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Rules and Regulations

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This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed 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.

DEPARTMENT OF AGRICULTURE

Federal Crop Insurance Corporation

7 CFR Part 401

[Amdt. 49; Docket No. 6939S]

General Crop Insurance Regulations; Safflower Endorsement

AGENCY: Federal Crop Insurance Corporation, USDA.

ACTION: Final rule.

SUMMARY: The Federal Crop Insurance Corporation (FCIC) amends the General Crop Insurance Regulations (7 CFR Part 401), effective for the 1990 and succeeding crop years, to: (1) amend the Safflower Endorsement with respect to cancellation and termination dates and the dates by which contract changes must be on file in the service offices in California and, (2) to review these regulations under the procedures of Department Regulation 1512-1 for the purpose of establishing a new sunset review date. The intended effect of this proposed rule is to provide cancellation, termination, and filing dates appropriate to the California safflower crop and to establish a new sunset review date.

EFFECTIVE DATE: August 9, 1989.

FOR FURTHER INFORMATION CONTACT: Peter F Cole, Secretary, Federal Crop Insurance Corporation, U.S. Department of Agriculture, Washington, DC 20250, telephone (202) 447-3325.

SUPPLEMