drug products: (1) "Overexposure to the sun may lead to premature aging of the skin and skin cancer. The liberal and regular use over the years of this product may help reduce the chance of these harmful effects," and (2) "Overexposure to the sun may lead to premature aging of the skin and skin cancer. The liberal and regular use over the years of this product may help reduce the chance of premature aging of the skin and skin cancer."

The Panel recommended these indications because it (1) believed that overexposure to sunlight/UV radiation is related to skin cancer and premature aging of the skin and (2) the regular use of sunscreens will reduce consumers' risk of these adverse effects (43 FR 38206 at 38210 and 38211). The agency notes that it is important that consumers be alerted to the risks of premature aging and skin cancer that may result from overexposure to the sun. The agency believes that including such information on all sunscreen drug
products would be an effective means of educating the public to use sunscreens to minimize the detrimental effects of long-term exposure to the sun. Therefore, because of the seriousness of these adverse effects, the agency is proposing not to include the statement as an optional indication but rather as a required statement in the labeling of all sunscreen drug products. The agency is proposing a different statement than that recommended by the Panel, however, because it believes that this statement will better alert and inform consumers that the sun may damage the skin and that using sunscreens may help to reduce the risk of damage. This statement is proposed in §352.52(e)(6) of this tentative final monograph under the heading “SUN ALERT” as follows: “The sun causes skin damage. Regular use of sunscreens over the years may reduce the chance of skin aging, some types of skin cancer, and other harmful effects due to the sun.” (See comment 56.)

It is very important that the labeling of sunscreen drug products convey accurate information to consumers and that consumers are not misled. The agency believes that any labeling on sunscreen drug products that refers to skin aging or skin cancer should not be taken out of context, and that the labeling should directly relate the skin aging or skin cancer as being due to sun exposure. Labeling that does not directly relate these adverse effects as being due to sun exposure is misleading. Therefore, in §352.52(e)(7) of this tentative final monograph, the agency is proposing the following: “Any variation of the statement in §352.52(e)(6) that does not relate skin aging or skin cancer as being “due to the sun” will cause the product to be misbranded, under §502 of the act (21 U.S.C. 352).” The agency will evaluate claims made on OTC sunscreen drug product labels on a product-by-product basis, under section 502 of the act (21 U.S.C. 352), to determine whether those claims are false or misleading.

For examples of acceptable and unacceptable labeling, (see section II.B.52 and 53—Summary of Agency Changes of this document.

References


52. The agency is aware that most manufacturers of sunscreen skin care products have recognized that the specific term “anti-aging” or similar absolute terms are not appropriate for use in labeling of either an OTC drug or cosmetic product. At the agency’s urging, the majority of manufacturers are not currently using such terms on products containing Category 1 sunscreen ingredients.

The agency issued a number of regulatory letters (Ref. 1) to companies marketing skin creams and lotions with therapeutic labeling claims. None of the products were marketed or promoted as beach products. Most of the products did not contain sunscreens and were marketed as facial creams with claims such as the following: “anti-aging total skin supplement,” “anti-age daytime skin treatment,” “reverses signs of facial aging,” “prevent, postpone, and minimize the effects of the aging process,” “recreate the structure of a youthful skin,” “helps to rebuild the intercellular structure of your skin,” and “cause cells to divide and reproduce faster.” However, some of the products contained sunscreen ingredients and, in addition to anti-aging claims similar to those described above, displayed claims such as “enhanced with two sunscreens: Filters for UV A and UV B,” “helps prevent lines and wrinkles by guarding against UV damage,” “special UV A and UV B screening agents help prevent permanent tissue damage caused by sun exposure * * * designed to shield the skin against the specific factors that accelerate the signs of aging,” and “filters out damaging UV light rays.”

In its regulatory letters, the agency pointed out that such claims represent and suggest (1) that the product is intended to affect the structure and function of the human body and (2) that the product is adequate and effective for such uses as recreating the structure of young skin, rebuilding the intercellular network of skin, and other claims. The agency stated that such claims cause the product to be regarded as a drug as defined in section 201(g) of the act (21 U.S.C. 321(g)). The agency also stated that because it was unaware of any substantial scientific evidence that demonstrated that the products were generally recognized as safe and effective for their intended uses, these products were “new drugs” within the meaning of section 201(p) of the act (21 U.S.C. 321(p)). In addition, many of the products that contained sunscreen ingredients were not labeled with adequate directions for use. Moreover, some products contained a purported sunscreen ingredient that was not generally recognized as safe and effective for its intended use and were, therefore, unapproved new drugs.

One regulatory letter was sent to a company that marketed a product, “ANTI-AGING COMPLEX,” that contained a sunscreen among other ingredients. According to the letter (Ref. 2), the labeling of the product stated or suggested that the product minimizes the aging effects that can result from ultraviolet rays, aids maturing skin while new cells rise to the surface through a special balance of skin cell protectors, and helps the skin hold vital moisture deep within the epidermis. The agency stated that these claims cause the product to be a drug, and that because the drug is not generally recognized as safe and effective for its intended use, the product is a new drug.

In a written response to the agency (Ref. 3), the company insisted that it had consistently labeled the product as an OTC drug/cosmetic in compliance with the act and the proposed rule for OTC sunscreen drug products. The company stated that the use of the name “Anti-Aging” for its product is not false or misleading because, when taken in the context of the claims, indications, and declaration of active ingredients, the terms clearly demonstrate that the product is intended to minimize the visible signs of aging associated with incidental sun exposure. According to the company, the product’s labeling included the following claims, among others: (1) “With proper care and protection, it is possible to moderate the influence of environmental factors, helping to minimize the visible signs of aging,” (2) “Minimizes the aging effects which can result from incidental sun exposure during everyday activities,” and (3) “A unique formula that contains ingredients designed to shield your skin against specific factors that accelerate the signs of aging.” As support for such claims, the manufacturer pointed to the indications proposed by the Topical Analgesic Panel in §350.50(b)(iv) and (b)(v) of its recommended monograph for OTC sunscreen drug products (e.g., “Overexposure to the sun may lead to premature aging of the skin and skin cancer. The liberal and regular use over the years of this product may help reduce the chance of harmful effects.” See 43 FR 38286 at 38287.) The company added that although its claims do not follow the language of the monograph verbatim, they are consistent with the language in the monograph and that consistency is all...
that is required under the agency's OTC labeling "flexibility policy."

Another regulatory letter (Ref. 4) was issued regarding "AGE-LESS ANTI-AGING DAILY FACE CAPSULES." The letter cited labeling statements such as the following: "AGE-LESS ANTI-AGING DAILY FACE CAPSULES." The agency responded that these claims are invalid and should be removed from the labeling of sunscreen drug products. The agency believes that use of the term "anti-aging" by itself is inadequate to describe the action of a sunscreen drug product and is in fact misleading. The agency is aware that the phrase "photoaging of the skin" refers to premature aging of the skin and should not be elevated to greater significance than other signs of premature aging of the skin unacceptable:

1. Statements that include only the term "anti-aging." As discussed above, the agency does not believe that the term "anti-aging" by itself is adequate language to describe the action of a sunscreen drug product and is in fact misleading.

2. "Helps prevent lines and wrinkles by guarding against UV damage." As discussed above, "premature aging of the skin" cannot be defined as "wrinkling" or "lines" because wrinkling is only a part of the process of premature aging of the skin and should not be elevated to greater significance than other signs of premature aging of the skin.

3. Statements including terms such as stops, reverses, or reduces the signs of aging. These statements make no reference to premature aging of the skin or that such aging is due to the sun. The agency is not aware of any data showing that the use of a sunscreen stops, reverses, or reduces the signs of aging.

4. "Helps to minimize the visible signs of aging," when used in conjunction with a sunscreen ingredient. This statement makes no reference to aging of the skin or that the skin aging is due to the sun. As noted above in (3), the agency is not aware of any data showing that the use of a sunscreen has any affect on aging.

5. "Prevent (or reduce) skin aging caused by exposure to ultraviolet rays." The agency objects to the absolute term "Prevent (or reduce)" used in this claim.
The statement proposed in §352.52(e)(6) of this tentative final monograph is a qualified statement that use of a sunscreen drug product "may reduce the chance of** * * adverse effects of the sun. The agency concludes that a qualified statement is appropriate, and that the use of absolute terms such as "prevent" is not justified in the labeling of sunscreen drug products.

(5) "Prevents skin cancer caused by exposure to the sun." The agency is aware of some investigations showing that sunscreens can promote the repair of UV radiation-induced dermal damage (Refs. 6 and 7). However, these results are not conclusive. Therefore, at the present time the use of such claims on sunscreen drug products would be premature.

The agency invites comments on these and any other related statements that might be used in the labeling of OTC sunscreen drug products.

References


53. Skin cancer is a serious concern to all consumers. According to the American Cancer Society, more than 600,000 people were diagnosed with basal-cell and squamous cell carcinomas in 1990, up from 400,000 in 1990. In addition, 35,000 people were diagnosed with melanoma in 1990 (Ref. 1). Because of the seriousness of skin cancer, the agency believes that sunscreen drug product labeling related to skin cancer should be especially limited and carefully stated. It is very important that the labeling of sunscreen drug products not include any phrases or terms that may induce a false sense of security in sunscreen users.

Although there is extensive epidemiological evidence supporting the direct role that UV radiation plays in basal cell and squamous cell carcinomas, the relationship between UV radiation exposure and melanoma is not as clear (Ref. 2). As noted in comment 56, the labeling statement proposed by the agency in §352.52(e)(6) of this tentative final monograph takes into account the likelihood that all skin cancers may not be correlated to UV radiation exposure. This labeling information states that "Regular use of sunscreens * * * may reduce the chance of * * * some types of skin cancer * * * due to the sun."

In addition, skin cancer is a long-term consequence of exposure to UV radiation. It normally manifests itself several years after the causative UV radiation exposure. Using a sunscreen now does not protect consumers against the development of a skin cancer that was initiated by UV exposure that occurred 20 or 30 years ago.

The agency is aware of at least one product, SKIN CANCER GARDE, that displays labeling that emphasizes the product's purported effectiveness in preventing skin cancer (Ref. 3). The product displays labeling statements such as: (1) "Skin Cancer Garde" in which the words "skin" is substantially smaller and less distinct than the words "Cancer Garde," and (2) "Many skin cancers may be avoided by taking adequate precaution against excessive sun exposure."

The agency considers the use of term "Cancer Garde" in the labeling of the product "SKIN CANCER GARDE" misleading. It is an overly positive statement that may lead consumers to assume that the use of the product will absolutely prevent skin cancer, when such is not necessarily the case. The proposed statement related to premature aging of the skin and skin cancer proposed by the agency in this tentative final monograph is qualified, i.e., "may reduce the chance of * * * skin cancer," and any skin cancer prevention language that is displayed in the labeling of sunscreen drug products should reflect the tentativeness of the FDA approved labeling. Such language should also clearly relate the skin cancer to exposure to the sun or ultraviolet rays.

The agency believes that the following claims are examples of acceptable labeling pertaining to skin cancer for sunscreen drug products:
(1) "May reduce the chance of some kinds of skin cancers caused by exposure to the sun that would otherwise appear 20 years from now."
(2) "Regular, everyday use of this product from childhood on, may reduce the chance of some types of skin cancers caused by exposure to the sun."

These statements accurately reflect the intent of the "premature aging/cancer" statement proposed by the agency in this tentative final monograph. The agency believes that this is important information that should be provided to consumers; however, the information must be stated in such a manner so that consumers are not misled to believe that the product will provide more protection than it actually does.

The agency considers the following claims as unacceptable labeling pertaining to skin cancer:
(1) "Cancer Garde" or "Cancer Guard" as the name of the product.
(2) "Prevents skin cancer that may result from exposure to the sun."

As discussed above, the agency considers such labeling to be misleading because consumers may be led to believe that use of the product will absolutely prevent cancer, when such is not the case.

The agency invites comments on these and any other related statements that might be used in the labeling of OTC sunscreen drug products.

References
(3) OTC Vol. 06ATFM, Docket No. 78N-0038, Dockets Management Branch.

IV. Recent Developments
A. Padimate O Safety Concerns

In the advance notice of proposed rulemaking for OTC sunscreen drug products, the Topical Analgesic Panel recommended that 21 ingredients, including padimate O, be generally recognized as safe and effective for use...
in OTC sunscreen drug products. Padimate O is octyl dimethyl amino benzoic acid ester. In evaluating the safety of padimate O, the Panel reviewed animal and human toxicological data that included oral LD_{50} results, primary irritation and sensitization studies, and eye irritation studies (43 FR 38206 at 38244). However, the Panel did not review any mutagenicity or carcinogenicity data for padimate O or for any other sunscreen ingredient.

Recently, FDA identified a new nitrosamine contaminant isolated from sunscreen drug products that contain the ingredient padimate O. Chou, Yates, and Wenninger (Ref. 1) developed a method for the identification and determination of this new nitrosamine, N-methyl-N-nitrosaminobenzoate octyl ester (NMPABAO), chemically known as 2-ethylhexyl 4-(N-methyl-N-nitrosamino) benzoate. They used this method to analyze 17 commercially available sunscreen drug products containing padimate O and demonstrated that 14 of the products contained NMPABAO at levels ranging from 60 to 1,960 parts per billion (ppb). The presence of NMPABAO in all samples with more than 1,000 ppb was confirmed by mass spectroscopy.

Three discreet problems arose as a result of discovering the NMPABAO contamination of padimate O-containing sunscreen drug products: (1) Because NMPABAO was a new nitrosamine, its mutagenic and carcinogenic potential was unknown, (2) many questions were raised regarding the validity of the analytical methods used by the agency to isolate the nitrosamine, and (3) the photostability of NMPABAO was not known.

1. Toxicological Data

An unpublished report describing the results from an Ames test of NMPABAO was submitted to the agency (Ref. 2). The results of this test were purported to indicate that NMPABAO might be mutagenic. The agency is also aware of unpublished studies examining NMPABAO for mutagenicity in tests using Salmonella typhimurium (Ref. 3) and mouse lymphoma cells (Ref. 4). The results of another study were submitted to the agency in which the carcinogenic potential of NMPABAO was tested by measuring unscheduled deoxyribonucleic acid (DNA) synthesis (UDS) in the Rat Hepatocyte Primary Culture/DNA Repair Assay (Ref. 5). The agency has also tested NMPABAO and padimate O using the same assay (Ref. 6).

In the unpublished report describing positive results from an Ames test (Ref. 2), an ingredient purported to be NMPABAO was tested with two Salmonella strains (Salmonella typhimurium TA 100 and TA 1535) with and without in vitro metabolic activation by Aroclor-induced rat liver S-9 preparation. Doses ranged from 0.5 to 50 micromoles (mmoles) per plate in the presence of the metabolic activation system. The data for the experiments without metabolic activation are from strain TA 1535 only, and doses ranged from 1 to 50 mmole per plate. Concurrent solvent and positive controls were performed with each experiment.

No increase in mutant counts was seen in strain TA 1535 in the absence of metabolic activation. In the presence of metabolic activation, increases in mutant counts occurred at doses of 10 mmoles per plate and higher, and these increases were dose related up to the 50 mmole maximum dose. In strain TA 100, in the presence of metabolic activation, increases exceeded a doubling of the spontaneous count at doses of 1 mmole per plate and higher. These increases were dose related up to the 50 mmole maximum dose. This indicates that the test sample used is mutagenic, but that its mutagenic activity is not very strong in the assay as performed. Impurities in the sample could account for the mutagenic activity at this dose and at higher doses.

The methodology used for these experiments is not explained in any detail, and the report contained no information on the purity of the compound. For example, the amount of S-9 used per plate is not given. The report does not state whether a plate incubation protocol or a preincubation protocol was used. The report states that the positive responses seen exceed those seen with the well-known carcinogen dimethyl nitrosamine (DMN). The agency notes that DMN is generally considered to be a very weak mutagen and gives a positive response only under proper conditions in the S. typhimurium mutagenicity assay.

The report on this Salmonella assay (Ref. 2) states that interpretation of these results should include the following considerations: (1) Metabolic activation in this assay was provided by liver enzymes, and, therefore, the results cannot be extrapolated to assume that skin enzymes would also activate this compound to a mutagenic form, (2) the results obtained with rat enzymes cannot be extrapolated to human enzymes, and (3) the report noted that mutagenic activity does not imply carcinogenic activity.

The agency points out that there are a number of nitrosamines that give very weak responses in the standard plate incorporation Salmonella assay. The mutagenicity of such compounds can often be better detected by using a preincubation protocol or by using Syrian golden hamster S-9 rather than rat S-9 for the metabolic activation system.

In another study (Ref. 3), other investigators were unable to duplicate the positive results described in the above assay (Ref. 2). NMPABAO and a structurally related positive control, N-nitrosopiperidine, were tested for mutagenicity in the S. typhimurium assay (Ref. 3). The two compounds were initially tested in the Salmonella plate incorporation assay using dimethyl sulfoxide (DMSO) as the solvent. NMPABAO was negative with all five Salmonella tester strains without metabolic activation and with liver S-9 preparations from Fischer 344 rats and Syrian golden hamsters. In contrast, N-nitrosopiperidine induced positive responses in tester strains TA 98 and TA 100, but only in the presence of hamster S-9.

Because it has been reported that neither the plate incorporation assay nor the use of DMSO may be the optimal conditions for expression of a mutagenic response for some nitrosamines, the compounds were retested with Salmonella using a preincubation procedure and acetone as the solvent. Under these conditions, the results were the same with NMPABAO as those obtained in the plate incorporation assay. There were no increases in the number of revertants in any of the five tester strains. With N-nitrosopiperidine, dose-related responses were observed with TA 98, TA 100, and TA 1535, in the presence of hamster S-9. The investigators concluded that NMPABAO is not mutagenic in S. typhimurium.

NMPABAO and two positive control chemicals, 3-methylcholanthrene (MCA) and ethyl methanesulfonate (EMS), were tested in the mouse lymphoma (L5178Y) mutagenesis assay (Ref. 4). NMPABAO was negative with and without Aroclor-induced rat liver S-9 metabolic activation using either DMSO or acetone as the solvent. In contrast, the direct-acting mutagens, EMS and MCA, in the presence of rat liver S-9, induced mutations.

In another test for genotoxicity (Ref. 5), NMPABAO was tested for its ability to induce DNA repair in primary rat hepatocytes. The positive control in this test was 4-(methylnitrosamino)-1-(pyridyl)-1-butane (NNK). NMPABAO and the positive control, NNK, were examined at three concentrations: 10^{-2}, 10^{-3}, and 5 x 10^{-3} moles [M]. NMPABAO showed no apparent
induction of UDS at all test concentrations. In contrast, the positive control, NNK, showed significant and dose-dependent induction of UDS at $10^{-2}$ and $5 \times 10^{-3}$ M.

Although the results of this assay were negative, indicating that NMPABAO is not genotoxic, the agency notes that there were several problems in the performance of this test. Because all the slides in this experiment were scored, the agency questions the suitability of the hepatocyte preparation. If cell attachment and survival are poor, a very potent inducer of UDS may score positive with only a few cells. However, a weak inducer of UDS may be missed. Because this report does not include data on cell survival (cell attachment or cytotoxicity), it is difficult to evaluate the cell status on UDS data alone.

A recently published consensus report on the Primary Rat Hepatocyte Assay for UDS (Ref. 7) states the need for three experiments per data point and an initial screening experiment for an assessment of cytotoxicity. Another report, by Swierenga, et al. (Ref. 8), also stresses the need for information on cytotoxicity.

In 1991, the agency tested both NMPABAO and padimate O for UDS in primary rat hepatocytes (Ref. 6). Two UDS experiments were performed. One experiment tested NMPABAO at dose levels ranging from 0.713 to 2.92 micrograms/milliliter (pg/mL), and the second tested padimate O at dose levels ranging from 0.010 to 10 microliters/milliliter (µL/mL). The controls were (1) a solvent control (1 percent DMSO), (2) a negative medium control, and (3) a positive control of 2-acetylaminofluorene (2-AAF) at 1.0 and 2.5 µg/mL.

Both NMPABAO and padimate O were soluble in DMSO. However, doses of 0.73, 1.46, and 2.92 mg/mL of NMPABAO and 1, 5, and 10 µL/mL of padimate O were insoluble when added to the aqueous cell culture medium. Heavy, oil-like droplets that dispersed evenly in the aqueous medium when vortexed were noted at the above doses of NMPABAO and padimate O.

Although faint turbidity was observed at lower dose levels, no heavy oil droplets were apparent as with the higher doses. The data show that neither NMPABAO nor padimate O induced UDS in rat hepatocyte cultures. Values for both net nuclear grain count and percent cells in repair were similar to the negative control and solvent control values. In contrast, the positive control, 2-AAF, induced a dose dependent increase in net nuclear grain counts.

Cytotoxicity was qualitatively evaluated as cell number and morphology. Intermediate doses of NMPABAO (11.4 to 365 µg/mL) and padimate O (0.1 to 0.5 µL/mL) showed evidence of cytotoxicity compared to control values. Cytotoxicity was not observed at the lower doses of NMPABAO (0.71 to 5.7 µg/mL) or padimate O (0.01 to 0.05 µL/mL) nor at the higher doses of NMPABAO (730 to 2920 µg/mL) or padimate O (1 to 10 µL/mL). However, the heavy oil appearance of some test agents in media at these higher dose levels suggests that the compounds may not have reached the cells attached to the bottom of the culture dish. The agency, however, concludes that, in these experiments, neither NMPABAO nor padimate O appears to induce UDS at cytotoxic or non-cytotoxic dose levels.

The agency believes that the results of this study confirm the lack of solubility of NMPABAO at concentrations of 0.73 to 2.92 mg/mL and the moderate solubility of NMPABAO at concentrations of 11.4 µg/mL and 365 µg/mL, thus explaining some of the questions raised by the results of the first DNA repair assay (Ref. 5) discussed above. Furthermore, cytotoxicity was evident in hepatocyte cultures between 11.4 and 365 µg/mL NMPABAO, which suggests that NMPABAO reached the cells at the bottom of the culture dish at these dose levels. NMPABAO and padimate O do not appear to damage DNA, as evaluated by the DNA repair assay, at non-toxic doses when the chemical is soluble in the medium, at cytotoxic doses when the chemical is both soluble and partially soluble in the medium, and at non-cytotoxic doses when the chemical is insoluble in the medium.

The structure-activity relationships in carcinogenesis by N-nitroso compounds is well known (Ref. 8). Some 250 N-nitroso compounds have been studied in rats, and many have been studied in mice and hamsters, to provide reliable carcinogenesis data. The similar carcinogenic actions of certain groups of N-nitroso compounds can be related to their generation of similar simple moieties having certain organs as their target.

Although NMPABAO has not been tested in an animal bioassay for carcinogenesis, certain predictions can be made based on its chemical structure. Most nitrosamines that are carboxylic acids or esters are not carcinogenic, probably due primarily to their being ionized (esters are likely to be hydrolyzed), which prevents their entry into cells; and also possibly because of electronic effects (Ref. 9). For example, N-nitrosopiperidine (which is structurally related to NMPABAO) produces tumors of the nasal mucosa, esophagus, and liver of the rat. An esterified derivative, α-phényl-2-piperidinacetic acid methyl ester, tested negative for carcinogenesis in the rat. Based on this correlation, esterification of a carcinogenic nitrosamine greatly reduces or eliminates the carcinogenic potential of the compound. Chemically, NMPABAO is an ester of a carboxylic acid and, based on its chemical structure, would not be predicted to be carcinogenic in an animal bioassay.
“foreign” reagents, the comment added that the method demonstrates excellent recovery of NMPABAO from spiked samples. The comment added that, in limited trials, recovery of NMPABAO from spiked samples has been demonstrated to be up to 90 percent depending upon the complexity of the sample being assayed. The comment maintained that, conversely, one sample assayed by the FDA method showed approximately 500 ppb of NMPABAO. However, the same sample showed less than 20 ppb (lowest detectable limit) of NMPABAO when assayed by the comment’s proposed HPLC/Thermal Energy Analyzer method. The comment maintained that this discrepancy is further evidence that the FDA method generates artifact nitrosamines.

The agency recently received new data (Ref. 13) purporting to verify the validity of the alternative assay method proposed by the comment (Ref. 12). A series of experiments were undertaken by two independent laboratories. These experiments included studies to establish the linearity of the HPLC-Thermal Energy Analyzer detector response, to measure the original background levels of NMPABAO in the lotion, to determine the recovery and reproducibility of NMPABAO from spiked lotion, and to ascertain if the method itself promotes artificial formation of NMPABAO. Both laboratories used the same SPF 15 sunscreen lotion containing 8 percent padimate O and the same batch of purified NMPABAO. The results obtained by both laboratories agree well and demonstrate that the proposed alternative method can be performed by analysts in different laboratories to yield reproducible and accurate determinations of NMPABAO in commercial sunscreen drug products. The data demonstrate that the method is applicable to all vehicle systems evaluated thus far, including lotions, creams, gels, and oils. The results show a minimum detectable limit of approximately 30 ppb by this procedure, NMPABAO recovery of greater than 80 percent, and high reproducibility. The results demonstrate that the procedure does not generate NMPABAO artificially during the sample preparation.

The proposed alternative assay method was used by one of the laboratories to evaluate 22 randomly selected commercial sunscreen drug products for NMPABAO levels. Four of these sunscreen drug products contained NMPABAO at levels higher than 100 ppb. The highest level of NMPABAO detected was 216 ppb. The submission concluded that these studies, as well as the biological studies submitted to the agency (Ref. 5), indicate that the presence of NMPABAO in sunscreen drug products containing padimate O is not a public health concern. The submission contended that, when analyzed using a scientifically validated method, commercial sunscreen drug products contained less than 20 ppb of NMPABAO. The submission concluded that the results of these tests support the long history of padimate O as a safe and effective sunscreen ingredient.

The agency recently reevaluated its method for the identification and determination of NMPABAO (Ref. 14). Its reevaluation included recovery studies for NMPABAO from representative sunscreen drug products, as well as studies of possible chromatographic interference with NMPABAO and of the nitrosation potential of the test reagents. The tests also investigated, by use of inhibitors and a secondary amine marker, the occurrence of artifact nitrosation. The basic method used for detecting nitrosation potential of the sample preparation system involved the addition of a readily-nitrosatable secondary amine (marker) to the product prior to analysis. Detection of the nitrosated marker would suggest that one or more components of the system had the potential for causing artifact nitrosation during sample preparation.

The agency found that the solvents and reagents used in its procedure for assaying NMPABAO contained no compounds that could interfere with the HPLC/Thermal Energy Analyzer determination of NMPABAO. The studies also demonstrated that the presence of nitromusk fragrances in sunscreen drug products would not interfere with the HPLC/Thermal Energy Analyzer determination of NMPABAO. The evaluation of Celite for nitrosation potential demonstrated that some batches of Celite contained a readily-nitrosatable agent. Therefore, to avoid artifact nitrosation resulting from Celite used in this method, each batch of Celite must be tested for nitrosating potential before use. Results of these studies also showed that ammonium sulfamate, mixed tocopherols, ascorbyl palmitate, squalene, Volpo 5, and ammonium sulfamate mixed with Volpo 5 are not effective as nitrosation inhibitors in sunscreen matrices.

The agency method was corroborated by recovery studies in which a known quantity of NMPABAO and a known quantity of padimate O were added to a nitrosating agent-free sunscreen drug product that did not contain padimate O. The results of the recovery studies indicate that this analytical method adequately recovers NMPABAO from sunscreen matrices.

In June 1990, the agency agreed to participate in a joint laboratory study to compare the recovery efficiency of its analytical method for NMPABAO and the proposed alternative method developed by a manufacturer of sunscreen drug products (Ref. 15). The agency recommended that the manufacturer prepare the samples for the study and submit them to FDA as “blind” samples. The manufacturer submitted to FDA four 50 gram (g) samples, in duplicate, fortified with NMPABAO at different levels. The manufacturer also provided duplicate 100 g blank lotions containing padimate O with no added NMPABAO for blank and artifact determinations, and a reference NMPABAO standard in isooctane. The manufacturer disclosed to FDA the NMPABAO fortification levels after the analyses were completed. The FDA method utilized a column chromatographic extraction of a sample-Celite mixture with organic solvents, concentration of the resulting eluate, and determination of NMPABAO by HPLC coupled to a Thermal Energy Analyzer (Ref. 16). The proposed alternative method involved partition of a sample with organic solvent, concentration of the extract, reconstitution in an organic solvent, centrifugation, and analysis by HPLC coupled to a Thermal Energy Analyzer (Ref. 13). Both methods utilized a nitrosation inhibitor to prevent artificial formation of NMPABAO during sample analysis. The agency analyzed the test samples using both its and the proposed alternative methods. The manufacturer analyzed the samples by the proposed alternative method. The agency made two modifications to the proposed alternative method before analyzing samples: (1) A valve between the HPLC and the Thermal Energy Analyzer, specified in the proposed alternative method to divert the HPLC mobile phase from the Thermal Energy Analyzer, was omitted because it was not available in the FDA laboratory, and (2) a single HPLC column was used instead of the prescribed two-column system, because satisfactory separation of the components of interest could be obtained with one column.

Using its methodology for NMPABAO detection, the agency performed duplicate analyses of each sample and obtained good agreement between analyses of the same samples. The recovery of added NMPABAO using the FDA method ranged from 39 to 83...
percent, with an overall average of 58 percent. The same samples were analyzed using the modified proposed alternative method. Recovery of added NMPABAO ranged from 56 to 93 percent, with an overall average of 77 percent. Using its own method, the manufacturer reported recoveries ranging from 79 to 100 percent, with an overall average of 86 percent. The agency concludes that NMPABAO was more efficiently recovered from the sunscreen matrix by the proposed alternative method than by the FDA method. Data obtained by the proposed alternative method in both laboratories were in good agreement throughout the entire NMPABAO fortification range.

The agency has determined that partial losses of NMPABAO by the FDA method occurred by premature elution of the N-MPA from the petroleum ether wash of the silica gel column. Similar losses previously observed using the FDA method were found to be caused by inactivation of the silica gel by samples containing significant water levels. The FDA method was modified to improve recovery efficiency of NMPABAO from samples containing substantial amounts of water. Reanalysis of the sunscreen samples by the modified FDA method resulted in recoveries of NMPABAO ranging from 78 to 88 percent, with an average of 83 percent.

The agency concludes that the proposed alternative method, as modified by FDA, and the FDA method, modified to accommodate matrices with high levels of water, result in comparable recoveries of NMPABAO from a sunscreen drug product. Although the proposed alternative method provides the most accurate recoveries of NMPABAO, either method can successfully detect NMPABAO in sunscreen drug products without artifact formation.

3. Photostability Data

One comment submitted data (Ref. 13) that included the results of photostability studies of NMPABAO. The results show that NMPABAO, even in films containing UV absorbers, is extremely unstable when exposed to UV light. When added to sunscreen lotions of both low (SPF 4) and high (SPF 25) photoprotection levels, NMPABAO decomposed rapidly. After exposure to radiation for 1 minute, approximately 50 percent of the NMPABAO in the SPF 25 product and 60 percent of the NMPABAO in the SPF 4 product were degraded. After exposure for 4 minutes, the extent of NMPABAO decomposition was 91 percent for the SPF 25 product and 97 percent for the SPF 4 product.

The agency also conducted a study designed to investigate the photodecomposition of NMPABAO in a model system and in a commercial sunscreen drug product with an SPF of 15 (Ref. 17). The model system consisted of dimethyl silicone as the carrier base, approximately 3,000 ppb NMPABAO, and either 0 or 4 percent padimate O. The commercial sunscreen drug product contained padimate O and approximately 14,000 ppb NMPABAO. Samples of the model system and the sunscreen product were exposed to UV radiation from a high intensity solar simulator for periods of up to 60 minutes, with 1 minute of exposure being approximately equivalent to 0.2 MED. The samples were spread on glass plates as films of approximately 20 micrometer (µm) for the model system and approximately 50 µm for the commercial product. NMPABAO concentrations were determined by HPLC separation and Thermal Energy Analyzer detection before and after UV radiation exposure. NMPABAO in the model system was totally decomposed following exposure of 1 minute (i.e., radiation equivalent to approximately 0.2 MED) even in the presence of 4 percent padimate O. The decomposition of the NMPABAO in the commercial sample was found to follow first order reaction kinetics; the half-life was 2.6 minutes, i.e., approximately 0.5 MED. The results of this study indicate that NMPABAO decomposes upon exposure to UV radiation and corroborate the photodegradation results submitted to the agency (Ref. 13).

4. Conclusions

Two analytical methods with which NMPABAO contamination of OTC sunscreen drug products can be accurately determined are available: (1) The agency’s method (Refs. 1 and 14), and (2) the method submitted by one of the comments (Ref. 12). Either method can successfully detect NMPABAO in OTC sunscreen drug products.

Regarding the safety concerns associated with the presence of NMPABAO in padimate O-containing sunscreen drug products, the agency notes that the toxicological data available to the agency at this time indicate that NMPABAO does not have mutagenic or carcinogenic potential. Although the agency does not contemplate additional toxicological testing at this time, it cannot be stated with certainty that NMPABAO is not carcinogenic. This can only be resolved by a carcinogenic bioassay. The agency is not planning any such studies nor is it aware of any such studies currently in progress. However, the agency believes that the risk associated with NMPABAO contamination of sunscreen drug products is very low. For example, in addition to low mutagenicity and carcinogenicity potential, photostability studies done with NMPABAO demonstrate that the nitrosamine decomposes rapidly when exposed to UV radiation (Refs. 13 and 17). The agency believes that padimate O, if formulated in a sunscreen drug product properly, is a safe and effective sunscreen ingredient. The presence of NMPABAO in padimate O-containing sunscreen drug products is the result of poor manufacturing practices, and demonstrates that the product has not been formulated properly. For example, the agency recently analyzed 25 commercially available sunscreens for NMPABAO (Ref. 18). NMPABAO was found in 11 samples of levels up to 21,020 ppb. Four of these samples also contained 2-bromo-2-nitro-1,3-propanediol, an indirect nitrosating agent. If these products were formulated without the nitrosating agent, there would be no nitrosamine contamination.

According to § 330.1(a), OTC sunscreen drug products must be manufactured in compliance with current good manufacturing practices, as established in 21 CFR Parts 210 and 211. The agency believes that the presence of NMPABAO in sunscreen drug products indicates that the product has not been manufactured under current good manufacturing practices, and therefore, the product is adulterated under section 501(a) of the act (21 U.S.C. 351(a)). The agency is considering establishing limits for the amount of NMPABAO that may be present in a sunscreen drug product. If these limits were surpassed, the product would be considered to be adulterated. Although not proposed in this tentative final monograph, the agency is including for comment a proposal that OTC sunscreen drug products must contain less than 500 ppb of NMPABAO.

As stated above, the agency believes that padimate O is a safe and effective OTC sunscreen ingredient. Therefore, in this tentative final monograph, padimate O remains in Category I.

References


monograph, the agency is proposing to amend the cosmetic regulations in 21 CFR part 700 by adding § 740.19 as follows: "Suntanning preparations. The labeling of suntanning preparations that do not contain a sunscreen ingredient must display the following warning: ‘Warning—This product does not contain a sunscreen and does not protect against sunburn.’" This warning also applies to sunless tanning lotions.

References
(2) "Artificial Suntan Preparations" in "Harry's Cosmeticsology" in OTC Vol. 06ATFM, Docket No. 78N-0038, Dockets Management Branch.

The agency has examined the economic consequences of this proposed rulemaking in conjunction with other rules resulting from the OTC drug review. In a notice published in the Federal Register of February 8, 1983 (48 FR 5806), the agency announced the availability of an assessment of these economic impacts. The assessment determined that the combined impacts of all the rules resulting from the OTC drug review do not constitute a major rule according to the criteria established by Executive Order 12291. The economic assessment also concluded that the overall OTC drug review was not likely to have a significant economic impact on a substantial number of small entities as defined in the Regulatory Flexibility Act (Pub. L. 96–354). Therefore, this sunscreen proposed rule, which applies only to a single drug category, does not require a regulatory impact analysis or a regulatory flexibility analysis.

The agency recognizes, however, that some products currently marketed by manufacturers as cosmetics would be affected by this rulemaking, e.g., suntanning products, and daily use make-up preparations and skin lotions that contain sunscreens or make drug claims. The presence of a sunscreen ingredient in such products and labeling that includes a drug claim would cause these products to be drugs under the act. While all affected firms are currently subject to general regulatory requirements under the act, some companies would be subject, for the first time, to current good manufacturing practices (CGMP) for drugs, as established in 21 CFR Parts 210 and 211. The agency has limited data but believes that most major manufacturers of sunscreen-containing products already follow these procedures and are familiar with agency regulations for manufacturing drug products. In addition, some states, including California and New York, regulate cosmetic products as drugs and conduct on-site inspections of manufacturing facilities.

Nonetheless, some clear differences exist between cosmetic and drug regulations. For example, current agency regulations allow for the voluntary registration of cosmetic manufacturers, while registration is compulsory for drug manufacturers. The agency attempts to inspect each drug manufacturer every two years, whereas cosmetic inspections are done less frequently. Therefore, many current cosmetic plants can expect more frequent inspection as drug manufacturers.

The agency has attempted to define the possible economic consequences of this proposal but has been hindered by the paucity of data concerning the manufacture of these products. The industry segment that currently manufacturers sunscreen-containing lipsticks, skin lotions, and make-up preparations that would be covered by this regulation would need either to: (1) reformulate or relabel the products to eliminate sunscreen ingredients and omit drug claims, or (2) comply with drug regulations if they do not already do so. The agency will continue to gather economic information and solicit industry comment on the extent of any additional costs of compliance, or other regulatory burdens, that would be associated with this proposed rule.

In addition, the agency specifically invites public comment regarding any substantial or significant economic impact that this rulemaking would have on OTC sunscreen drug products or on manufacturers who elect to reformulate or relabel their product(s) so that the products' status would continue to be cosmetics. Types of impact may include, but are not limited to, costs associated with product testing, relabeling, repackaging, reformulating, or costs related to conversion to drug manufacturing capabilities to meet CGMPs. Comments regarding the impact of this rulemaking should be accompanied by appropriate documentation. Because the agency has not previously invited specific comment on the economic impact of the OTC drug review on sunscreen drug products, a period of 180 days from the date of publication of this proposed rulemaking in the Federal Register will be provided for comments on this subject to be developed and submitted. The agency will evaluate any comments and supporting data that are received and will reassess the economic impact of this rulemaking in the preamble to the final rule.

The agency has determined under 21 CFR 25.24(c)(6) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Interested persons may, on or before November 8, 1993, submit to the Dockets Management Branch written comments, objections, or requests for oral hearing before the Commissioner on the proposed regulation. A request for an oral hearing must specify points to be covered and time requested. Written comments on the agency's economic impact determination may be submitted on or before November 8, 1993. Three copies of all comments, objections, and requests are to be submitted, except that individuals may submit one copy. Comments, objections, and requests are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by a supporting memorandum or brief. Comments, objections, and requests may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. Any scheduled oral hearing will be announced in the Federal Register.

Interested persons, on or before May 12, 1994, may also submit in writing new data demonstrating the safety and effectiveness of those conditions not classified in Category I. Written comments on the new data may be submitted on or before July 12, 1994. These dates are consistent with the time periods specified in the agency's final rule revising the procedural regulations for reviewing and classifying OTC drugs, published in the Federal Register of September 29, 1981 (46 FR 47730). Three copies of all data and comments on the data are to be submitted, except that individuals may submit one copy, and all data and comments are to be identified with the docket number found in the heading of this document. Data and comments should be addressed to the Dockets.
Management Branch. Received data and comments may also be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

In establishing a final monograph, the agency will ordinarily consider only data submitted prior to the closing of the administrative record on July 12, 1994. Data submitted after the closing of the administrative record will be reviewed by the agency after only a final monograph is published in the Federal Register, unless the Commissioner finds good cause has been shown that warrants earlier consideration.

List of Subjects in 21 CFR

**Part 352**

Labeling, Over-the-counter drugs, Sunscreen drug products.

**Part 700**

Cosmetics, Packaging and containers.

**Part 740**

Cosmetic product warning statements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, it is proposed that 21 CFR Chapter I be amended as follows:

1. Part 352 is added to read as follows:

**PART 352—SUNSCREEN DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE**

**Subpart A—General Provisions**

Sec. 352.1 Scope.

(a) An over-the-counter sunscreen drug product in a form suitable for topical administration is generally recognized as safe and effective and is not misbranded if it meets each condition in this part and each general condition established in §330.1 of this chapter.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to Chapter I of Title 21 unless otherwise noted.

**§352.3 Definitions.**

As used in this part:

(a) Minimal erythema dose (MED). The smallest dose of ultraviolet (UV) radiation (expressed as Joules per meter squared) that produces redness reaching the borders of the exposure site.

(b) Product category designation (PCD). A labeling designation for sunscreen drug products to aid in selecting the type of product best suited to an individual's complexion (pigmentation) and desired response to UV radiation.

(1) Minimal sun protection product. A sunscreen product that provides a sun protection factor (SPF) value of 2 to under 4, and offers the least protection, but permits suntanning.

(2) Moderate sun protection product. A sunscreen product that provides an SPF value of 4 to under 8, and offers moderate protection from sunburning, but permits some suntanning.

(3) High sun protection product. A sunscreen product that provides an SPF value of 8 to under 12, offers high protection from sunburning, and permits limited suntanning.

(4) Very high sun protection product. A sunscreen product that provides an SPF value of 12 to under 20, offers very high protection from sunburning, and permits little or no suntanning.

(5) Ultra high sun protection product. A sunscreen product that provides an SPF value of 20 to 30, offers the most protection from sunburning, and permits no suntanning.

(c) Sunscreen active ingredient. An active ingredient that absorbs at least 85 percent of the radiation in the UV range at wavelengths from 290 to 320 nanometers, but may or may not transmit radiation at wavelengths longer than 320 nanometers.

(d) Sunscreen opaque sunblock. An opaque sunscreen active ingredient that reflects or scatters all light in the UV and visible range at wavelengths from 290 to 777 nanometers and thereby prevents or minimizes suntan and sunburn.

(e) Sun protection factor (SPF) value. The UV energy required to produce an MED on protected skin divided by the UV energy required to produce an MED on unprotected skin, which may also be defined by the following ratio: SPF value = MED (protected skin (PS))/MED (unprotected skin (US)), where MED (PS) is the minimal erythema dose for protected skin after application of 2 milligrams per square centimeter of the final formulation of the sunscreen product, and MED (US) is the minimal erythema dose for unprotected skin, i.e., skin to which no sunscreen product has been applied. In effect, the SPF value is the reciprocal of the effective transmission of the product viewed as a UV radiation filter.

**Subpart B—Active Ingredients**

**§352.10 Sunscreen active ingredients.**

The active ingredient of the product consists of any of the following when used in the concentration established for each ingredient, and the finished product provides a minimum sun protection factor value of not less than 2 as measured by the testing procedures established in subpart D of this part:

(a) Aminobenzoic acid up to 15 percent.

(b) Cinoxate up to 3 percent.

(c) Diethanolamine methoxycinnamate up to 10 percent.

(d) Digalloyl triclate up to 5 percent.

(e) Dioxybenzone up to 3 percent.

(f) Ethyl 4-[bis(hydroxypropyl)] aminobenzoate up to 5 percent.

(g) Glyceryl aminobenzoate up to 3 percent.

(h) Homosalate up to 15 percent.

(i) Lawsone up to 0.25 percent with dihydroxyacetone up to 3 percent.

(j) Methyl anthranilate up to 5 percent.

(k) Octocrylene up to 10 percent.

(l) Octyl methoxycinnamate up to 7.5 percent.

(m) Octyl salicylate up to 5 percent.

(n) Oxybenzone up to 6 percent.

(o) Padimate O up to 8 percent.

(p) Phenylbenzimidazole sulfonic acid up to 4 percent.

(q) Red petrolatum up to 100 percent.

(r) Sulfisobenzone up to 10 percent.

(s) Titanium dioxide up to 25 percent.

(t) Trolamine salicylate up to 12 percent.

**§352.20 Permitted combinations of active ingredients.**

(a) Combinations of sunscreen active ingredients.

(1) Two or more sunscreen active ingredients identified in §352.10 may be combined when used in the concentrations established for each
ingredient in paragraph (e)(2) of this section and the finished product has a minimum sun protection factor value of not less than 2 as measured by the testing procedures established in subpart D of this part.

(2) Sunscreen active ingredients shall be used within the following concentrations when used in combination with another sunscreen or when the combination is used with any other permitted active ingredient:

(i) Aminobenzoic acid 3 to 15 percent.

(ii) Cinoxate 1 to 3 percent.

(iii) Diethanolamine methoxyacinnamate 8 to 10 percent.

(iv) Dihydroxyacetone 5 to 15 percent.

(v) Dioxybenzone 3 percent.

(vi) Ethyl 4-[bis(hydroxypropyl)j aminobenzoate 1 to 5 percent.

(vii) Glycerol aminobenzoate 2 to 3 percent.

(viii) Homosalate 4 to 15 percent.

(ix) Lawsone 0.25 percent with dihydroxyacetone 3 percent.

(x) Methyl anthranilate 3.5 to 5 percent.

(xi) Octocrylene 7 to 10 percent.

(xii) Octyl methoxycinnamate 2.0 to 7.5 percent.

(xiii) Octyl salicylate 3 to 5 percent.

(xiv) Oxybenzone 2 to 6 percent.

(xv) Padimate O 1.4 to 8 percent.

(xvi) Phenylbenzimidazole sulfonic acid 1 to 4 percent.

(xvii) Red petrolatum 30 to 100 percent.

(xviii) Sulisobenzone 5 to 10 percent.

(xix) Titanium dioxide 2 to 25 percent.

(xx) Trolamine salicylate 5 to 12 percent.

(b) Sunscreen and skin protectant combinations.

(1) Any single sunscreen active ingredient when used in the concentration established in § 352.10 may be combined with one or more skin protectant active ingredients identified in § 347.10(a), (d), (e), (f), (h), (l), and (j) of this chapter, provided the finished product has a minimum SPF value of not less than 2 as measured by the testing procedures established in subpart D of this part and provided the product is labeled according to § 352.60.

(2) Two or more sunscreen active ingredients when used in the concentrations established in § 352.20(a)(2) may be combined with one or more skin protectant active ingredients identified in § 347.10(a), (d), (e), (f), (h), (l), and (j) of this chapter, provided the finished product has a minimum SPF value of not less than 2 as measured by the testing procedures established in subpart D of this part and provided the product is labeled according to § 352.60.

(c) For sunscreen and skin bleaching combinations. See § 358.50 of this chapter.

Subpart C—Labelling

§ 352.50 Principal display panel of all sunscreen drug products.

In addition to the statement of identity required in § 352.52, the following labeling statements shall be prominently placed on the principal display panel:

(a) For products that do not satisfy the water resistant or very water resistant sunscreen product testing procedures in § 352.76. "SPF (insert tested SPF value of the product up to 30)."

(b) For products that satisfy the water resistant sunscreen product testing procedures in § 352.76.

(1) "Water Resistant."

(2) "SPF= (insert SPF value before water resistant testing) before" (select one of the following: "sweating" or "perspiring") "or going into the water. SPF=(insert SPF value resulting from water resistant testing) after 40 minutes of" (select one of the following: "sweating" or "perspiring") "or activity in the water."

(c) For products that satisfy the very water resistant sunscreen product testing procedures in § 352.76.

(1) "Very Water Resistant."

(2) "SPF=(insert SPF value before very water resistant testing) before" (select one of the following: "sweating" or "perspiring") "or going into the water. SPF=(insert SPF value resulting from very water resistant testing) after 80 minutes of" (select one of the following: "sweating" or "perspiring") "or activity in the water."

§ 352.52 Labelling of sunscreen drug products.

(a) Statement of identity. The labeling of the product contains the established name of the drug, if any, and identifies the product as a "sunscreen."

(b) Indications. The labeling of the product states, under the heading "Indications" any of the phrases listed in paragraph (b) of this section, as appropriate. Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in this paragraph, may also be used, as provided in § 330.11c(2) of this chapter, subject to the provisions of section 502 of the Federal Food, Drug, and Cosmetic Act (the act) relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(1) For products containing any ingredient identified in § 352.10—(i) "Sunscreen to help prevent sunburn."

(ii) (Select one of the following: "Filters" or "Screen") "out the sun’s" (select one of the following: "burning" or "harsh and often harmful") "rays to prevent sunburn."

(iii) "Allows you to stay in the sun up to (insert SPF of product up to 30) times longer than without sunscreen protection."

(iv) "Provides up to (insert SPF of product up to 30) times your natural protection from sunburn."

(2) Additional indications. In addition to the indications provided above in § 352.52(b)(1), the following may be used:

(i) For products containing any ingredient in § 352.10 that provide an SPF of 2 to under 4, any of the following labeling statements may be used—(A) (Select one of the following: "Provides minimal," "Provides minimum," "Minimal," or "Minimum") "protection against sunburn."

(B) "Prolongs exposure time before sunburn occurs."

(C) "Permits" (select one of the following: "tanning" or "suntanning") "and" (select one of the following: "reduces chance of" or "minimizes") "sunburning."

(D) "Helps prevent sunburn on limited exposure of untanned skin."

(E) "Helps to protect the skin against sunburn while permitting tanning."

(ii) For products containing any ingredient in § 352.10 that provide an SPF of 4 to under 8, any of the following labeling statements may be used—(A) (Select one of the following: "Provides moderate" or "Moderate") "protection against sunburn."

(B) "Prolongs exposure time before sunburn occurs."

(C) "Permits" (select one of the following: "tanning" or "suntanning") "and" (select one of the following: "reduces chance of" or "minimizes") "sunburning.

(D) "Helps prevent sunburn on limited exposure of untanned skin."

(E) "Helps to protect the skin against sunburn while permitting tanning."

(F) "Helps prevent sunburn on limited exposure of untanned skin."

(G) "Helps to protect the skin against sunburn while permitting tanning."
(D) “Helps prevent sunburn on moderate exposure of untanned skin.”

(iii) For products containing any ingredient in § 352.10 that provide an SPF of 8 to under 12, any of the following labeling statements may be used—(A) (Select one of the following: “Provides high” or “High”) “protection against sunburn.”

(B) “Prolongs exposure time before sunburn occurs.”

(C) “Permits” (select one of the following: “tanning” or “suntanning”)

and “(select one of the following: “reduces chance of” or “minimizes”)

“sunburning.”

(D) “Helps prevent sunburn.”

(E) “For sun-sensitive skin.”

(F) “High protection against sunburn for blondes, redheads, and fairskinned persons.”

(iv) For products containing any ingredient in § 352.10 that provide an SPF of 12 to under 20, any of the following labeling statements may be used—(A) (Select one of the following: “Provides very high” or “Very high”) “protection against sunburn.”

(B) “Prevents sunburn and limits tanning.”

(C) “For sun-sensitive skin.”

(D) “Very high protection against sunburn for blondes, redheads, and fairskinned persons.”

(E) “Provides the highest degree of” (select one of the following: “sunburn” or “sunscreen”) “protection and permits no tanning.”

(3) For products containing the active ingredient identified in § 352.10(s) that provide an SPF of 12 to 30, any of the following labeling statements may be used—(A) (Select one of the following: “Provides the most” or “The most”) “protection against sunburn.”

(B) “Pretends tanning and sunburn.”

(C) “For highly sun-sensitive skin.”

(D) “The most protection against sunburn for blondes, redheads, and fairskinned persons.”

(E) “Provides the highest degree of” (select one of the following: “sunburn” or “sunscreen”) “protection and permits no tanning.”

(3) For products containing the active ingredient identified in § 352.10(s) that provide an SPF of 8 to 12, the following labeling statement may be used.

“Reflects the burning rays of the sun.”

(c) Warnings. The labeling of the product contains the following warnings under the heading “Warnings:”

(1) For products containing any ingredient in § 352.10—(i) “For external use only, not to be swallowed.”

(ii) “Avoid contact with the eyes. If contact occurs, rinse eyes thoroughly with water.”

(iii) “Discontinue use if signs of irritation or rash appear. If irritation or rash persists, consult a doctor.”

(2) For products containing the ingredient identified in § 352.10(i)—(i)“This product consists of two solutions. Do not mix the contents of the two solutions. Use both solutions; one alone will not provide protection.”

(ii) “Use only on skin free of rash and abrasions.”

(iii) “May stain clothing when freshly applied.”

(3) For products containing any ingredient identified in § 352.10 formulated as a lip balm or lipstick. The warning in paragraph (c)(1)(ii) of this section is not required.

(4) For products containing any ingredient identified in § 352.10 formulated as a lipstick. The warning in paragraph (c)(1)(ii) of this section is not required.

(d) Directions. The labeling of the product contains the following information under the heading “Directions.” More detailed directions applicable to a particular product formulation (e.g., cream, gel, lotion, oil, spray, etc.) may also be included.

(1) For products containing any ingredient in § 352.10 that do not satisfy the water resistant or very water resistant testing procedures in § 352.76. “Adults and children 6 months of age and over: Apply” (select one or more of the following, as applicable: “liberally,” “generously,” “smoothly,” or “evenly”) “before sun exposure. Reapply after swimming, excessive” (select one of the following: “sweating” or “perspiring”) “or anytime after towel drying. Children under 2 years of age should use sunscreen products with a minimum SPF of 4. Children under 6 months of age consult a doctor.”

(2) For products containing any ingredient in § 352.10 that satisfy the water resistant or very water resistant testing procedures in § 352.76. “Adults and children 6 months of age and over: Apply” (select one or more of the following, as applicable: “liberally,” “generously,” “smoothly,” or “evenly”) “after a period followed by a waiting period as needed) before sun or water exposure. Reapply after” (select one of the following: “40 minutes” if water resistant) or “60 minutes” if (if water resistant) “of swimming or excessive” (select one of the following: “sweating” or “perspiring”) “or anytime after towel drying. Children under 2 years of age should use sunscreen products with a minimum SPF of 4. Children under 6 months of age consult a doctor.”

(3) For products containing the ingredient identified in § 352.10. “Products are composed of two separate formulations. Solution 1 contains 3 percent dihydroxyacetone and Solution 2 contains 0.5 percent lawsone.”

“Adults and children 6 months of age and over: Apply liberally before sun exposure as follows: First application. The evening prior to sun exposure: Apply Solution 1. Wait 15 minutes then apply Solution 2 to the same areas of skin. Wait until dried. Then repeat application of solutions alternately as before until a total of three applications of both solutions have been applied. Leave on skin without washing. Repeated application. After first day, apply one application of each solution. Reapply after swimming, excessive” (select one of the following: “sweating” or “perspiring”) “or anytime after towel drying. Children under 2 years of age should use sunscreen products with a minimum SPF of 4. Children under 6 months of age consult a doctor.”

(4) For products containing any ingredient identified in § 352.10 labeled with only the indications in § 352.52(b)(1)(iv) and/or (b)(1)(vi) and formulated as a make-up preparation or lipstick. “Apply liberally as often as necessary.”

(5) For products containing any ingredient identified in § 352.10 labeled with only the indications in § 352.52(b)(1)(iv) and/or (b)(1)(vi) and formulated as a lip balm or skin preparation. “Adults and children 6 months of age and over: Apply liberally as often as necessary. Children under 2 years of age should use sunscreen products with a minimum SPF of 4. Children under 6 months of age consult a doctor.”

(e) Statement on product performance—(1) For products containing any ingredient identified in § 352.10, the following PCD labeling claims may be used—(i) For products containing active ingredient(s) that provide an SPF value of 2 to under 4. “Minimal Sun Protection Product.”

(ii) For products containing active ingredient(s) that provide an SPF value of 4 to under 8. “Moderate Sun Protection Product.”

(iii) For products containing active ingredient(s) that provide an SPF value of 8 to under 12. “High Sun Protection Product.”

(iv) For products containing active ingredient(s) that provide an SPF value of 20 to 30. “Ultra High Sun Protection Product.”

(v) For products containing active ingredient(s) that provide an SPF value of 10 to under 20. “Very High Sun Protection Product.”

(2) For products containing any ingredient in § 352.10 that provide an SPF of 8 to 12, the following labeling statements may be used—(i) “Retains its sun protection for at least 40 minutes in the water.”
(ii) “Resists removal by” (select one of the following: “perspiring” or “sweating.”)

(iii) (Select one of the following: “Sweat” or “Perspiration”) “resistant.”

(3) For products containing any ingredient in § 352.10 that satisfy the very water resistant testing procedures identified in § 352.76, any of the following labeling statements may be used—(i) “Retain its sun protection for at least 80 minutes in the water.”

(ii) “Resists removal by” (select one of the following: “perspiring” or “sweating.”)

(iii) (Select one of the following: “Sweat” or “Perspiration”) “resistant.”

(4) For products containing any ingredient identified in § 352.10, the following compilation of skin types and SPF’s shall be appropriately included in labeling as a guide.

### RECOMMENDED SUNSCREEN PRODUCT GUIDE

<table>
<thead>
<tr>
<th>Sunburn and tanning history</th>
<th>Recommended sun protection product</th>
</tr>
</thead>
<tbody>
<tr>
<td>Always burns easily; rarely tans,</td>
<td>SPF 20 to 30.</td>
</tr>
<tr>
<td>Always burns easily; tends minimally.</td>
<td>SPF 12 to under 20.</td>
</tr>
<tr>
<td>Burns moderately; tends gradually.</td>
<td>SPF 8 to under 12.</td>
</tr>
<tr>
<td>Burns minimally; always tans well.</td>
<td>SPF 4 to under 8.</td>
</tr>
<tr>
<td>Rarely burns; tends profusely.</td>
<td>SPF 2 to under 4.</td>
</tr>
</tbody>
</table>

(5) For products containing the active ingredient identified in § 352.10(s) that provide an SPF of 12 to 30, the following labeling statement may be used.

“Sunblock.”

(6) For products containing any ingredient identified in § 352.10, the following labeling statement shall be used. “SUN ALERT: The sun causes skin damage. Regular use of sunscreens over the years may reduce the chance of skin damage, some types of skin cancer, and other harmful effects due to the sun.”

(7) For products containing any ingredient identified in § 352.10. Any variation of the statement in § 352.32(a)(6) that does not relate skin aging or skin cancer as being “due to the sun” will cause the product to be misbranded under section 502 of the Federal Food, Drug, and Cosmetic Act.

(f) The word physician may be substituted for the word doctor in any of the labeling statements in this part.

§ 352.60 Labeling of permitted combinations of active ingredients.

Statement of identity, indications, warnings, and directions for use, respectively, applicable to each ingredient in the product may be combined to eliminate duplicative words or phrases so that the resulting information is clear and understandable.

(a) Statement of identity. For a combination drug product that has an established name, the labeling of the product states the established name of the combination drug product, followed by the statement of identity for each ingredient in the combination, as established in the statement of identity sections of the applicable OTC drug monographs. For a combination drug product that does not have an established name, the labeling of the product states the statement of identity for each ingredient in the combination, as established in the statement of identity sections of the applicable OTC drug monographs, unless otherwise stated below.

(b) Indications. The labeling of the product states under the heading “Indications,” the indication(s) for each ingredient in the combination as established in the indications sections of the applicable OTC drug monographs, unless otherwise stated in this paragraph. Other truthful and nonmisleading statements, describing only the indications for use that have been established in the applicable OTC drug monographs or listed in this paragraph, may also be used, as provided by § 330.1(c)(2) of this chapter, subject to the provisions of section 502 of the Federal Food, Drug, and Cosmetic Act (the Act) relating to misbranding and the prohibition in section 301(d) of the Act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the Act. In addition to the required information identified in this paragraph, the labeling of the product may contain any of the “other allowable statements” that are identified in the applicable monographs, provided such statements are neither placed in direct conjunction with information required to appear in the labeling nor occupy labeling space with greater prominence or conspicuousness than the required information.

(1) For permitted combinations containing a sunscreen and a skin protectant identified in § 352.20(b). The warning for skin protectants in § 347.50(c)(3) of this chapter is not required.

(2) [Reserved]

(d) Directions. The labeling of the product states, under the heading “Directions,” directions that conform to the directions established for each ingredient in the directions sections of the applicable OTC drug monographs, unless otherwise stated in this paragraph. When the time intervals or age limitations for administration of the individual ingredients differ, the directions for the combination product may not contain any dosage that exceeds those established for any individual ingredient in the applicable OTC drug monograph(s), and may not provide for use by any age group lower than the highest minimum age limit established for any individual ingredient.

(1) For permitted combinations containing a sunscreen and a skin protectant identified in § 352.20(b). The directions for sunscreens in § 352.52(d) should be used.

(2) [Reserved]

Subpart D—Testing Procedures

§ 352.70 Standard sunscreen.

(a) Laboratory validation. A standard sunscreen shall be used concomitantly in the testing procedures for determining the sun protection factor value of a sunscreen drug product to ensure the uniform evaluation of sunscreen drug products. The standard sunscreen shall be an 8-percent homosalate preparation with a mean SPF value of 4.47 (standard deviation = 1.275). In order for the SPF determination of a test product to be considered valid, the SPF of the standard sunscreen must fall within the standard deviation range of the expected SPF (i.e., 4.47 ± 1.275) and the 95-percent confidence interval for the mean SPF must contain the value 4.

(b) Preparation of the standard homosalate sunscreen. The standard homosalate sunscreen is prepared from two different preparations (preparation A and preparation B) with the following compositions:
Preparation A and preparation B are heated separately to 77 to 82 °C, with constant stirring, until the contents of each part are solubilized. Add preparation A slowly to preparation B while stirring. Continue stirring until the emulsion formed is cooled to room temperature (15 to 30 °C). Add sufficient purified water to obtain 100 grams of standard sunscreen preparation.

(c) Assay of the standard homosalate sunscreen. Assay the standard homosalate sunscreen preparation by the following method to ensure proper concentration:

(1) Preparation of the assay solvent. The solvent consists of 1 percent glacial acetic acid (V/V) in denatured ethanol. The denatured ethanol should not contain a UV absorbing denaturant.

(2) Preparation of a 1-percent solution of the standard homosalate sunscreen preparation. Accurately weigh 1 gram of the standard homosalate sunscreen preparation into a 100-milliliter volumetric flask, and add 50 milliliters of the assay solvent. Heat on a steam bath and mix well. Cool the solution to room temperature (15 to 30 °C). Then dilute the solution to volume with the assay solvent and mix well to make a 1-percent solution.

(3) Preparation of the test solution (1:50 dilution of the 1-percent solution). Filter a portion of the 1-percent solution through number 1 filter paper. Discard the first 10 to 15 milliliters of the filtrate. Collect the next 20 milliliters of the filtrate (second collection). Add 1 milliliter of the second collection of the filtrate to a 50-milliliter volumetric flask. Dilute this solution to volume with assay solvent and mix well. This is the test solution (1:50 dilution of the 1-percent solution).

(4) Spectrophotometric determination. The absorbance of the test solution is measured in a suitable double beam spectrophotometer with the assay solvent and reference beam at a wavelength near 306 nanometers.

§ 352.71 Light source (solar simulator). A solar simulator used for determining the SPF of a sunscreen drug product should be filtered so that it provides a continuous emission spectrum from 290 to 400 nanometers similar to sunlight at sea level from the sun at a zenith angle of 10°; it has less than 1 percent of its total energy output contributed by nonsolar wavelengths shorter than 290 nanometers; and it has not more than 5 percent of its total energy output contributed by wavelengths longer than 400 nanometers. In addition, a solar simulator should have no significant time-related fluctuations in radiation emissions after an appropriate warm-up time, and it should have good beam uniformity (within 10 percent) in the exposure plane. To ensure that the solar simulator delivers the appropriate spectrum of UV radiation, it must be measured periodically with an accurately-calibrated spectroradiometer system or equivalent instrument.

§ 352.72 General testing procedures. (a) Selection of test subjects (male and female). Only fair-skinned volunteers with skin types I, II, or III using the following guidelines shall be selected:

Selection of Fair-skin Subjects

Skin Type and Sunburn and Tanning History (Based on first 30 to 45 minutes sun exposure after a winter season of no sun exposure.)

I—Always burns easily; never tans (sensitive).
II—Always burns easily; tans minimally (sensitive).
III—Burns moderately; tans gradually (light brown) (normal).
IV—Burns minimally; always tans well (moderate brown) (normal).
V—Rarely burns; tans profusely (dark brown) (insensitive).
VI—Never burns; deeply pigmented (insensitive).

A medical history shall be obtained from all volunteers with emphasis on the effects of sunlight on their skin. To be ascertained are the general health of the individual, the individual's skin type (I, II, or III), whether the individual is taking medication (topical or systemic) that is known to produce abnormal sunlight responses, and whether the individual is subject to any abnormal responses to sunlight, such as a phototoxic or photoallergic response.

(b) Test site inspection. The physical examination shall determine the presence of sunburn, suntan, scars, active dermal lesions, and uneven skin tones on the areas of the back to be tested. The presence of nevi, blemishes, or moles will be acceptable if in the physician's judgment they will not interfere with the study results. Excess hair on the back is acceptable if the hair is clipped or shaved.

(c) Informed consent. Legally effective written informed consent must be obtained from all individuals.

(d) Test site delineation. (1) Test site area. A test site area serves as an area for determining the subject's MED after application of either the sunscreen standard or the test sunscreen product, or for determining the subject's MED when the skin is unprotected (control site). The area to be tested shall be the back between the beltline and the shoulder blade (scapulae) and lateral to the midline. Each test site area for applying a product or the standard sunscreen shall be a minimum of 50 square centimeter, e.g., 5 x 10 centimeter. The test site areas are outlined with ink. If the person is to be tested in an upright position, the lines shall be drawn on the skin with the subject upright. If the subject is to be tested while prone, the markings shall be made with the subject prone.

(2) Test subsite area. Each test site area shall be divided into at least three test subsite areas that are at least 1 square centimeter. Usually four or five subsites are employed. Each test subsite within a test site area is subjected to a specified dosage of UV radiation, in a series of UV radiation exposures, in which the test site area is exposed for the determination of the MED.

(e) Application of test materials. To ensure standardized reporting and to define a product's SPF value, the application of the product shall be expressed on a weight basis per unit area which establishes a standard film. Both the test sunscreen product and the standard sunscreen application shall be 2 milligrams per square centimeter. For oils and most lotions, the viscosity is such that the material can be applied with a volumetric syringe. For creams,
heavy gels, and butters, the product shall be warmed slightly so that it can be applied volumetrically. On heating, care shall be taken so as not to alter the product's physical characteristics, especially separation of the formulations. Pastes and ointments shall be weighed, then applied by spreading on the test site area. A product shall be spread by using a finger cot. If two or more sunscreen drug products are being evaluated at the same time, the test products and the standard sunscreen, as specified in §352.70, should be applied in a blinded, randomized manner. If only one sunscreen drug product is being tested, the testing subsites should be exposed to the varying doses of UV radiation in a randomized manner.

(f) Waiting period. Before exposing the test site areas after applying a product, a waiting period of at least 15 minutes is required.

(g) Number of subjects. A test panel shall consist of not more than 25 subjects with the number fixed in advance by the investigator. From this panel, at least 20 subjects must produce valid data for analysis.

(h) Response criteria. In order that the person who evaluates the MED response does not know which sunscreen formulation was applied to which site or what doses of UV radiation were administered, he/she must not be the same person who applied the sunscreen drug product to the test site or administered the doses of UV radiation. After UV radiation exposure to the solar simulator is completed, all immediate responses shall be recorded. These include several types of typical responses such as the following: an immediate darkening or tanning, typically greyish or purplish in color, fading in 30 to 60 minutes, and attributed to photo-oxidation of existing melanin granules; immediate reddening, fading rapidly, and viewed as a normal response of capillaries and venules to heat, visible and IR radiation; and an immediate generalized heat response, resembling prickly heat rash, fading in 30 to 60 minutes, and apparently caused by heat and moisture generally irritating to the skin's surface. After the immediate responses are noted, each subject shall shield the exposed area from further UV radiation for the remainder of the test day. The MED is determined 22 to 24 hours after exposure. The erythema responses of the test subject should be evaluated under the following conditions: the source of illumination should be either a tungsten light bulb or a warm white fluorescent light bulb that provides a level of illumination at the test site within the range of 450 to 550 lux, and the test subject should be in the same position used when the test site was irradiated. Testing depends upon determining the smallest dose of energy that produces redness reaching the borders of the exposure site at 22 to 24 hours postexposure for each series of exposures. To determine the MED, somewhat more intense erythemas must also be produced. The goal is to have some exposures that produce absolutely no effect, while of those exposures that produce an effect, the maximal exposure should be no more than twice the total energy of the minimal exposure.

(i) Rejection of test data. Test data shall be rejected if the exposure series fails to elicit an MED response on either the treated or unprotected skin sites or if the responses on the treated sites are randomly absent, which indicates the product was not spread evenly or for the subject was noncompliant (e.g., subject withdraws from the test due to illness or work conflicts, subject does not shield the exposed testing sites from further UV radiation until the MED is read, etc.).

§352.73 Determination of SPF value.

(a) The following erythema action spectrum shall be used to calculate the erythema effective exposure of a solar simulator:

\[
V_{\lambda}(\lambda) = \begin{cases} 
1.0 & (250 < \lambda < 298 \text{ nm}) \\
10^{0.094(298 - \lambda)} & (298 < \lambda < 328 \text{ nm}) \\
10^{0.015(328 - \lambda)} & (328 < \lambda < 400 \text{ nm})
\end{cases}
\]

The data contained in this action spectrum are to be used as spectral weighting factors to calculate the erythema effective exposure of a solar simulator as follows:

\[
E = \sum_{\lambda=405}^{250} V_{\lambda}(\lambda) \times I(\lambda)
\]

where:
- \(E\) = Erythema Effective Exposure (dose)
- \(V_{\lambda}\) = Weighting Factor (Erythema Action Spectrum)
- \(I(\lambda)\) = Spectral Irradiance (Watts per meter squared per nanometer)

(b) Determination of MED of the unprotected skin. A series of UV radiation exposures expressed as Joules per meter squared (adjusted to the erythema action spectrum calculated according to §352.73(a)) is administered to the subsite areas on each volunteer with an accurately calibrated solar simulator. A series of five exposures shall be administered to the untreated, unprotected skin to determine the subject's inherent MED. The doses selected shall be a geometric series represented by (1.25\(n\)), wherein each exposure time interval is 25 percent greater than the previous time to maintain the same relative uncertainty (expressed as a constant percentage), independent of the subject's sensitivity to UV radiation, regardless of whether the subject has a high or low MED. Usually, the MED of a person's unprotected skin is determined the day prior to testing a product. This MED(US) shall be used in the determination of the series of UV radiation exposures to be administered to the protected site in subsequent testing. The MED(US) should be determined again on the same day as the standard and test sunscreens and this MED(US) should be used in calculating the SPF.

(c) Determination of individual SPF values. A series of UV radiation exposures expressed as Joules per meter squared (adjusted to the erythema action spectrum calculated according to §352.73(a)) is administered to the subsite areas on each subject with an accurately-calibrated solar simulator. A series of seven exposures shall be administered to the protected test sites to determine the MED of the protected skin (MED(PS)). The doses selected shall consist of a geometric series of five exposures, where the middle exposure is placed to yield the expected SPF plus two other exposures placed symmetrically around the middle exposure. The exact series of exposures to be given to the protected skin shall be determined by the previously established MED(US) and the expected SPF of the test sunscreen. For products with an expected SPF less than 8, the
exposures shall be the MED(US) times 0.64X, 0.80X, 0.90X, 1.00X, 1.10X, 1.25X, and 1.56X, where X equals the expected SPF of the test product. For products with an expected SPF between 8 and 15, the exposures shall be the MED(US) times 0.68X, 0.83X, 0.91X, 1.00X, 1.09X, 1.20X, and 1.44X, where X equals the expected SPF of the test product. For products with an expected SPF greater than 15, the exposures shall be the MED(US) times 0.76X, 0.87X, 0.93X, 1.00X, 1.07X, 1.15X, and 1.32X, where X equals the expected SPF of the test product. The MED is the lowest dose of radiation that produces uniform redness reaching the borders of the exposure site at 22 to 24 hours postexposure. The SPF value of the test sunscreen is then calculated from the dose of UV radiation required to produce the MED of the protected skin and from the dose of UV radiation required to produce the MED of the unprotected skin (control site) as follows:

\[ \text{SPF value} = \frac{\text{MED value of the protected skin}}{\text{MED value of the unprotected skin}} \]

(d) Determination of the test product's SPF value and PCD. Use data from at least 20 test subjects with n representing the number of subjects used. First, for each subject, compute the SPF value as stated in § 352.73 (b) and (c). Second, compute the mean SPF value, \( \bar{X} \), and the standard deviation, s, for these subjects. Third, obtain the upper 5-percent point for the standard normal distribution, which is \( Z_{0.05} \). Then calculate the SPF value for a product according to the equation:

\[ \text{SPF value} = \frac{\bar{X} + Z_{0.05} s}{n^{-1/2}} \]

(1) Apply sunscreen product (followed by the waiting period after application of the sunscreen product indicated on the product labeling).

(2) 20 minutes moderate activity in water.

(3) 20-minute rest period.

(4) 20 minutes moderate activity in water.

(5) Conclude water test (air dry test sites without toweling).

(6) Begin solar simulator exposure to test site areas as described in § 352.73.

(b) Procedure for testing a very water resistant sunscreen product. If the sunscreen product retains the same PCD after 40 minutes of water immersion as it had before water immersion, the claim of “water resistant” may be made. The testing procedure shall be used for the water resistance test:

(1) Apply sunscreen product (followed by the waiting period after application of the sunscreen product indicated on the product labeling).

(2) 20 minutes moderate activity in water.

(3) 20-minute rest period.

(4) 20 minutes moderate activity in water.

(5) Conclude water test (air dry test sites without toweling).

Procedure for testing a very water resistant sunscreen product. If the sunscreen product retains the same PCD after 80 minutes of water immersion as it had before water immersion, the claim of “very water resistant” may be made. The testing procedure shall be used for the very water resistant test:

(1) Apply sunscreen product (followed by the waiting period after application of the sunscreen product indicated on the product labeling).

(2) 20 minutes moderate activity in water.

(3) 20-minute rest period.

(4) 20 minutes moderate activity in water.

(5) 20-minute rest period.

(6) 20 minutes moderate activity in water.

(7) 20-minute rest period.

(8) 20 minutes moderate activity in water.

(9) Conclude water test (air dry test sites without toweling).

(10) Begin solar simulator exposure to test site areas as described in § 352.73.

§ 352.77 Test modifications.

The formulation or mode of administration of certain products may require modification of the testing procedures in this subpart. In addition, alternative methods (including automated or in vitro procedures) employing the same basic procedures as those described in this subpart may be used. Any proposed modification or alternative procedure shall be submitted as a petition under the rules established in § 10.30 of this chapter. The petition should contain data to support the modification or data demonstrating that an alternative procedure provides results of equivalent accuracy. All information submitted will be subject to the disclosure rules in Part 20 of this chapter.

PART 700—GENERAL

4. The authority citation for 21 CFR Part 700 continues to read as follows:


5. Section 700.35 is added to subpart B to read as follows:

§ 700.35 Cosmetics containing sunscreens.

(a) A product that includes a sunscreen active ingredient and the term “sunscren” in its labeling or in any other way represents or suggests that it is intended to prevent, cure, treat, or mitigate disease or to affect a structure or function of the body comes within the definition of a drug in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act. Sunscreen active ingredients affect the structure or function of the body by screening, reflecting, or scattering the harmful, burning rays of the sun, thereby altering the normal physiological response to solar radiation. These ingredients also help to prevent diseases such as sunburn and reduce the chance of premature skin aging or skin cancer due to the sun. Moreover, when consumers see the term “sunscren” on the label of a product, they expect the product to protect them in some way from the harmful effects of the sun, irrespective of other labeling statements.

Consequently, the use of the term “sunscren” in a product’s labeling normally makes that product a drug. However, sunscreen ingredients may also be used in some cosmetic products for nontherapeutic uses. In order to avoid consumer misunderstanding, if a cosmetic product uses the term “sunscren” anywhere in its labeling, the term “sunscren” must be qualified by describing the cosmetic benefit provided by the sunscreen. For example: “This product contains a sunscreen that assists in protecting the hair from damage by the sun.”

(b) Any information describing the purpose of the sunscreen in the product shall appear in direct conjunction with the term “sunscren.”

PART 740—COSMETIC PRODUCT WARNING STATEMENTS

6. The authority citation for 21 CFR Part 740 continues to read as follows:

7. Section 740.19 is added to subpart B to read as follows:

§ 740.19 Suntanning preparations.

The labeling of suntanning preparations that do not contain a sunscreen ingredient must display the following warning:

Warning—This product does not contain a sunscreen and does not protect against sunburn.


Michael R. Taylor,
Deputy Commissioner for Policy.

[FR Doc. 93-10888 Filed 5-11-93; 8:45 am]

BILLING CODE 4160-01-P
Part IV

Department of Labor

Office of Labor-Management Standards

29 CFR Parts 402 and 403
Labor Organization Annual Financial Reports and Abbreviated Annual Financial Reports for Small Labor Organizations; Final Rule
SUPPLEMENTARY INFORMATION:

I. Background and Overview

Section 201(b) of the Labor-Management Reporting and Disclosure Act of 1959, as amended (LMRDA) (Pub. L. 86-257, 73 Stat. 519), requires each covered labor organization to file annually with the Secretary of Labor a financial report signed by its president and treasurer or corresponding principal officers, containing information in the detail necessary to disclose accurately its financial condition and operations for the preceding fiscal year. The Secretary of Labor has delegated his authority under the LMRDA to the Assistant Secretary for Employment Standards. See Secretary's Order No. 9-92 (57 FR 53514, 57 FR 56641).

The requirements of LMRDA section 201 apply to all labor organizations in the private sector including those representing employees under the provisions of the National Labor Relations Act, as amended, and the Railway Labor Act, as amended. Section 1209(b) of the Postal Reorganization Act made the LMRDA applicable to labor organizations representing employees of the U.S. Postal Service. Section 701 of the Civil Service Reform Act of 1978 (CSRA) and section 1017 of the Foreign Service Act of 1980 (FSA), as implemented by Department of Labor regulations at 29 CFR parts 457-459, extended the LMRDA reporting requirements to labor organizations representing certain employees of the Federal government.

Section 206 of the LMRDA authorizes the Secretary to issue rules prescribing the form and publication of the annual financial reports required by section 201, and to provide a simplified report for labor organizations for whom the Secretary finds that virtue of their size a detailed report would be unduly burdensome. Under the preexisting regulations issued pursuant to section 208, the Secretary has prescribed Form LM-2 for labor organizations with total annual receipts of less than $100,000. (The preexisting regulations at 29 CFR 403.4(b) also provide that for a labor organization which is not in trusteeship and which has no assets, liabilities, receipts, or disbursements, the parent national or international may fulfill that organization's reporting obligation by filing basic information on its behalf in a simplified format.)

On December 30, 1992, the Department published final rules revising the annual financial reporting Forms LM-2 and LM-3 and issuing a new abbreviated annual financial reporting Form LM-4 (57 FR 49282 and 49356). The effective date of these final rules was December 31, 1993. The revised financial reporting Forms LM-2 and LM-3, among other things, added a requirement that labor organizations report expenditures by functional categories, provided the option of completing the reporting forms on the cash or accrual basis of accounting, and raised the annual receipts ceiling for use of the simplified Form LM-3 from $100,000 to $200,000.

A new abbreviated Form LM-4 for use by small labor organizations with total annual receipts of less than $10,000 was also issued. Since the annual financial reports disclose details of each labor organization's financial condition and operations for the preceding year, labor organizations filing reports for fiscal years ending on or after December 31, 1993, effective date would have had to begin maintaining records to comply with the new functional reporting requirement on or shortly after the beginning of their fiscal year, which for the majority of labor organizations was January 1, 1993. The addition of the functional reporting requirement to Forms LM-2 and LM-3 would have also required many labor organizations to modify their recordkeeping systems in order to collect and report the required information. The December 31, 1993, effective date of the final rule thus would have compelled labor organizations to begin implementing new procedures as early as January 1, 1993, only two months after the publication of the final rules on October 30, 1992.

During the formal comment period prior to the issuance of the October 30, 1992, final rules, the Department received a number of comments stating that a lead time of less than one year would be insufficient to establish and operate new accounting systems needed to comply with the proposed functional requirements. In addition, the Department has continued to receive comments and inquiries from labor organizations and accounting firms regarding difficulties in interpreting and applying the new rules. Reexamination of the initial comments the Department received on the proposed effective date, the Department's own difficulties in adequately responding to labor organizations' inquiries regarding the final rule, and labor organizations' continuing problems in preparing to comply with the new functional reporting requirements led the Department to propose extending the effective date of the final rules until December 31, 1994 (Federal Register, 58
FR 8418, February 19, 1993). The purpose of the postponement is to alleviate these compliance problems and allow for reevaluation of these new rules, including whether modification or rescission of some or all of the revisions may be appropriate.

Public comment on the proposed rule was invited, with the comment period ending on March 22, 1993. The comments, the Department's responses, and the Department's decision are discussed in detail below.

For the reasons discussed below, the Department has decided to extend, for one year, the effective date of the two final rules published on October 30, 1992. As a result of this extension, labor organizations filing financial reports for fiscal years ending before December 31, 1994, will continue to file reports on the preexisting Form LM-2 or LM-3.

II. Comments on the Proposal and the Department's Responses and Decision

Forty-six timely comments were received from the public; forty-one from labor organizations, four from accounting firms, and one from another organization. Ten of the comments from labor organizations were identical. Additionally, five identical comments were submitted by various officers of one labor organization.

The AFL-CIO and the following national and international labor organizations commented on the proposed rule:

- Utility Workers;
- Chemical Workers;
- Aluminum, Brick and Glass Workers;
- Ladies Garment Workers;
- Laundry and Dry Cleaning;
- Postal Workers;
- Service Employees;
- Auto Workers;
- Food and Commercial Workers;
- Teachers;
- Bricklayers;
- Steelworkers;
- Letter Carriers;
- Iron Workers;
- Machinists.

Other labor organizations which commented on the proposal are:

- Local 278, Electrical Workers, IBEW;
- Local 1031, Electrical Workers, IBEW;
- District 14, Steelworkers;
- Local 604-605, Postal Workers;
- Local 512, Transport Workers;
- Local 218, Sheet Metal Workers;
- Local 293, Plumbers;
- Local 189, Operating Engineers;
- Local 150, Operating Engineers;
- Local 383, Plumbers;
- Local 18, Operating Engineers;
- Local 204, Electrical Workers, IBEW;
- Local 82, Electrical Workers, IBEW (five comments);
- Washington County Central Labor Council;
- Local 2327, Electrical Workers, IBEW;
- Local 336, Electrical Workers, IBEW;
- Local 383, Electrical Workers, IBEW;
- Local 95, Plumbers;
- Local 7200, Communications Workers;
- Local 95, Electrical Workers, IBEW;
- Local 280, Electrical Workers, IBEW.

Accounting firms which commented on the proposal are:

- Daniel A. Winters and Company;
- Potter and Company (on behalf of seven client labor organizations);
- Demore, Hamric and Schneider;
- Winkler and Forner.

The one other organization which commented on the proposed rule is:

- The National Right to Work Legal Defense Foundation.

The Department has carefully reviewed and considered all statements made in the comments in developing this final rule. The following is a summary of the comments and the Department's responses.

A. Discussion of the Comments

Thirty comments specifically support the extension. Sixteen of these addressed why the organizations believed the extension is necessary, arguing generally that:

- A two-month implementation period was inadequate to make necessary revisions to international union records and to train local union officers;
- The Department should review and evaluate the soundness of the October 30, 1992, revisions.

The other fourteen comments which supported the extension did not provide specific reasons but expressed opposition to the October 30, 1992, revisions.

Fifteen comments did not specifically address the extension but only expressed opposition to the October 30, 1992, revisions.

One organization, the National Right to Work Legal Defense Foundation, opposed the extension, arguing generally that:

- The two-month lead time for implementation of the revised forms was adequate to make the necessary internal recordkeeping revisions and resolve compliance difficulties;
- There is no need for the Department to further review and examine the soundness of the October 30, 1992, revisions.

1. Revision of Internal Union Records

Nine of the organizations which supported the extension stated that the two-month implementation period was inadequate because the revised reporting requirements necessitate extensive revision of unions' internal records prior to the beginning of their fiscal year to accurately compile the necessary data to complete the revised Form LM-2 or LM-3 at the end of the fiscal year.

One international union (Ladies Garment Workers) noted that any necessary revisions to its recordkeeping procedures should have been in place on December 31, 1992, but stated the Union "struggled to develop the necessary internal procedures in the early months of 1993, but has not yet succeeded * * *. The Union's staff will be required to maintain detailed time records, geared to the LM reports, so that their salaries may be allocated to each of the respective functions * * *.

Literally hundreds of questions arise in the development of such a system, and it is impossible to resolve them overnight and then adequately train staff throughout the nation." This union also stated that "it is unclear whether [the time records supporting officer and employee payments] would also support the functional allocation for the other required line items. In particular, the Union has many unanswered questions concerning the proper allocation of office and administrative expenses."

The Ladies Garment Workers also noted that in January 1993, they sought advice from the Department and learned that the Department was in the process of developing compliance assistance programs for unions but had not had sufficient time to complete such programs.

Another international union (Bricklayers) stated that: "[A]t the very least, the proposed extension of effective date will give labor organizations an opportunity to become familiar with and adjust to the new reporting requirements by implementing necessary accounting changes and modifying recordkeeping systems. Without the extension, unions are afforded inadequate lead time to prepare for these revised reporting methods."

On other international (Letter Carriers) which supported the extension indicated that the two-month implementation period was "not sufficient to accommodate required revisions to [the Union's] computerized accounting system. An extension * * * would permit [the Union] to identify the appropriate allocation methods based on the definitions of the functional categories and make the necessary revisions to its computerized accounting system."
One local union (Local 383, Electrical Workers, IBEW) provided comments on its attempts to revise internal procedures to comply with the revised forms. This union stated that "(t)he amount of time required to process the vouchers each month increased as it was necessary to establish a separate data base to cover the salary/salary reimbursement allocations. My accounting system was able to accommodate the expense allocation, however, the amount of paper involved in each month’s activities more than doubled." Local 383, Electrical Workers, IBEW also pointed out that "there was no one who was able to explain where the double."

The AFL-CIO comments a survey (prepared on its behalf) of accounting firms that work extensively with labor organizations. According to the survey, "(m)any of the accountants surveyed add that the 60-day lead-time * * * has substantially exacerbated the inherent difficulties of coming into compliance with these complex bookkeeping and recordkeeping requirements."

The comment opposing the extension (National Right to Work Legal Defense Foundation) stated that "(f)unctional reporting simply means that paid officers and staff must keep contemporaneous records of their time in certain categories. Those categories are defined by the Rules, themselves * * *. (T)he design of a form for officers and employees to record time by function cannot reasonably take two hours, never mind two weeks, or two months."

Another comment (Letter Carriers) noted that time to train local officers is necessary, observing that many of their 600 locals cannot afford accounting assistance and that the international will have to consider developing a national training program to assist local officials.

3. Department of Labor Implementation Difficulties

The Department of Labor's Office of Labor-Management Standards (OLMS) determined that proper implementation of the revised reporting requirements would require OLMS to train its field staff, respond to inquiries on the revisions, develop compliance assistance materials for union officials, and change internal operations to accommodate the revised reporting forms.

During November and December, 1992, OLMS developed procedures for notifying unions prior to the beginning of their fiscal year of the revised reporting requirements, prepared summary sheets for labor organizations highlighting the major revisions, and sent notification letters to approximately 21,000 unions.

Preliminary plans were developed for: Printing and distributing the revised forms; redesigning OLMS' computer database system to align with the new reports; revising internal procedure and enforcement manuals; and revising existing pamphlets and publications. In addition, OLMS began developing staff training and compliance assistance materials and programs for union officials. OLMS' experience demonstrated that it would not be possible to complete all necessary actions to implement the revised forms in the allotted time.

After the final rules were published in the Federal Register on October 30, 1992, OLMS received numerous requests from its field staff seeking guidance and raising issues related to the accrual and functional reporting requirements. OLMS also received many interpretative and technical questions from union officials and accountants, which arose as they began to revise their internal recordkeeping systems to comply with the revised reporting requirements. Examples of issues raised include: the proper allocation of expenses on multi-purpose business trips by union officials, the reasonable use of a sample period for allocating officer and staff time for the entire reporting period, and the proper allocation of general overhead expenses.

OLMS was unable to provide adequate guidance on many interpretative and technical issues because of insufficient time to analyze all the relevant factors and develop policy positions. Three of the comments noted that the inability of the Department to provide guidance prior to the beginning of the affected reporting period exacerbated the difficulties labor organizations were experiencing in revising their internal reporting requirements.

One comment (National Right To Work Legal Defense Foundation) opposed the extension arguing that the Department’s statement concerning its implementation difficulties "proceeds on a false premise. It assumes that there was a 'short time for implementation' and, therefore, that OLMS personnel had no reasonable time within which to determine responses to reasonable compliance inquiries. This is simply not
the case. The basic form which provided the basis for the Modern Forms [i.e., revised forms] was initially developed within OLMS (then Labor-Management Services Administration) in 1983 * * *. The Modern Forms are not nacked, with OLMS and reporting labor organizations left to grope for instructions on their completion. To the contrary, there are thirty one (31) pages of instructions for completion of the LM-2 * * *. Thus, there is no absence of instructive educational material concerning completion of the Modern Forms."

4. Reevaluation of the Revised Rules

Forty-two of the comments urged the Department to review and rescind the revised reporting requirements. These comments supported reevaluation or recision because of the increased recordkeeping and financial burden caused by the revisions.

The AFL-CIO also submitted a December 1992 study (completed on its behalf) on the cost to unions of complying with the revised reports. This study suggests that "the first year compliance costs imposed on unions * * * will be $58 million over and above what would have been spent on reporting under the LM-2/LM-3 regime previously in effect * * *. This figure includes $28 million in start-up costs to institute new recordkeeping systems as well as the costs and effort required to compile the data required by the revised LM forms and $30 million in annual increased costs for filling out the revised forms." This comment also asserts that the Department's burden and associated cost figures for the revised forms significantly underestimate the burden associated with the revised reports.

A CPA firm (Daniel A. Winters & Company) submitted comments recommending that the revisions be reevaluated because the "time and effort required to submit the additional information is wasteful and counterproductive." The comment argued that since no method is prescribed for the functional allocation of expenses, "some unions will undoubtedly choose to maintain records of time spent by union officials and employees to provide a basis of allocation. Some unions will probably estimate broad across-the-board percentages * * *. Accordingly, the information which the government will receive will not be useful or meaningful on a micro or macro level and * * * the cost of providing this information will be great to individual unions and to the unionized community in the aggregate."

Two comments suggested that the initial comments submitted prior to the publication of the October 30 final rule were not given proper consideration by the Department and reevaluation is necessary.

Thirteen comments stated that, contrary to what was stated in the preamble to the October 30 final rule, they believed that the functional allocation requirement was an attempt to further implement the Supreme Court's decision in Communications Workers of America v. Beck, 467 U.S. 735 (1988) and that requiring all unions to report in this manner is an unreasonable and unnecessary burden.

Two comments indicated that some local unions which are required to prepare special reports for agency fee payers are now required to maintain an additional set of records to fulfill the functional reporting requirement. The comment opposing the extension (National Right To Work Legal Defense Foundation) stated that "complete evaluation by OLMS has already taken place; it resulted in the New Forms. There is no need for 'modification * * * of some * * * of the revisions', and no case has been made for such action. There is no need, either, for 'recession of * * * all of the revisions'."

B. The Department's Responses and Decision

After considering the comments and the Department's difficulties in attempting to implement the reporting revisions, the Department has concluded that an effective date of December 31, 1993, which, in effect, allowed only a two-month implementation period was insufficient. Therefore, the Department has decided to extend the effective date of the final rules to December 31, 1994.

The comments which supported the extension as discussed above have convinced the Department that the implementation period for the revised reports must allow adequate time for labor organizations to revise their internal records and accounting systems in order to properly classify financial transactions prior to the beginning of the fiscal year for which the revised reporting forms must be used. The Department recognizes that national and international unions often develop recordkeeping and reporting procedures for their subordinate unions so that, as a first step in implementing major revisions to the reporting process, the national or international must revise the format of their internal records to coincide with the revised reporting categories on Forms LM-2 and LM-3.

Additionally, the comments concerning the need to train union officials who will be required to maintain the revised internal union records and ultimately to complete the revised Form LM-2 or LM-3, have demonstrated the need for the one-year extension. The Department's own experiences in attempting to develop and conduct training for its staff as well as to develop associated compliance assistance materials for use by union officials further support the need for the extension.

Finally, the comments urging the Department to reevaluate the revisions, the questions and requests for assistance directed to the Department, and the Department's own implementation difficulties suggest the need to reevaluate the revisions. During the extension period, the Department will reevaluate the October 30 final rules and determine whether modification or rescission of some or all of the revisions may be appropriate.

The Department is not persuaded by the comments of the National Right To Work Legal Defense Foundation opposing the extension. Listed below are the Foundation's principal arguments and the Department's response:

(1) Additional "lead" time is not necessary because functional reporting only requires paid union officers and staff to keep contemporaneous records of their time in certain categories.

Functional reporting not only requires maintaining time records for officers and staff but also requires unions to make determinations concerning the proper allocation categories for various activities of officers and staff.

Additionally, functional reporting will require labor organizations to allocate expenditures for administrative items such as rent, office supplies, and utilities and several other types of expenditures to functional categories. As illustrated in the discussion of the comments and the Department's experience in preparing to implement the revised forms, labor organizations must revise their internal reporting records prior to the beginning of the fiscal year to which the revisions apply in order to properly allocate expenditures during the reporting period. Additionally, the Department has a responsibility to provide the
regulated organizations with adequate guidance for making those allocations. The record illustrates that a two-month implementation period was not sufficient.

(2) Compliance difficulties could not have been "serious and substantial" since they were not specified in the February 19 proposed extension, and, in any case, "(t)he experience confirms that the best means to ferret out the 'difficulties', if any, caused by the reporting requirements of the Modern Forms is to require the reporting in accordance with the present deadline." It is clear from the above discussion of the comments that serious compliance difficulties exist. The Department has decided that implementing the revised forms without adequate time to answer questions, resolve issues, and provide sufficient guidance to affected labor organizations would result in the submission of reports which may be so fraught with errors that the functional information reported would be misleading and/or of little value to union members and others.

The Department also notes that both the Department and the reporting labor organizations will have to alter internal operating systems and procedures to implement the revised reports. It would be a waste of taxpayers' and union members' monies to expend funds to revise computer systems, accounting systems, training programs, etc., only to determine at the end of the first reporting period that there may be serious flaws in the reports necessitating further revisions.

(3) There is no need for additional guidance as the revised forms contain numerous pages of instructions and, in any event, the Department should not need additional time to develop responses to inquiries since "(t)he basic form which provided the basis for the Modern Forms was initially developed within OLMs * * * in 1983."

Although the reporting instructions identify what information is to be reported on the forms, the Department must be able to provide guidance on the application of the instructions to specific circumstances in individual reporting organizations. In addition, while it is true that a preliminary draft form was developed by OLMs in 1982-83, that draft contained a substantially different version of functional reporting. Moreover, that proposal was never approved by the Department and the project was terminated in 1983.

(4) There is no need for reevaluation of the revisions as all necessary review and evaluation was conducted prior to the publication of the October 30 final rules.

The experience of the labor organizations required to file the revised reports and the Department's experience during the implementation period as described in the comments and discussion above illustrate the need to reevaluate the revisions. The Department will determine whether modification or reversion of the revised rules is appropriate after reevaluating the revisions.

III. Comments on the October 30, 1982, Revisions

Forty-two comments expressed opposition to some or all of the revisions contained in the October 30 final rule, fifteen comments recommended reversion of all changes, and twenty-seven recommended reversion of the functional reporting requirement. However, four comments supported raising the annual receipts ceiling for use of the simplified Form LM-3 from $100,000 to $200,000 or higher, and five expressed support for the abbreviated Form LM-4.

During the postponement period, the Department will reexamine the October 30 rules and, if it is determined that these rules should be revised, a Notice of Proposed Rulemaking requesting comments on proposed changes will be published in the Federal Register. Comments concerning any proposed changes will be considered at that time.

IV. Administrative Requirements

A. Effective Date

This document will become effective upon publication pursuant to 5 U.S.C. 553(d). The undersigned have determined that good cause exists for waiving the customary requirement for delay in the effective date of a final rule for 30 days following its publication. As a result of this final rule, labor organization financial reports for fiscal years beginning January 1, 1993, and thereafter through December 31, 1993, will be filed on the preexisting Form LM-2 or LM-3 rather than the revised Form LM-2 or LM-3 or the new Form LM-4. Because of the significant differences in the information required to be reported on the preexisting and revised forms, and because the postponement relieves the obligation of labor organizations to revise their recordkeeping systems for the above-mentioned fiscal years, it is appropriate to have this postponement become effective upon publication.

B. Executive Order 12291

The Department of Labor has determined that this rule is not a major rule as defined by Executive Order 12291 in that it will not have an annual effect on the economy of $100 million or more, not cause a major increase in costs or prices, and not have an adverse effect on competition in the marketplace. Therefore, a regulatory impact analysis is not required.

C. Regulatory Flexibility Act

In accordance with section 605(b) of the Regulatory Flexibility Act (5 U.S.C. 601 et seq.), the Department certifies that this rule will not have a significant economic impact on a substantial number of small entities. The rule will only apply to labor organizations, and the Department has determined that labor organizations regulated pursuant to the statutory authority granted under the LMRDA do not constitute small entities. Therefore, a regulatory analysis is not required.

D. Paperwork Reduction Act

The Final Rule has resulted in a one-year continuation of the pre-existing approved labor organization reporting requirements. The burden hour estimate of 250,185 remains unchanged. Therefore, it is not subject to section 3504(h) of the Paperwork Reduction Act, 44 U.S.C. 3504(h).

List of Subjects in 29 CFR Parts 402 and 403

Labor unions, Reporting and recordkeeping requirements.

Postponement of Effective Date of Final Rules

In consideration of the foregoing, the Department of Labor postpones the effective date for the final rules published in the Federal Register on October 30, 1992, 57 FR 49282 and 49356, which revised Forms LM-2 and LM-3, issued Form LM-4, and amended 29 CFR parts 402 and 403, from December 31, 1993, until December 31, 1994.

Signed in Washington, DC, this 7th day of May, 1993.

Robert B. Reich,
Secretary of Labor.

John R. Fraser,
Acting Assistant Secretary for Employment Standards.

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BILLING CODE 4510-06-M
Part V

Department of Health and Human Services

Office of Community Services

Request for Application Under the Office of Community Services' Fiscal Year 1993 Job Opportunities for Low-Income Individuals Program (Demonstration Projects); Notice
DEPARTMENT OF HEALTH AND HUMAN SERVICES
Office of Community Services
[Program Announcement No. OCS-93-3]

Request for Applications Under the Office of Community Services’ Fiscal Year 1993 Job Opportunities for Low-Income Individuals Program (Demonstration Projects)

AGENCY: Administration for Children and Families (ACF), DHHS.

ACTION: Announcement of availability of funds and request for applications under the Office of Community Services’ FY 1993 Job Opportunities for Low-Income Individuals Programs (Demonstration Projects).

SUMMARY: The Administration for Children and Families (ACF), Office of Community Services (OCS), announces that competing applications will be accepted for new grants pursuant to the Secretary’s discretionary authority under section 505 of the Family Support Act of 1998. This Program Announcement consists of eight parts:

Part I covers information on legislative authorities, eligible applicants, definition of terms used in the Program Announcement and describes the purpose of the program;

Part II describes the types of projects that will be considered for funding;

Part III provides details on application requirements, funds available, limitations on grant amounts, project and budget periods, mobilization of resources, who should benefit from the programs, partnership agreements, prohibition and restrictions on the use of funds and multiple submittals, third-party evaluation, economic development strategy, and maintenance of effort;

Part IV describes the criteria used in the assessment of applications;

Part V describes the application procedures, including the availability of forms, where and how to submit an application and the intergovernmental review. It also includes the initial screening, pre-rating review and factors considered in the selection process;

Part VI provides instructions for completing the SF-424.

Note: OCS has included specific instructions for completing Section B of the SF-424:

Part VII describes the contents of the application package, how the project narrative should be ordered and presented and the receipt process; and

Part VIII details post-award information and reporting requirements.

CLOSING DATE: The closing date for submission of applications is June 28, 1993.

FOR FURTHER INFORMATION CONTACT: Office of Community Services, Administration for Children and Families, 370 L’Enfant Promenade SW., Washington, DC 20447, Telephone (202) 401-2333, Contact: Margaret Washnitzer.

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Part I—Preamble

A. Legislative Authority

The FY 1993 Senate Appropriations Committee’s recommendation includes $5,000,000 for job creation demonstration activities authorized under section 505 of the Family Support Act of 1988. No funds were included in the budget request for these projects. These grants provide technical and financial assistance to businesses that agree to target new jobs and enterprise opportunities to welfare individuals at or below 100 percent of the poverty threshold. The Committee directs that the funds for section 505 be administered by the Office of Community Services within HHS and that funds be made available on a priority basis to community development corporations with a record of achievement in job and business for low-income people. Section 505 of the Family Support Act of 1988 also authorizes the Secretary to enter into agreements with not less than 5 nor more than 10 nonprofit organizations for the purpose of conducting demonstration projects to create employment and business opportunities for certain low-income individuals.

B. Eligible Applicants

The organization eligible to apply for funding under this program is any nonprofit organization (including community development corporations) that is exempt from taxation under section 501(a) of the Internal Revenue Code of 1986 by reason of paragraph (3) or (4) of section 501(c) of such Code.

C. Definition of Terms

For purposes of this Program Announcement the following definitions apply:

—Budget Period: The interval of time into which a multi-year period of assistance (project period) is divided for budgetary and funding purposes.

—Community-Level Data: Key information to be collected by each grantee that will allow for a national-level analysis of common features of JOLI projects. This includes data on the population of the target area, the percentage on public assistance, the percentage whose incomes fall below the poverty line, the unemployment rate, the number of new business starts and business closings, and a description of the major employers and average wage rates.

—Community Development Corporation: A private, locally initiated, nonprofit entity, governed by a board consisting of residents of the community and business and civic leaders, which has a record of implementing economic development projects or whose Articles of Incorporation and/or By-Laws indicate that it has a focus in the area of economic development.

—Hypothesis: An assumption made in order to test its validity. It should assert a cause-and-effect relationship between a program intervention and its expected result. Both the
intervention and result must be measured in order to confirm the hypothesis. For example: Eighty hours of classroom training in small business planning will be sufficient for participants to prepare a successful loan application. In this example, data would be obtained on the number of hours of training actually received by participants (the intervention), and the quality of loan applications (the result).

-Intervention: Any planned activity within a project that is intended to produce changes in the target population and/or the environment and can be formally evaluated. For example, assistance in the preparation of a business plan and loan package are planned interventions.

-Job Creation: To bring about, new jobs, that is jobs that were not in existence before the start of the project. These activities can include self-employment/entrepreneurial training, the development of new businesses or the expansion of existing businesses.

-Non-profit organizations: Any organization (including a community development corporation) exempt from taxation under section 501(a) of the Internal Revenue Code of 1986 by reason of paragraph (3) or (4) of section 501(c) of such Code.

-Private employers: Third-party private non-profit organizations or third-party for-profit businesses operating in the same community as the applicant.

-Process evaluation: The ongoing examination of the implementation of a program. It focuses on the effectiveness and efficiency of the program’s activities, or usefulness of follow-up procedures. It should answer questions such as: “Who is receiving what services?”, “Are the services being delivered as planned?”, and “Are client competencies improving?” It is also known as “formative” evaluation because it gathers information that can be used to improve the way a program is in progress.

-Program participant/beneficiary: Any individual eligible to receive Aid to Families with Dependent Children under Part A of Title IV of the Social Security Act and any other individual whose income level does not exceed 100 percent of the official poverty line as found in the most recent Annual Revision of Poverty Income Guidelines published by the Department of Health and Human Services. (See Attachment A.)

-Project Period: The term “project period” refers to the total time a project is approved for support, including any extensions.

-Self-Sufficiency: A condition where an individual or family, by reason of employment, does not need and is not eligible for public assistance.

D. Purpose
The purpose of this program is to demonstrate and evaluate ways of creating new employment and business opportunities for certain low-income individuals through the provision of technical and financial assistance to private employers in the community. A low-income individual eligible to participate in a project conducted under this program is any individual eligible to receive Aid to Families with Dependent Children (AFDC) under Part A of Title IV of the Social Security Act and any other individual whose income level does not exceed 100 percent of the official poverty line. (See Attachment A.) Within these categories, emphasis should be on individuals who are unemployed, those residing in public housing, and those who are homeless.

Part II—Program Priority Areas

A. General Projects 1.0
The Congressional Conference Report on the FY 1992 appropriations for the Departments of Labor, Health and Human Services, and Education and related agencies directs the ACF to require economic development strategies as part of the application process to ensure that highly qualified organizations participate in the demonstration. H.R. Conf. Rep. No. 282, 102d Cong., 1st Sess. 39 (1991). The inclusion of these strategies was a valuable addition to the application materials and will be continued this year. Proposed projects should demonstrate how their program will impact the overall community/communities served by the applicant. OCS will only fund projects that create new jobs and/or business opportunities for eligible program participants. Projects funded under this program must demonstrate how the proposed project will enhance the participants’ ability and skills in their progress toward self-sufficiency. Therefore, proposed projects must show promise toward progress of achieving self-sufficiency among the target population. OCS expects that the jobs and/or business/self employment opportunities to be created under this program will contribute to the goal of self-sufficiency.

The employment opportunities should provide hourly wages that exceed the minimum wage and also provide benefits such as health insurance, transportation, child care, career development opportunities, etc. Applicants must show that the proposed project will create a significant number of new full-time permanent jobs through the expansion of a pre-identified business or new business development and by providing opportunities for self-employment to eligible participants.

While projected employment in future years may be included in the application, it is essential that the focus of employment opportunities concentrate on new full-time, permanent jobs created during the duration of the grant project period and/or on the creation of new business development opportunities for low-income individuals.

In creating self-employment business opportunities for eligible participants, the applicant must detail how it will work with private employers in identifying potential entrepreneurs. The assistance to be provided to potential entrepreneurs must include, at a minimum, technical assistance in basic business planning and management concepts, and assistance in preparing a business plan (see Part IV, Criterion III for requirements) and loan application.

Any funds that are used for training purposes must be limited to providing specific job-related training to eligible participants who have been selected for employment and/or self-employment business opportunities.

In the review process, favorable consideration will be given to applicants with a demonstrated record of achievement in creating job and enterprise opportunities for low-income people. Favorable consideration will also be given to those applicants who show the lowest cost-per-job created for low-income individuals. For this program, OCS views $15,000 as the maximum amount for the creation of a job and, unless there are extenuating circumstances, will not fund projects where the cost-per-job in OCS funds exceeds this amount. Only those jobs created and filled by low-income people will be counted in the cost-per-job formula. (See Part IV, Criterion IV)

Technical assistance should be specifically addressed to the needs of the private employer in creating new jobs to be filled by eligible individuals and/or to the individuals themselves such as skills training, job preparation, self-esteem building, etc. Financial assistance also may include assistance to the private employer as well as...
assistance to the individual. If the technical and/or financial assistance is to be provided to pre-identified businesses that will be expanded or franchised, written comments from the businesses must be included with the application.

The creation of a revolving loan fund with funds received under this program is an allowable activity. However, OCS encourages the use of funds from other sources for this purpose. Points will be awarded in the review process to those applicants who leverage funds from other sources. (See Part IV, Criterion VI.) Loans made to eligible beneficiaries for business development activities must be at or below market rate.

(Note: Interest accrued on revolving loan funds may be used to continue or expand the activities of the approved project.)

Grant funds received under this program may not be used for construction.

A formal, cooperative relationship between the applicant and the agency (State IV-A agency) responsible for administering the Job Opportunities and Basic Skills (JOBS) training program (as provided for under title IV-A of the Social Security Act) in the area served by the project is a requirement for funding. The application must include a signed, written agreement between the applicant and the State IV-A agency, or a letter of commitment (contingent only on receipt of OCS funds), which describes the cooperative relationship, including specific activities and/or actions each of these entities proposes to carry out over the course of the grant period in support of the project. The agreement, at a minimum, must cover activities that will be provided to the target population and which are related to one or more of the mandatory or optional components offered by the appropriate State’s JOBS program. The mandatory activities offered by the States’ JOBS programs consist of the following components: Basic education activities, job skills training, job readiness activities, job development and job placement. The optional components offered by the States’ JOBS programs include: group and individual job search counseling and training on job seeking skills; on-the-job-training; work supplementation; and community work experience.

(Note: A signed written agreement or a signed letter of commitment between the applicant and the State IV-A agency must be submitted with the application in order to be reviewed and evaluated competitively.)

Projects also must include an independent, methodologically sound evaluation of the effectiveness of the activities carried out with the grant in creating new jobs and business opportunities. (See Part IV, Criterion V.)

Applications should include a plan for disseminating the results of the project after expiration of the grant period. Applicants may budget up to $1,000 for dissemination purposes. Priority will be given to applications proposing to serve those areas containing the highest percentage of individuals receiving Aid to Families with Dependent Children under Title IV-A of the Social Security Act. (See Part IV, Criterion II.)

Applicants must be aware that it is expected that projects will be operational by the end of the project period, i.e., that the jobs and/or businesses that the applicant committed itself in the application to creating will be in place, and low-income individuals will actually be employed in those jobs and/or businesses.

See Part IV, Criterion III for special instructions on developing a work program.

B. Community Development Corporations Set-Aside 2.0

For Fiscal Year 1993, a set-aside fund of $1 million will be included for community development corporations. A set-aside fund is a private, non-profit entity which has a record of implementing economic development projects or, whose articles of incorporation and/or By-Laws indicate that it has a focus in the area of economic development, and which has a tax exempt determination under Section 501(a) of the Internal Revenue Code of 1986 by reason of paragraph (3) or (4) of Section 501(c) of such code. Such projects must conform to the purposes, requirements, and prohibitions applicable to those submitted under Part II, General Projects 1.0.

Applications for these set-aside funds which are not funded due to the limited amount of funds available will also be considered competitively within the larger pool of eligible applicants.

Part III—Application Requirements

A. Background Information

1. Availability of Funds and Grant Amounts

The Office of Community Services expects to award approximately $5,000,000 by September 30, 1993 for new grants under this program.

A maximum of $500,000 for the three-year project period will be awarded to selected organizations under this program in FY 93. OCS will award no less than 5 and no more than 10 grants under this program. Due to the limited funds available under this program only one grant will be allowed to any organization.

2. Project and Budget Periods

Project and budget periods will be 36 months. Full funding of the three-year project and budget periods in FY 93 assures stability for these 36 months.

3. Mobilization of Resources

OCS will give favorable consideration in the review process to applicants who mobilize cash and/or third-party in-kind contributions for direct use in the project. (See Part IV, Criterion VI.)

4. Program Participants/Beneficiaries

Projects proposed for funding under this announcement must result in direct benefits to low-income people as defined in the most recent Annual Revision of Poverty Income Guidelines published by DHHS and individuals eligible to receive Aid to Families with Dependent Children under Part A of Title IV of the Social Security Act.

Attachment A to this announcement is an excerpt from the guidelines currently in effect. Annual revisions of these guidelines are normally published in the Federal Register in February or early March of each year. Grantees will be required to apply the most recent guidelines throughout the project period. These revised guidelines also may be obtained at public libraries, Congressional offices, or by writing the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.

No other government agency or privately-defined poverty guidelines are applicable for the determination of low-income eligibility for this program.

5. Cooperative Partnership Agreement

A signed written agreement or letter of commitment between the applicant and the State IV-A agency must be submitted with the application in order to be reviewed and evaluated competitively. The agreement/letter must describe the cooperative relationship and include specific activities and/or actions that each of the entities proposes to carry out over the course of the grant period in support of the project. (Please review section II A for additional specific information related to this agreement.)

6. Prohibition and Restrictions on the Use of Funds

The use of funds for new construction or the purchase of real property is prohibited. Costs incurred for rearrangement and alteration of facilities
required specifically for the grant program are allowable when specifically approved by ACF in writing.

If the applicant is proposing a project which will affect a property listed in, or eligible for inclusion in the National Register of Historic Places, it must identify this property in the narrative and explain how it has complied with the provisions of section 106 of the National Historic Preservation Act of 1966 as amended. If there is any question as to whether the property is listed in or eligible for inclusion in the National Register of Historic Places, the applicant should consult with the State Historic Preservation Officer. (See Attachment D: SF-424B, Item 13 for additional guidelines.) The applicant should contact OCS early in the development of its application for instructions regarding compliance with the Act and data required to be submitted to the Department of Health and Human Services. Failure to comply with the cited Act must result in the application being ineligible for funding consideration.

7. Multiple Submittals

Due to the limited number of grants which will be made under this program, only one proposal from an eligible applicant will be funded by OCS for either the general project fund or the community development corporation set-aside fund.

8. Third-Party Project Evaluation

Projects also must include an independent, methodologically sound evaluation of the effectiveness of the activities carried out with the grant in creating new jobs and business opportunities.

9. Economic Development Strategy

Applicants must include an economic development strategy in accordance with the legislative reference cited in Part II, Section A.

10. Maintenance of Effort

The application must include an assurance that activities funded under this program announcement are in addition to, and not in substitution for, activities previously carried on without Federal assistance.

Part IV—Application Review Criteria

Applications which pass the pre-rating review will be assessed and scored by reviewers. Each reviewer will give a numerical score for each application reviewed. These numerical scores will be supported by explanatory statements on a formal rating form describing major strengths and weaknesses under each applicable criterion published in the announcement.

The in-depth assessment and review process will use the following criteria coupled with the specific requirements described in Part III. Scoring will be based on a total of 100 points.

(Note: the following review criteria reference the collection of information requirements contained in Part VI of this announcement. These requirements are approved under OMB Control Number 0970-0062 expiration 09-30-93.)

A. Criteria for Review and Assessment of Applications in Priority Areas 1.0 and 2.0

Criterion I: Organizational Experience in Program Area and Staff Responsibilities

(Maximum: 10 points)

(i) Organizational experience in program area. Documentation provided indicates that projects previously undertaken have been relevant and cost-effective and have provided permanent benefits to the low-income population.

The organization has detailed competence in the specific program area and as a deliverer with expertise in the area of technical assistance. The applicant has demonstrated the ability to implement major activities in such areas as human development, business development, economic development or financial services; the ability to mobilize funds from sources such as the private sector (corporations, banks, etc.), foundations, the public sector, including State and local governments, or individuals; that it has a sound organizational structure and proven organizational capability; and an ability to develop and maintain a stable program in terms of business or job creation activities that will provide needed permanent jobs and/or business development opportunities.

(Note: The maximum number of points will be given only to those organizations with a demonstrated record of achievement in promoting job creation and enterprise opportunities for low-income people.)

(ii) Staff skills, resources and responsibilities. The application describes in brief resume form the experience and skills of the project director who is not only well qualified, but his/her professional capabilities are relevant to the successful implementation of the project. If the key staff person has not yet been identified, the application contains a comprehensive position description which indicates that the responsibilities to be assigned to the project director are relevant to the successful implementation of the project. The assigned responsibilities of the staff are appropriate to the tasks identified for the project and sufficient time of senior staff will be budgeted to assume timely implementation and cost effective management of the project.

The applicant has included the minimum qualifications for the third-party evaluator (independent entity, i.e., an entity organizationally distinct from, and not under the control of the applicant). A third-party evaluator must have knowledge about and have experience in conducting process and outcome evaluations, evaluating issues in the job creation field, expansion of businesses and the creation of self-employment and small business opportunities for low-income neighborhoods and understands the complexity of the problems the target population faces. The competitive procurement regulations (45 CFR part 74, appendix G) apply to service contracts such as those for evaluators when the costs of such service will exceed $5,000.

The applicant should include an adequate position description for the third-party evaluator.

The applicant has described the facilities and resources (i.e., space, equipment, etc.) that it has available to carry out the project.

Criterion II: Analysis of Need

(Maximum: 10 points)

The applicant includes a description of the geographic area and population to be served as well as a discussion of the nature and extent of the problem to be solved. It should indicate what the unemployment rates are in the geographic areas to be served and (to the extent practicable) cites how the proposed businesses and subsequent jobs will impact on the nature and extent of the problem. It should also include documentation regarding the number and percentage of individuals receiving Aid to Families with Dependent Children and the total number of individuals which make up the population in the area where the project will operate.

Criterion III: Work Program

(Maximum: 25 points)

The work plan and business plan(s), where appropriate, are both sound and feasible. If the applicant is proposing to use project funds to provide technical and/or financial assistance to a third-party private employer to develop or expand a pre-identified business, the application must include a complete business plan. An application that does not include a business plan where one...
is appropriate may be disqualified and returned to the applicant.

The project is responsive to the needs identified in the Analysis of Need.

(i) Work plan. The work plan includes a hypothesis or hypotheses that is significant and that includes the key interventions and permits measurement of the extent to which the target population can achieve greater self-sufficiency as a result of its involvement in the project. The key interventions should include the types of technical and financial assistance to be provided to the recipients, the level of effort, as well as other activities. If the technical and/or financial assistance is to be provided to pre-identified businesses that will be expanded or franchised, written commitments from the businesses are included with the application. The work program sets forth realistic quarterly time targets by which the various work tasks will be completed. Critical issues or potential problems that might impact negatively on the project are defined and the project objectives can be reasonably attained despite such potential problems. The application provides a description of the process evaluation which will culminate in the development of a policies and procedures manual.

(ii) Business plan. The business plan, where appropriate, is one of the major components that will be evaluated by OCS to determine the feasibility of a Jobs Opportunities project. It must be well prepared and address all the major issues noted herein.

Because the guidelines were written to cover a variety of possibilities, rigid adherence to them is not possible nor even desirable for all projects. For example, a plan for a service business would not require a discussion of manufacturing nor product design. The business plan should include the following:

—The Business and its Industry. This section should describe the nature and history of the business if the proposal is an expansion of an existing business, including the following:

1. Products and services;  
2. Market research and evaluation (show that the product or service has a substantial market and can achieve sales in the face of competition);  
3. Marketing plan (including the estimated market share and sales)  
4. Manufacturing and operations plan (describe the kind of facilities, plant location, space, capital equipment and labor force [part and/or full-time wage structure] that are required to provide the company's product or service).

5. Critical risk and assumptions (include a description of the risks and critical assumptions relating to the industry, its personnel, the product's market appeal, and the timing and financing of the venture).

6. Community benefits (identify low-income individuals to be employed); and  
7. A financial plan (In developing the financial plan, the following exhibits must be prepared for the first three years of the business' operation: (a) Profit and Loss Forecasts—for each year; (b) Cash Flow Projections—for each year; (c) pro forma balance sheets—for each year; (d) initial uses of project funds; and (e) any future capital requirements and sources.

(iii) Facilities. If the rearrangement or alteration of facilities will be required in implementing the project, the applicant has described and justified such changes.

Criterion IV: Significant and Beneficial Impact (Maximum: 25 points)

(i) Quality of JOBS/business opportunities. The proposed project is expected to produce permanent and measurable results that will reduce the incidence of poverty in the community. Expected results are quantifiable in terms of the creation of permanent, full-time jobs or business opportunities developed. In developing business opportunities and self-employment for low-income individuals the applicant proposes, at a minimum, to provide basic business planning and management concepts, and assistance in preparing a business plan and loan package. The application documents that:

—The business opportunities to be developed for eligible participants will contribute significantly to their progress toward self-sufficiency; and/or  
—Jobs to be created for eligible participants will contribute significantly to their progress toward self-sufficiency; they provide, for example, wages that exceed the minimum wage, plus benefits such as health insurance, transportation, child care and career development opportunities.

(ii) Cost-per-job. During the project period the proposed project will create new, permanent jobs or business opportunities for low-income residents at a cost-per-job below $15,000 in OCS funds, (e.g. cost per job is calculated by dividing the total amount of grant funds requested ($420,000) divided by the number of jobs to be created (60) equals the cost-per-job ($7,000)). If any other calculations are used, please include your methodology in this section.  

[Note: Except in those instances where independent reviewers identify extenuating circumstances related to business development activities, the maximum number of points will be given only to those applicants proposing cost-per-job created estimates of $5,000 or less of OCS requested funds. Higher cost-per-job estimates will receive correspondingly fewer points.]

Criterion V: Third-Party Evaluation (Maximum: 10 points)

A plan for a methodological sound third-party (i.e. independent) evaluation of the demonstration project must be included in the application.

The Evaluation Plan:

—includes a specific working definition of "self-sufficiency" (consistent with the broad definition contained in Part I) that permits the measurement of incremental progress of eligible individuals and their families from dependency toward self-sufficiency;  
—clearly defines the changes or benefits (outcomes) to be produced, the activities (interventions) that will produce the changes, and the measures of client progress toward self-sufficiency for which information will be collected (for example: Increases in income, decreases in public assistance payments);  
—provides for the annual compilation of community-level data on the characteristics of the population in the project area, including percentage on public assistance, percentage below the poverty line, unemployment rate, business starts and failures, and major employers;  
—provides for the conduct of a continuing process evaluation. This should include the periodic assessment of the following: Client characteristics, pertinent policies and procedures, staffing, cooperative partnerships with state and local agencies, use of other community resources, client outreach and recruitment, client service delivery, cost of services, and level of technical and financial assistance to employers. The types of data and information, measures and indicators to be used for the process evaluation, as well as the methods and timeframe for collecting and analyzing the required data should be indicated;  
—provides for the completion of two interim evaluation reports and a final report. The final evaluation report will describe the program design and
any changes from the original workplan, outreach and recruitment results, interventions, and accomplishments. The measurement instruments, data collection procedures, and analysis techniques should be discussed, and the report should yield conclusions as to how well the program works and why. It should also discuss the program's potential for replication in other communities; and

- includes a realistic plan for disseminating the project findings to other interested organizations and public agencies.

Criterion VI: Public-Private Partnerships (Maximum: 15 points)

- The cooperative partnership arrangements are fully described and clearly relate to the objectives of the proposed project, and the activities include one or more of the mandatory or optional components of the State's JOBS program as described in Part II, Section A.

- The application documents that the applicant will mobilize from public and/or private sources cash and/or third-party in-kind contributions. Applications that document that the value of such contributions will be at least equal to the OCS funds requested, and demonstrate that the cooperative partnership arrangements clearly relate to the objectives of the proposed project, will receive the maximum number of points for this criterion. Lesser contributions will be given consideration based upon the value documented.

- Applicants should note that partnership relationships are not created via service delivery contracts; partners should be responsible for substantive project components or elements.

Criterion VII: Budget Appropriateness and Reasonableness (Maximum: 5 points)

Funds requested are commensurate with the level of effort necessary to accomplish the goals and objectives of the project.

The application includes a detailed budget break-down for each of the budget categories in the SF-424A. The applicant presents a reasonable administrative cost if an indirect cost rate has not been negotiated with the cognizant Federal agency (See Part VI, Section B, Line 6).

The estimated cost to the government of the project also is reasonable in relation to the anticipated results.

Part V—Application Procedures

A. Availability of Forms

Attachments B, C and D contain all of the standard forms necessary for the application for awards under this OCS program. These attachments and Parts D and F of this announcement contain all of the instructions required for submittal of applications. These forms may be photocopied for the application.

Copies of the Federal Register containing this announcement are available at most local libraries and Congressional District Offices for reproduction. If copies are not available at these sources, they may be obtained by writing or telephoning the office listed under the section entitled FOR FURTHER INFORMATION at the beginning of this announcement.

The applicant must be aware that in signing and submitting the application for this award, it is certifying that it will comply with the Federal requirements concerning the drug-free workplace and debarment regulations set forth in Attachments E and F.

B. Application Submission

The closing date for submission of applications is June 28, 1993.

1. Deadlines

Applications shall be considered as meeting the deadline if they are either:

a. Received on or before the deadline date at the Department of Health and Human Services, Administration for Children and Families, Division of Discretionary Grants, room 341–P–1, 200 Independence Avenue, SW., Washington, DC 20201, or

b. Sent on or before the deadline date and received by the granting agency in time for them to be considered during the competitive review and evaluation process under Chapter 1–62 of the Health and Human Services Grants Administration Manual. (Applicants are cautioned to request a legibly dated U.S. Postal Service postmark or to obtain a legibly dated receipt from a commercial carrier or the U.S. Postal Service. Private metered postmarks are not acceptable as proof of timely mailing.)

2. Applications Submitted by Other Means

Applications which are not submitted in accordance with the above criteria shall be considered as meeting the deadline only if they are physically received before the close of business on or before the deadline date. Hand delivered applications will be accepted at the Department of Health and Human Services, Administration for Children and Families, Division of Discretionary Grants, room 341–P–1, 200 Independence Avenue, SW., Washington, DC during the normal working hours of 8:30 a.m. to 5 p.m., Monday through Friday.

3. Late Applications

Applications which do not meet one of these criteria are considered late applications. The ACF Division of Discretionary Grants will notify each late applicant that its application will not be considered in this competition.

4. Extension of Deadline

The ACF Office of Community Services may extend the deadline for all applicants because of acts of God such as floods, hurricanes, etc. resulting in a disruption of the mails. However, if the granting agency does not extend the deadline for all applicants, it may not waive or extend the deadline for any applicant. Applicants are responsible to meet deadlines and are encouraged to submit applications as far in advance as possible to avoid unforeseen events which may inhibit their ability to submit an application on the closing date.

Applications once submitted are considered final and no additional materials will be accepted.

One signed original application and four copies should be submitted.

C. Intergovernmental Review

This program is covered under Executive Order 12372, "Intergovernmental Review of Federal Programs," and 45 CFR part 300, "Intergovernmental Review of Department of Health and Human Services Programs and Activities." Under the Order, States may design their own processes for reviewing and commenting on proposed Federal assistance under covered programs. All States and Territories except Alabama, Alaska, Idaho, Kansas, Louisiana, Minnesota, Nebraska, Pennsylvania, Oklahoma, Oregon, Virginia, Washington, American Samoa and Palau have elected to participate in the Executive Order process and have established Single Points of Contact (SPOCs).

Applicants from these fourteen jurisdictions need take no action regarding E.O. 12372. Applicants for projects to be administered by Federally-recognized Indian Tribes are also exempt from the requirements of E.O. 12372. Otherwise, applicants must submit any required material to the SPOCs as soon as possible to alert them of the prospective applications and
receive any necessary instructions, so that the ACF can obtain and review
SPOC comments as part of the award
process. It is imperative that the
applicant submit all required materials,
as and the SPOC and indicate the date
of this submittal (or the date of contact
if no submittal is required) on the
Standard Form 424, Item 16a.

Under 45 CFR 100.8(a)(2), a SPOC has
45 days from the application deadline
to comment on proposed new
awards. SPOCs are encouraged to
eliminate the submission of routine
endorsements as official
recommendations. Additionally, SPOCs
are requested to clearly differentiate
between mere advisory comments and
those official State process
recommendations which they intend to
triger the "accommodate or explain"
rule under 45 CFR 100.10.

When comments are submitted
directly to ACF, they should be
addressed to: Department of Health and
Human Services, Administration for
Children and Families, Division of
Discretionary Grants, 200 Independence
Avenue SW., room 341-F-1,
Washington, DC 20201.

A list of the Single Points of Contact
during application review for each State Territory is included as Attachment G of this announcement.

D. Application Consideration of OCS
Specific Requirements

Applications which meet the
screening requirements in Part V item E
below will be reviewed competitively.
Such applications will be referred to
reviewers for a numerical score and
explanatory comments based solely on
responsiveness to the guidelines and
evaluation criteria published in this
announcement.

Applications will be reviewed by
persons outside of the OCS unit which
will be directly responsible for
programmatic management of the grant.
The results of these reviews will assist
the Director and OCS program staff in
considering competing applications.
Reviewers’ scores will weigh heavily in
funding decisions but will not be the
only factors considered. Applications
generally will be considered in order of
the average scores assigned by
reviewers. However, highly ranked
applications are not guaranteed funding
since other factors are taken into
consideration including, but not limited to,
the timely and proper completion of
projects funded with OCS funds granted
in the last five (5) years; comments of
reviewers and government officials; staff
evaluation of the proposal; geographic
distribution; previous program
performance of applicants; compliance
with grant terms under previous DHHS
grants; audit reports; investigative
reports; and applicant’s progress in
resolving any final audit disallowances
on previous OCS or other Federal
agency grants.

OCS reserves the right to discuss
applications with other Federal or non-
Federal funding sources to ascertain the
applicant’s performance record.

E. Criteria for Screening Applicants

1. Initial Screening

All timely applicants will receive an
acknowledgement with an assigned
identification number. This number,
along with any identification code, must
be referenced in all subsequent
communications concerning the
application. If an acknowledgement is
not received within three weeks after
the deadline date, please notify
ACF by telephone at (202) 690-8243.

All applications that meet the
published deadline for submission will
be screened to determine completeness
and conformity to the requirements of
this announcement. Only those
applications meeting the following
requirements will be reviewed and
evaluated competitively. Others will be
returned to the applicants with a
notation that they were unacceptable.

a. The applications must contain a
Standard Form 424, "Application for
Federal Assistance" (SF-424), a budget
(SF-424A), and signed "Assurances"
(SF-424B) completed according to
instructions published in this announcement.

b. A project narrative must also accompany the standard forms.

c. The SF-424 and the SF-424B must be signed by an official of the
organization applying for the grant who has authority to obligate the
organization legally.

2. Pre-Rating Review

Applications which pass the initial
screening will be forwarded to
reviewers and/or OCS staff prior to the
programmatic review to verify that the
applications comply with this Program
Announcement in the following areas:

a. Eligibility: Applicant meets the
eligibility requirements described in
Part I, Section B. Proof of non-profit
status must be included in the
Appendices to the Project Narrative (See
Part VII, Section A, 11).

b. Applicant’s legal name as required
in the SF-424 is matched with the
Employer Identification Number (Item 6).

c. Target populations: The application
clearly targets the specific outcomes and
benefits of the project to those types of
low-income participants and
beneficiaries described in Part III,
Section A. Program Participants/
Beneficiaries.

d. Cooperative partnership
Agreement. The application contains a
written agreement or letter of
commitment that includes, at a
minimum, the activities cited in Part II,
Section A. The agreement must be
signed by an official of the agency
responsible for administering the JOBS
program in the area to be served.

e. Third-party project evaluation. A
third-party project evaluation plan is included.

f. Business plan. If a third-party
private employer is part of the proposed
project, a complete business plan is included in the application.
An application will be disqualified
from the competition and returned if it
does not conform to all of the above
requirements.

Part VI—Instructions for Completing
Application Package

[Approved by the Office of Management
and Budget under Control Number
0970-0062 date of expiration 09-30-
93.]

The standard forms attached to this
announcement shall be used to apply
for funds under this program
announcement.

It is suggested that you reproduce
the SF-424 and SF-424A, and type your
application on the copies. In order to
assist applicants in correctly completing
the SF-424, and SF-424A. Please
prepare your application in accordance
with the following:

A. SF-424—"Application for Federal Assistance"

Top of Page

Please enter the single priority area
number under which the application is
being submitted. An application should
be submitted under only one priority
area.

Item 1. For the purposes of this
announcement, all projects are
considered “Applications”; there are no
“Pre-Applications.”

Prepare your application in
accordance with the standard
instructions given in Attachments B
and C corresponding to the forms, as well as
the OCS specific instructions set forth
below:

Item 2. “Date Submitted” and
“Applicant Identifier”—Date
application is submitted to ACF and
applicant's own internal control number, if applicable.

Item 3. "Date Received by State"—N/A

Item 4. "Date Received by Federal Agency"—Leave blank.

Items 5 and 6. The legal name of the applicant must match that listed as corresponding to the Employer Identification Number. Where the applicant is a previous Department of Health and Human Services grantees, enter the Central Registry System Employee Identification Number CRS/ EIN and the Payment Identifying Number, if one has been assigned, in the Block entitled "Federal Identifier", located at the top right hand corner of the form.

Item 7. If the applicant is a non-profit corporation, enter "N" in the box and specify "non-profit corporation" in the space marked "Other." Proof of non-profit status, such as IRS determination, Articles of Incorporation, or By-laws, must be included as an appendix to the project narrative.

Item 8. "Type of Application"—
Please indicate the type of application.

Item 9. "Name of Federal Agency"—
Enter DHHS-ACF/OCS.

Item 10. "The Catalog of Federal Domestic Assistance number for OCS programs covered under this announcement is 93.561. The title is "Job Opportunities for Low-Income Individuals Program (Demonstration Projects)."

Item 11. In addition to a brief descriptive title of the project, indicate for which priority area funds are being requested. The following letter designations must be used:

JQ—General Project
JS—Community Development Corporation Set-Aside

Item 12. "Areas Affected by Project"—List only the largest unit or units affected, such as State, county or city.

Item 13. "Proposed Project"—Enter the desirable starting date for the project and the proposed completion date.

Item 14. "Congressional District of Applicant/Project"—Enter the number of the Congressional District where the applicant's principal office is located and the number of the Congressional district(s) where the project will be located.

Item 15a. For purposes of this Announcement, this amount should reflect the amount requested for the entire project period. This amount should be no greater than the maximum amount specified in the priority area description.

Item 15b-e. These items should reflect both cash and third-party, in-kind contributions for the total project period.

Item 15f. N/A

Item 15g. Enter the sum of Items 15a–15e.

B. SF-424A—"Budget Information—Non-Construction Programs"

See instructions accompanying this form as well as the instructions set forth below:

In completing these sections, the "Federal Funds" budget entries will relate to the requested OCS funds only, and "Non-Federal" will include mobilized funds from all other sources—applicant, state, local, and other. Federal funds other than requested OCS funding should be included in "Non-Federal" entries.

Sections A and D of SF-424A must contain entries for both Federal (OCS) and non-Federal (mobilized) funds for the total project period. Section B contains entries for Federal (OCS) funds only.

Section A—Budget Summary

Lines 1–4

Col. (a):
Line 1—Enter "Job Opportunities for Low-Income Individuals".
Col. (b):
Line 1—Catalog of Federal Domestic Assistance number 93.561.
Col. (c) and (d):
Columns (c) and (d) are not relevant to this program and should not be completed.
Column (e)–(g)
For line 1, enter in columns (e), (f) and (g) the appropriate amounts needed to support the project for the entire project period. (Maximum $500,000)
Line 5—Enter the figures from Line 1 for all columns completed (e), (f), and (g).

Section B—Budget Categories

Please Note: This information supersedes the instructions provided following SF-424A.

This section (B) should contain entries for OCS funds only.

Columns (1)–(5):
Column 1: Enter the first budget period of 12 months.
Column 2: Enter the second budget period of 12 months.
Column 3: Enter the third budget period of 12 months.
Column 4: Leave blank.
Column 5: Enter the total requirements for Federal funds by the Object Class Categories of this section.

Allocability of costs are governed by the cost principles set forth in OMB Circular A-122 and 45 CFR part 74.

Budget estimates for national administrative costs must be supported by adequate detail for the grants officer to perform a cost analysis and review. Adequately detailed calculations for each budget object class are those which reflect estimation methods, quantities, unit costs, salaries, and other similar quantitative detail sufficient for the calculation to be duplicated. For any additional object class categories included under the object class "other" identify the additional object class(es) and provide supporting calculations.

Supporting narratives and justifications are required for each budget category, with emphasis on unique/special initiatives large dollar amounts; local, regional, or other travels new positions; major equipment purchases and training programs.

A detailed itemized budget with a separate budget justification for each major item should be included as indicated below:

Personnel-line 6a. Enter the total costs of salaries and wages.

Justification: Identify the principal investigator or project director, if known. Specify by title or name the percentage of time allocated the project, the individual annual salaries, and the cost to the project of the organization's staff who will be working on the project. Do not include costs of consultants or personnel costs of delegate agencies or of specific project(s) or businesses to be financed by the applicant.

Fringe benefits-line 6b. Enter the total costs of fringe benefits unless treated as part of an approved retirement cost rate which is entered on line 6j.

Justification: Provide a breakdown of amounts and percentages that comprise fringe benefit costs, such as health insurance, FICA, retirement insurance, taxes, etc.

Travel-line 6c. Enter total costs of all travel by employees of the project. Do not enter costs for consultants' travel.

Justification: Include the total number of traveler(s), total number of trips, destinations, number of days, transportation costs and subsistence allowances. Travel costs to attend two national workshops in Washington, DC by the project director should be included.

Equipment-Line 6d. Enter the total costs of all non-expendable personal property to be acquired by the project. "Non-expendable personal property" means tangible personal property having an acquisition cost per unit of $500 or more for non-profit organizations and $5,000 or more for public organizations and having a useful life of one year.

Justification: Only equipment required to conduct the project may be purchased with Federal funds. The
applicant organization or its subgrantees must not have such equipment, or a reasonable facsimile, available for use in the project. The justification also must contain plans for future use or disposal of the equipment after the project ends. An applicant may use its own definition of non-expendable personal property, provided that such a definition would at least include all tangible personal property as defined above. (See Line 21 for additional requirements).

**Supplies**-line 6e. Enter the total costs of all tangible personal property (supplies) other than that included on line 6d.

**Justification:** Specify general categories of supplies and their costs.

**Contractual-line 6f.** Enter the total costs of all contracts, including (1) the estimated cost of the third-party evaluation contract; travel costs for the chief evaluator to attend two national workshops in Washington, DC should be included; (2) procurement contracts (except those which belong on other lines such as equipment, supplies, etc.) and (3) contracts with secondary recipient organizations including delegate agencies and specific project(s) or businesses to be financed by the applicant.

**Justification:** Attach a list of contractors, indicating the names of the organizations, the purposes of the contracts, the estimated dollar amounts, and selection process of the awards as part of the budget justification. Also provide back-up documentation identifying the name of contractor, purpose of contract, and major cost elements.

Note: Whenever the applicant/grantee intends to delegate part of the program to another agency, the applicant/grantee must submit Sections A and B of this Form SF-424A, completed for each delegate agency by the applicant/grantee, along with the required supporting information referenced in the applicable instructions. The total costs of all such agencies will be part of the amount shown on Line 6f. Provide draft Request for Proposal in accordance with 45 CFR part 74, appendix H. Applicants who anticipate evaluation procurements that will exceed $5,000 and are requesting an award without competition should include a sole source justification in the proposal which at a minimum should include the basis for contractor’s selection, a description of the survey conducted of other service providers, justification for lack of competition when competitive bids or offers are not obtained and basis for award cost or price.

(Note: Previous or past experience with a contractor is not sufficient justification for sole source.)

For successful applicants, the Notice of Grant Award will cite under Remarks, item 18, approval of this action. Also include any contracts with organizations for the provision of technical assistance.

**Construction-line 6g.** Not applicable.

**Other-line 6h.** Enter the total of all other costs. Such costs, where applicable, may include but are not limited to insurance, food, medical and dental costs (noncontractual), fees and travel paid directly to individuals, consultants, space and equipment rentals, printing and publication, computer use, travel costs, including tuition and stipends, training services costs including wage payments to individuals and supportive service payments, and staff development costs.

**Total direct charges-lines 6i.** Show the total of Lines 6a through 6h.

**Indirect charges-line 6j.** Enter the total amount of indirect costs. This line should be used only when the applicant currently has an indirect cost rate approved by the Department of Health and Human Services or another cognizant Federal agency. With the exception of local governments, applicants should enclose a copy of the current rate agreement if it was negotiated with a cognizant Federal agency other than the Department of Health and Human Services. If the applicant organization is in the process of developing or renegotiating a rate, it should immediately upon notification that an award will be made, develop a tentative indirect cost rate proposal based on its most recently completed fiscal year in accordance with the principles set forth in the pertinent DHHS Guide for Establishing Indirect Cost Rates, and submit it to the appropriate DHHS Regional Office. Applicants awaiting approval of their indirect cost proposals may also request indirect costs. It should be noted that when an indirect cost rate is requested, those costs included in the indirect cost pool should not be also charged as direct costs to the grant.

**Totals-line 6k.** Enter the total amounts of Lines 6i and 6j.

**Program income-line 7.** Enter the estimated amount of income, if any, expected to be generated from this project. Separately show expected program income generated from OCS support and income generated from other mobilized funds. Do not add or subtract this amount from the budget total. Show the nature and source of income in the program narrative statement.

**Justification:** Describe the nature, source and anticipated use of program income in the Program Narrative Statement. Column 5: Carry totals from Column 1 to Column 5 for all line items.

---

**Section C—Non-Federal Resources**

This section is to record the amounts of "non-Federal" resources that will be used to support the project. "Non-Federal" resources mean those other than OCS funds. Therefore, mobilized funds from other Federal programs should be entered on these lines. Provide a brief listing of the non-Federal resources on a separate sheet and describe whether it is a grantee-incurred cost or a third-party in-kind contribution. The firm commitment of these resources must be documented and submitted with the application in order to be given credit in the Public-Private Partnerships criterion.

Except in unusual situations, this documentation must be in the form of letters of commitment from the organization(s)/individuals from which funds will be received.

**Justification:** Describe third-party, in-kind contributions, if included.

**Grant program-line 8.**

Column (a): Enter the project title.

Column (b): Enter the amount of contributions to be made by the applicant to the project.

Column (c): Enter the State contribution. If the applicant is a State agency, enter the non-Federal funds to be contributed by the State other than the applicant.

Column (d): Enter the amount of cash and third-party in-kind contributions to be made from all other sources.

Column (e): Enter the total of columns (b), (c), and (d).

**Grant program-lines 9, 10, and 11 should be left blank.**

**Grant program-line 12.** Carry the total of each column of Line 8, (a) through (e).

The amount in Column (e) should be equal to the amount on Section A, Line 5, column (f).

**Section D—Forecasted Cash Needs**

**Federal-line 13.** Enter the amount of Federal (OCS) cash needed for this grant, by quarter, during the first 12-month budget period.

**Non-federal-line 14.** Enter the amount of cash from all other sources needed by quarter during the first year.

**Totals-line 15.** Enter the total of Lines 13 and 14.

**Section E—Budget Estimates of Federal Funds Needed for Balance of Project(s)**

Not applicable.

**Section F—Other Budget Information**

**Direct charges-line 21.** Use this space and continuation sheets as necessary to fully explain and justify the major items included in the budget categories shown in Section B. Include sufficient detail to facilitate determination of allowability.
relevance to the project, and cost benefits. Particular attention must be given to the explanation of any requested direct cost budget item which requires explicit approval by the Federal agency. Budget items which require identification and justification shall include, but not be limited to, the following:

A. Salary amounts and percentage of time worked for those key individuals who are identified in the project narrative;
B. Any foreign travel;
C. A list of all equipment and estimated cost of each item to be purchased wholly or in part with grant funds which meet the definition of nonexpendable personal property provided on Line 6d, Section B. Need for equipment and non-expendable materials shall be explained in program narrative;
D. Contractual: major items or groups of smaller items; and
E. Other: group into major categories all costs for consultants, local transportation, space, rental, training allowances, staff training, computer equipment, etc. Provide a complete breakdown of all costs that make up this category.

Indirect charges-line 22. Enter the type of HHS or other cognizant Federal agency approved indirect cost rate (provisional, predetermined, final or fixed) that will be in effect during the funding period, the estimated amount of the base to which the rate is applied and the total indirect expense. Also, enter the date the rate was approved and return the “Assurances” with the application which can be attached to this acknowledgment postcard. This number and the program letter code must be referred to in all subsequent communication with OCS concerning the application. If an acknowledgment is not received within three weeks after the deadline date, please notify ACF by telephone (202) 690-8243.

Part VII—Contents of Application and Receipt Process

A. Contents of Application

Each application submission should include a signed original and four additional copies of the application. Each application should include the following in the order presented:

1. Table of Contents;
2. Completed Standard Form 424 which has been signed by an Official of the organization applying for the grant who has authority to obligate the organization legally; and

4. A narrative budget justification for each object class category required under Section B, SF-424A.
5. Filled out, signed, and dated “Assurance—Non-Construction Programs” (SF-424B).
6. By signing and submitting this application, the applicant is certifying that it will comply with the Federal requirements concerning debarment regulations set forth in attachments E and F.

7. Restrictions on Lobbying, Certification for Contracts, Grants, Loans, and Cooperative Agreements: fill out, sign and date form found at Attachment H.
8. Disclosure of Lobbying Activities, SF-LLL: Fill out, sign, and date form found at Attachment H, if appropriate.
9. An Executive Summary—not to exceed 300 words.
10. A Project Narrative consisting of the following elements preceded by a consecutively numbered Table of Contents that will describe the project in the following order:
   (i) Eligibility Confirmation
   (ii) Organizational Experience and Staff Responsibilities
   (iii) Analysis of Need
   (iv) Project Design/Work Program
   (v) Business Plan (If appropriate)
   (vi) Third-Party Evaluation
   (vii) Cooperative Partnership Agreement
   (viii) Budget Appropriateness and Reasonableness
11. Appendices, including proof of non-profit status; proof that the organization is a community development corporation, if applying under the CDC Set-aside; commitments from officials of businesses that will be expanded or from franchises, where applicable; Maintenance of Effort Certification and resumes.

The total number of pages for the entire application package, excluding Appendices, should not exceed 50 pages. Pages should be numbered sequentially throughout, excluding Appendices, beginning with the SF-424 as Page 1.

Applications must be uniform in composition since OCS may find it necessary to duplicate them for review purposes. Therefore, applications must be submitted on white 8½ x 11 inch paper only. They must not include colored, oversized or folded materials. Do not include organizational brochures or other promotional materials, slides, films, clips, etc. in the proposal. They will be discarded if included. The applications should be two-holed punched at the top center and fastened separately with a compressor slide paper fastener, or a binder clip. The submission of bound applications, or applications enclosed in binders, is specifically discouraged.

Attachment K provides a checklist to applicants in preparing a complete application package.

B. Acknowledgment of Receipt

Applicants who meet the initial screening criteria outlined in part V, section E, 1, will receive an acknowledgment postcard with an assigned identification number. Applicants are requested to supply a self-addressed mailing label with their application which can be attached to this acknowledgment postcard. This number and the program letter code must be referred to in all subsequent communication with OCS concerning the application. If an acknowledgment is not received within three weeks after the deadline date, please notify ACF by telephone (202) 690-8243.

Part VIII—Post Award Information and Reporting Requirements

Following approval of the applications selected for funding, notice of project approval and authority to draw down project funds will be made in writing. The official award document is the Notice of Grant Award which provides the amount of Federal funds approved for use in the project, the project and budget period for which support is provided, the terms and conditions of the award, and the total project period for which support is contemplated.

Project directors and chief evaluators will be required to attend two national evaluation workshops in Washington, DC. A program planning and evaluation workshop will be scheduled shortly after the effective date of the grant. They also will be required to attend, as presenters, the final evaluation workshop on utilization and dissemination to be held at the end of the project period.

Grantees will be required to submit quarterly progress and financial reports (SF 269) as well as a final progress and financial report within 90 days of the expiration of the grant. Interim evaluation reports, along with a written policies and procedures manual based on the findings of the process evaluation, will be due 30 days after the first twelve months, and the second interim evaluation 30 days after the second twelve months, and a final evaluation report will be due 180 days after the expiration of the grant. This final report will cover 36 months of activities related to project participants.
Grantees are subject to the audit requirements in 45 CFR parts 74 (non-profit organization) and OMB Circular A-133.

Section 319 of Public Law 101-121, signed into law on October 23, 1989, imposes new prohibitions and requirements for disclosure and certification related to lobbying on recipients of Federal contracts, grants, cooperative agreements, and loans. It provides limited exemptions for Indian tribes and tribal organizations. Current and prospective recipients (and their sub-tier contractors and/or grantees) are prohibited from using appropriated funds for lobbying Congress or any Federal agency in connection with the award of a contract, grant, cooperative agreement or loan. In addition, for each award action in excess of $100,000 (or $150,000 for loans) the law requires recipients and their sub-tier contractors and/or subgrantees (1) to certify that they have neither used nor will use any appropriated funds for payment to lobbyists, (2) to submit a declaration setting forth whether payments to lobbyists have been or will be made out of non-appropriated funds and, if so, the name, address, payment details, and purpose of any agreements with such lobbyists whom recipients or their sub-tier contractors or subgrantees will pay with the non-appropriated funds and (3) to file quarterly updates about the use of lobbyists if an event occurs that materially affects the accuracy of the information submitted by way of declaration and certification. The law establishes civil penalties for noncompliance and is effective with respect to contracts, grants, cooperative agreements and loans entered into or made on or after December 23, 1989. See Attachment H for certification and disclosure forms to be submitted with the applications for this program.

Attachment I indicates the regulations which apply to all applicants/grantees under the Discretionary Grants Program.

Dated: April 9, 1993.
Jacqueline G. Lemire,
Acting Director, Office of Community Services.

ATTACHMENT A—1993 POVERTY INCOME GUIDELINES FOR ALL STATES (EXCEPT ALASKA AND HAWAI)

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<td>8</td>
<td>30,260</td>
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For family units with more than 8 members, add $3,080 for each additional member.

ATTACHMENT A—1993 POVERTY INCOME GUIDELINES FOR ALASKA

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<td>27,780</td>
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For family units with more than 8 members, add $3,080 for each additional member.

ATTACHMENT A—1993 POVERTY INCOME GUIDELINES FOR HAWAI

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<th>Size of family unit</th>
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For family units with more than 8 members, add $2,460 for each additional member.

BILLING CODE 4184-01-11
**APPLICATION FOR FEDERAL ASSISTANCE**

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<td>Address (give city, county, state, and zip code)</td>
<td>Name and telephone number of the person to be contacted on matters involving this application (give area code)</td>
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<th>7. TYPE OF APPLICANT: (enter appropriate letter in box)</th>
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<td>A. State</td>
<td>H. Independent School Dist.</td>
</tr>
<tr>
<td>B. County</td>
<td>I. State Controlled Institution of Higher Learning</td>
</tr>
<tr>
<td>C. Municipal</td>
<td>J. Private University</td>
</tr>
<tr>
<td>D. Township</td>
<td>K. Indian Tribe</td>
</tr>
<tr>
<td>E. Interstate</td>
<td>L. Individual</td>
</tr>
<tr>
<td>F. Intermunicipal</td>
<td>M. Profit Organization</td>
</tr>
<tr>
<td>G. Special District</td>
<td>N. Other (Specify)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>8. TYPE OF APPLICATION:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>New</td>
<td>Continuation</td>
</tr>
<tr>
<td>Revision</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>9. NAME OF FEDERAL AGENCY:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>12. AREAS AFFECTED BY PROJECT (Cities, counties, states, etc.):</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>13. PROPOSED PROJECT:</th>
<th>14. CONGRESSIONAL DISTRICTS OF:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Start Date</td>
<td>Ending Date</td>
</tr>
<tr>
<td>a. Applicant</td>
<td>b. Project</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>15. ESTIMATED FUNDING:</th>
<th>16. IS APPLICATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 12372 PROCESS?</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Federals</td>
<td>a. YES THIS PREAPPLICATION/APPLICATION WAS MADE AVAILABLE TO THE STATE EXECUTIVE ORDER 12372 PROCESS FOR REVIEW ON</td>
</tr>
<tr>
<td>$</td>
<td>DATE ____________________________________________________________________</td>
</tr>
<tr>
<td>b. Applicant</td>
<td>b. NO □ PROGRAM IS NOT COVERED BY E.O. 12372</td>
</tr>
<tr>
<td>$</td>
<td>□ OR PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW</td>
</tr>
<tr>
<td>c. State</td>
<td>□ No</td>
</tr>
<tr>
<td>$</td>
<td></td>
</tr>
<tr>
<td>d. Local</td>
<td></td>
</tr>
<tr>
<td>$</td>
<td></td>
</tr>
<tr>
<td>e. Other</td>
<td></td>
</tr>
<tr>
<td>$</td>
<td></td>
</tr>
<tr>
<td>f. Program income</td>
<td></td>
</tr>
<tr>
<td>$</td>
<td></td>
</tr>
<tr>
<td>g. TOTAL</td>
<td></td>
</tr>
<tr>
<td>$</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>17. IS THE APPLICANT DELINQUENT ON ANY FEDERAL DEBT?</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Yes</td>
<td></td>
</tr>
<tr>
<td>□ No</td>
<td></td>
</tr>
<tr>
<td>If &quot;Yes,&quot; attach an explanation</td>
<td></td>
</tr>
</tbody>
</table>

18. TO THE BEST OF MY KNOWLEDGE AND BELIEF, ALL DATA IN THIS APPLICATION/PREAPPLICATION ARE TRUE AND CORRECT. THE DOCUMENT HAS BEEN DULY AUTHORIZED BY THE GOVERNING BODY OF THE APPLICANT AND THE APPLICANT WILL COMPLY WITH THE ATTACHED ASSURANCES IF THE ASSISTANCE IS AWARDED.

<table>
<thead>
<tr>
<th>a. Typed Name of Authorized Representative</th>
<th>b. Title</th>
<th>c. Telephone number</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>d. Signature of Authorized Representative</td>
<td>e. Date Signed</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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Standard Form 424 (REV 4-88) Prescribed by OMB Circular A-102
Instructions for the SF 424

This is a standard form used by applicants as a required facesheet for preapplications and applications submitted for Federal assistance. It will be used by Federal agencies to obtain applicant certification that States which have established a review and comment procedure in response to Executive Order 12372 and have selected the program to be included in their process, have been given an opportunity to review the applicant's submission.

Item and Entry:
1. Self-explanatory.
2. Date application submitted to Federal agency (or State if applicable) & applicant's control number (if applicable).
3. State use only (if applicable).
4. If this application is to continue or revise an existing award, enter present Federal identifier number. If for a new project, leave blank.
5. Legal name of applicant, name of primary organizational unit which will undertake the assistance activity, complete address of the applicant, and name and telephone number of the person to contact on matters related to this application.
6. Enter Employer Identification Number (EIN) as assigned by the Internal Revenue Service.
7. Enter the appropriate letter in the space provided.
8. Check appropriate box and enter appropriate letter(s) in the space(s) provided:
   - "New" means a new assistance award.
   - "Continuation" means an extension for an additional funding/budget period for a project with a projected completion date.
   - "Revision" means any change in the Federal Government's financial obligation or contingent liability from an existing obligation.
9. Name of Federal agency from which assistance is being requested with this application.
10. Use the Catalog of Federal Domestic Assistance number and title of the program under which assistance is requested.
11. Enter a brief descriptive title of the project. If more than one program is involved, you should append an explanation on a separate sheet. If appropriate (e.g., construction or real property projects), attach a map showing project location. For preapplications, use a separate sheet to provide a summary description of this project.
12. List only the largest political entities affected (e.g., State, counties, cities).
14. List the applicant's Congressional District and any District(s) affected by the program or project.
15. Amount requested or to be contributed during the first funding/budget period by each contributor. Value of in-kind contributions should be included on appropriate lines as applicable. If the action will result in a dollar change to an existing award, indicate only the amount of the change. For decreases, enclose the amounts in parentheses. If both basic and supplemental amounts are included, show breakdown on an attached sheet. For multiple program funding, use totals and show breakdown using same categories as item 15.
16. Applicants should contact the State Single Point of Contact (SPOC) for Federal Executive Order 12372 to determine whether the application is subject to the State's intergovernmental review process.
17. This question applies to the applicant organization, not the person who signs as the authorized representative. Categories of debt include delinquent audit disallowances, loans and taxes.
18. To be signed by the authorized representative of the applicant. A copy of the governing body's authorization for you to sign this application as official representative must be on file in the applicant's office. (Certain Federal agencies may require that this authorization be submitted as part of the application.)

BILLING CODE 4100-01-M
## BUDGET INFORMATION — Non-Construction Programs

### SECTION A - BUDGET SUMMARY

<table>
<thead>
<tr>
<th>Grant Program Function or Activity (a)</th>
<th>Catalog of Federal Domestic Assistance Number (b)</th>
<th>Estimated Unobligated Funds</th>
<th>New or Revised Budget</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Federal (c)</td>
<td>Non-Federal (d)</td>
<td>Federal (e)</td>
</tr>
<tr>
<td>1.</td>
<td>$</td>
<td>$</td>
<td>$</td>
</tr>
<tr>
<td>2.</td>
<td>$</td>
<td>$</td>
<td>$</td>
</tr>
<tr>
<td>3.</td>
<td>$</td>
<td>$</td>
<td>$</td>
</tr>
<tr>
<td>4.</td>
<td>$</td>
<td>$</td>
<td>$</td>
</tr>
<tr>
<td>5. TOTALS</td>
<td>$</td>
<td>$</td>
<td>$</td>
</tr>
</tbody>
</table>

### SECTION B - BUDGET CATEGORIES

<table>
<thead>
<tr>
<th>GRANT PROGRAM FUNCTION OR ACTIVITY</th>
<th>Total (5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>6. Object Class Categories</td>
<td></td>
</tr>
<tr>
<td>a. Personnel</td>
<td></td>
</tr>
<tr>
<td>b. Fringe Benefits</td>
<td></td>
</tr>
<tr>
<td>c. Travel</td>
<td></td>
</tr>
<tr>
<td>d. Equipment</td>
<td></td>
</tr>
<tr>
<td>e. Supplies</td>
<td></td>
</tr>
<tr>
<td>f. Contractual</td>
<td></td>
</tr>
<tr>
<td>g. Construction</td>
<td></td>
</tr>
<tr>
<td>h. Other</td>
<td></td>
</tr>
<tr>
<td>i. Total Direct Charges (sum of 6a-6h)</td>
<td></td>
</tr>
<tr>
<td>j. Indirect Charges</td>
<td></td>
</tr>
<tr>
<td>k. TOTALS (sum of 6i and 6j)</td>
<td></td>
</tr>
<tr>
<td>7. Program Income</td>
<td></td>
</tr>
</tbody>
</table>
### SECTION C - NON-FEDERAL RESOURCES

<table>
<thead>
<tr>
<th>(a) Grant Program</th>
<th>(b) Applicant</th>
<th>(c) State</th>
<th>(d) Other Sources</th>
<th>(e) TOTALS</th>
</tr>
</thead>
<tbody>
<tr>
<td>8.</td>
<td>$</td>
<td>$</td>
<td>$</td>
<td>$</td>
</tr>
<tr>
<td>9.</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>10.</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>11.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12. TOTALS (sum of lines 8 and 11)</td>
<td>$</td>
<td>$</td>
<td>$</td>
<td>$</td>
</tr>
</tbody>
</table>

### SECTION D - FORECASTED CASH NEEDS

<table>
<thead>
<tr>
<th>13. Federal</th>
<th>1st Quarter</th>
<th>2nd Quarter</th>
<th>3rd Quarter</th>
<th>4th Quarter</th>
</tr>
</thead>
<tbody>
<tr>
<td>$</td>
<td>$</td>
<td>$</td>
<td>$</td>
<td>$</td>
</tr>
</tbody>
</table>

| 14. NonFederal |           |           |           |           |
| 15. TOTAL (sum of lines 13 and 14) | $ | $ | $ | $ |

### SECTION E - BUDGET ESTIMATES OF FEDERAL FUNDS NEEDED FOR BALANCE OF THE PROJECT

<table>
<thead>
<tr>
<th>16. Grant Program</th>
<th>FUTURE FUNDING PERIODS (Years)</th>
<th>(b) First</th>
<th>(c) Second</th>
<th>(d) Third</th>
<th>(e) Fourth</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>$</td>
<td>$</td>
<td>$</td>
<td>$</td>
</tr>
<tr>
<td>17.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>19.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>20. TOTALS (sum of lines 16 -19)</td>
<td>$</td>
<td>$</td>
<td>$</td>
<td>$</td>
<td></td>
</tr>
</tbody>
</table>

### SECTION F - OTHER BUDGET INFORMATION

(Attach additional Sheets if Necessary)

21. Direct Charges:

22. Indirect Charges:

23. Remarks

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Instructions for the SF-424A

General Instructions

This form is designed so that application can be made for funds from one or more grant programs. In preparing the budget, adhere to any existing Federal grantor agency guidelines which prescribe how and whether budgeted amounts should be separately shown for different functions or activities within the program. For some programs, grantor agencies may require budgets to be separately shown by function or activity. For other programs, grantor agencies may require a breakdown by function or activity. Sections A, B, C, and D should provide budget estimates for the whole project except when applying for assistance which requires Federal authorization in annual or other funding period increments. In the latter case, Sections A, B, C, and D should provide for the first budget period (usually a year) and Section E should present the need for Federal assistance in the subsequent budget periods. All applications should contain a brief description of the object class categories shown in Lines e-k of Section B.

Section A. Budget Summary—Lines 1-4, Columns (a) and (b)

For applications pertaining to a single Federal grant program (Federal Domestic Assistance Catalog number) and not requiring a functional or activity breakdown, enter on Line 1 under Column (a) the catalog program title and the catalog number in Column (b).

For applications pertaining to a single program requiring budget amounts by multiple functions or activities, enter the name of each activity or function on each line in Column (a), and enter the catalog number in Column (b). For applications pertaining to multiple programs where none of the programs require a breakdown by function or activity, enter the catalog program title on each line in Column (a) and the respective catalog number on each line in Column (b).

For applications pertaining to multiple programs where one or more programs require a breakdown by function or activity, prepare a separate sheet for each program requiring the breakdown. Additional sheets should be used when one form does not provide adequate space for breakdown of data required. However, when more than one sheet is used, the first page should provide the summary totals by programs.

Lines 1-4, Columns (c) Through (g)

For new applicants, leave Columns (c) and (d) blank. For each line entry in Columns (a) and (b), enter in Columns (c), (d), (f), and (g) the appropriate amounts of funds needed to support the project for the first funding period (usually a year).

For continuing grant program applications, submit these forms before the end of each funding period as required by the grantor agency. Enter in Columns (c) and (d) the estimated amounts of funds which will remain unobligated at the end of the grant funding period only if the Federal grantor agency instructions provide for this. Otherwise, leave these columns blank. Enter in Columns (e) and (f) the amounts of funds needed for the upcoming period.

The amount(s) in Column (g) should be the sum of amounts in Columns (e) and (f). For supplemental grants and changes to existing grants, do not use Column (c) and (d). Enter in Column (e) the amount of the increase or decrease of Federal funds and enter in Column (f) the amount of the increase or decrease of non-Federal funds. In Column (g) enter the new total budgeted amount (Federal and non-Federal) which includes the total previously authorized budgeted amounts plus or minus, as appropriate, the amounts shown in Columns (e) and (f). The amount(s) in Column (g) should not equal the sum of amounts in Columns (e) and (f).

Line 5—Show the totals for all columns used.

Section B. Budget Categories

In the column headings (1) through (4), enter the titles of the same programs, functions, and activities shown on Lines 1-4, Column A. When additional sheets are prepared for Section A, provide similar column headings on each sheet. For each program, function or activity, fill in the total requirements for funds (both Federal and non-Federal) by object class categories.

Lines 6a-1—Show the totals of Lines 6a to 6h in each column.

Line 6j—Show the amount of indirect cost.

Line 6k—Enter the total of amounts on Lines 6j, 6i, 6h, and 6f. For all applications for new grants and carryover grants the total amount shown in Column (j) for Line 6k should be the same as the total amount shown in Column A, Column (g). Line 5. For supplemental grants and changes to grants, the total amount of the increase or decrease as shown in Column (j), Line 6k should be the same as the sum of the amounts in Section A, Columns (e) and (f) on Line 5.

Line 7—Enter the estimated amount of income, if any, expected to be generated from this project. Do not add or subtract this amount from the total project amount. Show under the program narrative statement the nature and source of income. The estimated amount of program income may be considered by the Federal grantor agency in determining the total amount of the grant.

Section C. Non-Federal-Resources

Lines 8-11—Enter amounts of non-Federal resources that will be used on the grant. If in-kind contributions are included, provide a brief explanation on a separate sheet.

Column (a)—Enter the program titles identical to Column (a). A breakdown by function or activity is not necessary.

Column (b)—Enter the contribution to be made by the applicant.

Column (c)—Enter the amount of the State's cash and in-kind contribution if the applicant is not a State or State agency. Applicants which are a State or State agencies should leave this column blank.

Column (d)—Enter the amount of cash and in-kind contributions to be made from all other sources.

Column (e)—Enter totals of Columns (b), (c), and (d).

Line 12—Enter the total for each of the respective catalog number on each line in Column (a), and enter the catalog number in Column (b). For applications pertaining to multiple programs where none of the programs require a breakdown by function or activity, enter the catalog program title on each line in Column (a) and the respective catalog number on each line in Column (b).

For applications pertaining to multiple programs where one or more programs require a breakdown by function or activity, prepare a separate sheet for each program requiring the breakdown. Additional sheets should be used when one form does not provide adequate space for breakdown of data required. However, when more than one sheet is used, the first page should provide the summary totals by programs.

Lines 5-Show the totals for all columns used.

Section D. Forecasted Cash Needs

Line 13—Enter the amount of cash needed by quarter from the grantor agency during the first year.

Line 14—Enter the amount of cash from all other sources needed by quarter during the first year.

Line 15—Enter the total of amounts on Lines 13 and 14.

Section E. Budget Estimates of Federal Funds Needed for Balance of the Project

Lines 16-19—Enter in Column (a) the same grant program titles shown in Column (a), Section A. A breakdown by function or activity is not necessary. For new applications and continuation grant applications, enter in the proper columns amounts of Federal funds which will be needed to complete the program or project over the succeeding funding periods (usually in years). This section need not be completed for revisions (amendments, changes, or supplements) to funds for the current year of existing grants.

If more than four lines are needed to list the program titles, submit additional schedules as necessary.

Line 20—Enter the total for each of the Columns (b)-(e). When additional schedules are prepared for this Section, annotate accordingly and show the overall totals on this line.

Section F. Other Budget Information

Line 21—Use this space to explain amounts for individual direct object-class costs categories that may appear to be out of the ordinary or to explain the details as required by the Federal grantor agency.

Line 22—Enter the type of indirect rate (provisional, predetermined, final or fixed) that will be in effect during the funding period, the estimated amount of the base to which the rate is applied, and the total indirect expense.

Line 23—Provide any other explanations or comments deemed necessary.

Attachment D

Assurances—Non-Construction Programs

Note: Certain of these assurances may not be applicable to your project or program. If you have questions, please contact the awarding agency. Further, certain Federal awarding agencies may require applicants to certify to additional assurances. If such is the case, you will be notified.

As the duly authorized representative of the applicant I certify that the applicant:
1. Has the legal authority to apply for Federal assistance, and the institutional, managerial and financial capability (including funds sufficient to pay the non-Federal share of project costs) to ensure proper planning, management and completion of the project described in this application.
2. Will give the awarding agency, the Comptroller General of the United States, and if appropriate, the State, through any authorized representative, access to and the right to examine all records, books, papers, or documents related to the award; and will establish a proper accounting system in accordance with generally accepted accounting standards or agency directives.
3. Will establish safeguards to prohibit employees from using their positions for a purpose that constitutes or presents the appearance of personal or organizational conflict of interest, or personal gain.

4. Will initiate and complete the work within the applicable time frame after receipt of approval of the awarding agency.

5. Will comply with the Intergovernmental Personnel Act of 1970 (42 U.S.C. §§ 4728-4763) relating to prescribed standards for merit systems for programs funded under one of the nineteen statutes or regulations specified in Appendix A of OPM's Standards for a Merit System of Personnel Administration (5 C.F.R. 900, Subpart F).

6. Will comply with all Federal statutes relating to nondiscrimination. These include but are not limited to: (a) Title VI of the Civil Rights Act of 1964 (P.L. 88-352) which prohibits discrimination on the basis of race, color or national origin; (b) Title IX of the Education Amendments of 1972, as amended (20 U.S.C. §§ 1681-1683, and 1685-1686), which prohibits discrimination on the basis of sex; (c) Section 504 of the Rehabilitation Act of 1973, as amended (29 U.S.C. § 794), which prohibits discrimination on the basis of handicap; (d) the Age Discrimination Act of 1975, as amended (42 U.S.C. §§ 6101-6107), which prohibits discrimination on the basis of age; (e) the Drug Abuse Office and Treatment Act of 1972 (P.L. 92-255), as amended, relating to nondiscrimination on the basis of drug abuse; (f) the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment and Rehabilitation Act of 1970 (P.L. 91-616), as amended, relating to nondiscrimination on the basis of alcohol abuse or alcoholism; (g) §§ 523 and 827 of the Public Health Service Act of 1912 (42 U.S.C. §§ 290 dd-3 and 290 ee-3), as amended, relating to confidentiality of alcohol and drug abuse patient records; (h) Title VIII of the Civil Rights Act of 1968 (42 U.S.C. § 3601 et seq.), as amended, relating to nondiscrimination in the sale, rental or financing of housing; (i) any other nondiscrimination provisions in the specific statute(s) under which application for Federal assistance is being made; and (j) the requirements of any other nondiscrimination statute(s) which may apply to the application.

7. Will comply, or has already complied, with the requirements of Titles II and III of the Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970 (P.L. 91-646) which provide for fair and equitable treatment of persons displaced or whose property is acquired as a result of Federal or federally assisted programs. These requirements apply to all interests in real property acquired for project purposes regardless of Federal participation in purchases.

8. Will comply with the provisions of the Hatch Act (5 U.S.C. §§ 1501-1508 and 7324-7328) which limit the political activities of employees whose principal employment activities are funded in whole or in part with Federal funds.


10. Will comply, if applicable, with flood insurance purchase requirements of Section 102(a) of the Flood Disaster Protection Act of 1973 (P.L. 93-234), which requires recipients in a special flood hazard area to participate in the program and to purchase flood insurance if the total cost of insurable construction and acquisition is $10,000 or more.

11. Will comply with environmental standards which may be prescribed pursuant to the following: (a) institution of environmental quality control measures under the National Environmental Policy Act of 1969 (P.L. 91-190) and Executive Order (EO) 11514; (b) notification and violating facilities pursuant to EO 11738; (c) protection of wetlands pursuant to EO 11986; (d) evaluation of flood hazards in floodplains in accordance with EO 11988; (e) assurance of project consistency with the approved State management program developed under the Coastal Zone Management Act of 1972 (16 U.S.C. §§ 1451 et seq.); (f) conformity of Federal actions to State (Clear Air) Implementation Plans under Section 176(c) of the Clean Air Act of 1955, as amended (42 U.S.C. § 7401 et seq.); (g) protection of underground sources of drinking water under the Safe Drinking Water Act of 1974, as amended (P.L. 93-523); and (h) protection of endangered species under the Endangered Species Act of 1973, as amended, (P.L. 90-205).


14. Will comply with P.L. 93-348 regarding the protection of human subjects involved in research, development, and related activities supported by this award of assistance.

15. Will comply with the Laboratory Animal Welfare Act of 1966 (P.L. 89-544, as amended, 7 U.S.C. 2131 et seq.) pertaining to the care, handling, and treatment of warm blooded animals held for research, teaching, or other activities supported by this award of assistance.

16. Will comply with the Lead-Based Paint Poisoning Prevention Act (42 U.S.C. §§ 4801 et seq.) which prohibits the use of lead based paint in construction or rehabilitation of residence structures.

17. Will cause to be performed the required financial and compliance audits in accordance with the Single Audit Act of 1984.

18. Will comply with all applicable requirements of all other Federal laws, executive orders, regulations and policies governing this program.

Signature of Authorized Certifying Official

Title

Applicant Organization

Date Submitted

BILLING CODE 4154-01-M
By signing and/or submitting this application or grant agreement, the grantee is providing the certification set out below.

This certification is required by regulations implementing the Drug-Free Workplace Act of 1988, 45 CFR Part 76, Subpart F. The regulations, published in the May 25, 1990 Federal Register, require certification by grantees that they will maintain a drug-free workplace. The certification set out below is a material representation of fact upon which reliance will be placed when the Department of Health and Human Services (HHS) determines to award the grant. If it is later determined that the grantee knowingly rendered a false certification, or otherwise violates the requirements of the Drug-Free Workplace Act, HHS, in addition to any other remedies available to the Federal Government, may take action authorized under the Drug-Free Workplace Act. False certification or violation of the certification shall be grounds for suspension of payments, suspension or termination of grants, or governmentwide suspension or debarment.

Workplaces under grants, for grantees other than individuals, need not be identified on the certification. If known, they may be identified in the grant application. If the grantee does not identify the workplaces at the time of application, or upon award, if there is no application, the grantee must keep the identity of the workplace(s) on file in its office and make the information available for Federal inspection. Failure to identify all known workplaces constitutes a violation of the grantee’s drug-free workplace requirements.

Workplace identifications must include the actual address of buildings (or parts of buildings) or other sites where work under the grant takes place. Categorical descriptions may be used (e.g., all vehicles of a mass transit authority or State highway department while in operation, State employees in each local unemployment office, performers in concert halls or radio studios.) If the workplace identified to HHS changes during the performance of the grant, the grantee shall inform the agency of the change(s), if it previously identified the workplaces in question (see above).

Definitions of terms in the Nonprocurement Suspension and Debarment common rule and Drug-Free Workplace common rule apply to this certification. Grantees’ attention is called, in particular, to the following definitions from those rules:

- “Controlled substance” means a controlled substance in Schedules I through V of the Controlled Substances Act (21 USC 812) and as further defined by regulation (21 CFR 1308.11 through 1308.15).
- “Conviction” means a finding of guilt (including a plea of nolo contendere) or imposition of sentence, or both, by any judicial body charged with the responsibility to determine violations of the Federal or State criminal drug statutes;
- “Criminal drug statute” means a Federal or non-Federal criminal statute involving the manufacture, distribution, dispensing, use, or possession of any controlled substance;
- “Employee” means the employee of a grantee directly engaged in the performance of work under a grant, including: (i) All “direct charge” employees; (ii) all “indirect charge” employees unless their impact or involvement is insignificant to the performance of the grant; and, (iii) temporary personnel and consultants who are directly engaged in the performance of work under the grant and who are on the grantee’s payroll. This definition does not include workers not on the payroll of the grantee (e.g., volunteers, even if used to meet a matching requirement; consultants or independent contractors not on the grantee’s payroll; or employees of subrecipients or subcontractors in covered workplaces).

The grantee certifies that it will or will continue to provide a drug-free workplace by:

(a) Publishing a statement notifying employees that the unlawful manufacture, distribution, dispensing, possession or use of a controlled substance is prohibited in the grantee’s workplace and specifying the actions that will be taken against employees for violation of such prohibition;

(b) Establishing an ongoing drug-free awareness program to inform employees about:

(1) The dangers of drug abuse in the workplace; (2) The grantee’s policy of maintaining a drug-free workplace; (3) Any available drug counseling, rehabilitation, and employee assistance programs; and, (4) The penalties that may be imposed upon employees for drug abuse violations occurring in the workplace;

(c) Making it a requirement that each employee to be engaged in the performance of the grant be given a copy of the statement required by paragraph (a);

(d) Notifying the employee in the statement required by paragraph (a) that, as a condition of employment under the grant, the employee will:

(1) Abide by the terms of the statement; and, (2) Notify the employer in writing of his or her conviction for a violation of a criminal drug statute occurring in the workplace no later than five calendar days after such conviction;

(e) Notifying the agency in writing, within ten calendar days after receiving notice under subparagraph (d)(2) from an employee or otherwise receiving actual notice of such conviction. Employers of convicted employees must provide notice, including position title, to every grant officer or other designee on whose grant activity the convicted employee was working, unless the Federal agency has designated a central point for the receipt of such notices. Notice shall include the identification number(s) of each affected grant;
(f) Taking one of the following actions, within 30 calendar days of receiving notice under subparagraph (d)(2), with respect to any employee who is so convicted:

(1) Taking appropriate personnel action against such an employee, up to and including termination, consistent with the requirements of the Rehabilitation Act of 1973, as amended; or, (2) Requiring such employee to participate satisfactorily in a drug abuse assistance or rehabilitation program approved for such purposes by a Federal, State, or local health, law enforcement, or other appropriate agency.

(g) Making a good faith effort to continue to maintain a drug-free workplace through implementation of paragraphs (a), (b), (c), (d), (e) and (f).

The grantee may insert in the space provided below the site(s) for the performance of work done in connection with the specific grant (use attachments, if needed):

Place of Performance (Street address, City, County, State, ZIP Code)

Check ___ if there are workplaces on file that are not identified here.

Sections 76.630(c) and (d)(2) and 76.635(a)(1) and (b) provide that a Federal agency may designate a central receipt point for STATE-WIDE AND STATE AGENCY-WIDE certifications, and for notification of criminal drug convictions. For the Department of Health and Human Services, the central receipt point is: Division of Grants Management and Oversight, Office of Management and Acquisition, Department of Health and Human Services, Room 517-D, 200 Independence Avenue, S.W., Washington, D.C. 20201.
Certification Regarding Debarment, Suspension, and Other Responsibility Matters—Primary Covered Transactions

By signing and submitting this proposal, the applicant, defined as the primary participant in accordance with 45 CFR Part 76, certifies to the best of its knowledge and belief that it and its principals:

(a) are not presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in any federal department or agency;

(b) where the prospective lower tier participant is unable to certify to any of the above, such prospective participant shall attach an explanation to this proposal.

The prospective lower tier participant further agrees by submitting this proposal that it will include this clause entitled “Certification Regarding Debarment, Suspension, Ineligibility, and Voluntary Exclusion—Lower Tier Covered Transactions.” without modification in all lower tier covered transactions and in all solicitations for lower tier covered transactions.

Attachment G

State Single Points of Contact

Arizona
Ms. Janice Dunn, Arizona State Clearinghouse, 3800 N. Central Avenue, Fourteenth Floor, Phoenix, Arizona 85012, Telephone (602) 280–1315.

Arkansas
Mr. Joseph Gillese, Manager, State Clearinghouse, Office of Intergovernmental Service, Department of Finance and Administration, P.O. Box 3278, Little Rock, Arkansas 72203, Telephone (501) 371–1074.

California
Glenn Stober, Grants Coordinator, Office of Planning and Research, 1400 Tenth Street, Sacramento, California 95814, Telephone (916) 323–7400.

Colorado
State Single Point of Contact, State Clearinghouse, Division of Local Government, 1313 Sherman Street, Room 520, Denver, Colorado 80203, Telephone (303) 866–2156.

Connecticut

Delaware
Francine Booth, State Single Point of Contact, Executive Department, Thomas Collins Building, Dover, Delaware 19903, Telephone (302) 736–3326.

District of Columbia
Lovetta Davis, State Single Point of Contact, Executive Office of the Mayor, Office of Intergovernmental Relations, Room 416, District Building, 1350 Pennsylvania Avenue, NW, Washington, DC. 20004, Telephone (202) 727–9111.

Florida

Georgia
Charles H. Badger, Administrator, Georgia State Clearinghouse, 270 Washington Street, SW, Atlanta, Georgia 30334, Telephone (404) 658–3655.

Hawaii
Mr. Harold S. Masamoto, Acting Director, Office of State Planning, Department of Planning and Economic Development, Office of the Governor, State Capitol—Room 406, Honolulu, Hawaii 96813, Telephone (808) 548–5893, FAX (808) 548–8172.

Illinois

Indiana

Iowa
Steven R. McConnell, Division for Community Progress, Iowa Department of Economic Development, 200 East Grand Avenue, Des Moines, Iowa 50309, Telephone (515) 281–3725.

Kentucky
Debbie Anglin, State Single Point of Contact, Kentucky State Clearinghouse, 2nd Floor Capital Plaza Tower, Frankfort, Kentucky 40601, Telephone (502) 564–2382.

Maine
State Single Point of Contact, Attn: Joyce Benson, State Planning Office, State House Station #38, Augusta, Maine 04333, Telephone (207) 289–3261.

Maryland
Mary Abrams, Chief, Maryland State Clearinghouse, Department of State Planning, 301 West Preston Street, Baltimore, Maryland 21201–2365, Telephone (301) 225–4490.

Massachusetts
State Single Point of Contact, Attn: Beverly Boyle, Executive Office of Communities & Development, 100 Cambridge Street, Room 1803, Boston, Massachusetts 02202, Telephone (617) 727–7001.

Michigan

Please direct correspondence to: Manager, Federal Project Review, Michigan Department of Commerce, Michigan Neighborhood Builders Alliance, P.O. Box 30242, Lansing, Michigan 48909, Telephone (517) 373–6223.

Mississippi
Cathy Mallette, Clearinghouse Officer, Department of Finance and Administration, Office of Policy Development, 421 West Pascagoula Street, Jackson, Mississippi 39203, Telephone (601) 960–4280.

Missouri
of Administration, Division of Planning, 265 Melrose Street, Providence, Rhode Island 02907, Telephone (401) 277-2656. Please direct correspondence and questions to: Review Coordinator, Office of Strategic Planning.

South Carolina

Danny L. Cromer, State Single Point of Contact, Grant Services, Office of the Governor, 1205 Pendleton Street, Room 477, Columbia, South Carolina 29201, Telephone (803) 734-0493.

South Dakota

Susan Comer, State Clearinghouse Coordinator, Office of the Governor, 500 East Capitol, Pierre, South Dakota 57501, Telephone (605) 773-3212.

Tennessee


Texas

Tom Adams, Governors Office of Budget and Planning, P.O. Box 12428, Austin, Texas 78711, Telephone (512) 463-1778.

Utah

Utah State Clearinghouse, Office of Planning and Budget, ATTN: Carolyn Wright, Room 116 State Capitol, Salt Lake City, Utah 84114, Telephone (801) 538-1535.

Vermont

Bernard D. Johnson, Assistant Director, Office of Policy Research & Coordination, Pavilion Office Building, 100 State Street, Montpelier, Vermont 05602, Telephone (802) 828-3326.

West Virginia

Fred Cutlip, Director, Community Development Division, Governor's Office of Community and Industrial Development, Building #6, Room 553, Charleston, West Virginia 25305, Telephone (304) 348-4010.

Wisconsin

William C. Carey, Federal/State Relations, ICA Relations, 101 South Webster Street, P.O. Box 7864, Milwaukee, Wisconsin 53707, Telephone (608) 266-1741.

Wyoming


Territories

Guam

Michael J. Reidy, Director, Bureau of Budget and Management Research, Office of the Governor, P.O. Box 2950, Agana, Guam 96910, Telephone (671) 472-2285.

Northern Mariana Islands

State Single Point of Contact, Planning and Budget Office, Office of the Governor, Saipan, CM, Northern Mariana Islands 96950.

Puerto Rico

Patricia Custodio/Israel Soto Marerro, Chairwoman/Executive Director, Puerto Rico Planning Board, Minillas Government Center, P.O. Box 41119, San Juan, Puerto Rico 00940-9985, Telephone (809) 727-4444.

Virgin Islands

Jose L. George, Director, Office of Management and Budget, No. 32 & 33 Kongens Gade, Charlotte Amalie, V.I. 00802, Telephone (609) 774-0750.

Attachment H

Certification Regarding Lobbying

The undersigned certifies, to the best of his or her knowledge and belief, that:

(1) No Federal appropriated funds have been paid or will be paid, by or on behalf of the undersigned, to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the awarding of any Federal contract, the making of any Federal grant, the making of any Federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any Federal contract, grant, loan, or cooperative agreement.

(2) If any funds other than Federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this Federal contract grant, loan or cooperative agreement, the undersigned shall complete and submit Standard Form—LLL, "Disclosure Form to Report Lobbying," in accordance with its instructions.

(3) The undersigned shall require that the language of this certification be included in the award documents for all subawards at all tiers (including subcontracts, subgrants, and contracts under grants, loans, and cooperative agreements) and that all subrecipients shall certify and disclose accordingly.

This certification is a material representation of fact upon which reliance was placed when this transaction was made or entered into. Submission of this certification is a prerequisite for making or entering into the transaction imposed by section 1352, title 31, U.S. Code. Any person who fails to file the required certification shall be subject to a civil penalty of not less than $10,000 and not more than $100,000 for each such failure.
State for Loan Guarantee and Loan Insurance

The undersigned states, to the best of his or her knowledge and belief, that:

If any funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this commitment providing for the United States to insure or guarantee a loan, the undersigned shall complete and submit Standard Form-LLL “Disclosure Form to Report Lobbying,” in accordance with its instructions.

Submission of this statement is a prerequisite for making or entering into this transaction imposed by section 1352, title 31, U.S. Code. Any persons who fails to file the required statement shall be subject to a civil penalty of not less than $10,000 and not more than $100,000 for each such failure.

Signature

Title

Organization

Date

Attachment I

The following DHHS regulations apply to all applicants/grantees under the Job Opportunities for Low-Income Individuals Program:

Title 45 of the Code of Federal Regulations:

Part 80-Non-discrimination under Programs Receiving Federal Assistance through the Department of Health and Human Services Effection of Title VI of the Civil Rights Act of 1964

Part 81—Practice and Procedures for Hearings Under Part 80 of this Title

Part 83—Non-discrimination on the Basis of Sex in the Admission of Individuals to Training Programs

Part 84—Non-discrimination on the Basis of Handicap in Programs

Part 91—Non-discrimination on the Basis of Age in Health and Human Services Programs or Activities Receiving Federal Financial Assistance

Part 92—Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments (Federal Register, March 11, 1986)

Part 93—New Restrictions on Lobbying

Part 100—Intergovernmental Review of Agreements to State and Local Governments (Federal Register), March 11, 1988)

Part 111, 74.710

Part 111, 74.715

Part 16—Procedures of the Departmental Grant Appeals Board

Part 25—Informal Grant Appeal Procedures

Part 26—Debarment and Suspension Form Eligibility for Financial Assistance. Subpart F—Drug Free Workplace Requirements

Part 84—Non-discrimination under Programs Receiving Federal Assistance through the Department of Health and Human Services Effection of Title VI of the Civil Rights Act of 1964

Part 83—Non-discrimination on the Basis of Sex in the Admission of Individuals to Training Programs

Part 84—Non-discrimination on the Basis of Handicap in Programs

Part 91—Non-discrimination on the Basis of Age in Health and Human Services Programs or Activities Receiving Federal Financial Assistance

Part 92—Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments (Federal Register, March 11, 1986)

Part 93—New Restrictions on Lobbying

Part 100—Intergovernmental Review of Agreements to State and Local Governments (Federal Register), March 11, 1988)

Part 111, 74.710

Part 111, 74.715

Title 45 of the Code of Federal Regulations:

Program:

Opportunities for Low-Income Individuals

all applicants/grantees under the Job Opportunities

Attachment K

Certification Regarding Maintenance of Effort

The undersigned certifies that:

(i) Eligibility Confirmation

(ii) Organizational Experience and Staff Responsibilities

(iii) Analysis of Need

(iv) Project Design/Work Program

(v) Business Plan (If appropriate)

(vi) Third-Party Evaluation

(vii) Cooperative Partnership Agreement

(viii) Budget Appropriateness and Reasonableness

11. A signed copy of the Cooperative Partnership Agreement or letter of commitment.

12. Appendices, including proof of non-profit status; proof that the organization is a community development corporation, if applying under the CDC Set-aside; commitments from officials of businesses that will be expanded or from franchises, where applicable; Single Point of Contact comments, if applicable; Maintenance of Effort Certification and resumes.

13. A self-addressed mailing label which can be affixed to a postcard to acknowledge receipt of application.

The application should not exceed a total of 50 pages. It should include one original and four identical copies, printed on white 8½ by 11 inch paper, two-holed punched at the top center and fastened separately with a compressor slide paper faster, such as an ACCO clip, or a binder clip. The submission of bound applications, enclosed in binders, is specifically discouraged.

[FR Doc. 93–11265 Filed 5–11–93; 8:45 am]

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**LIST OF PUBLIC LAWS**

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S.J. Res. 66/P.L. 103-30

To designate beginning April 18, 1993, and April 17, 1994, each as "Nancy Moore Thurmond National Organ and Tissue Donor Awareness Week".

(May 7, 1993; 107 Stat. 76; 1 page)

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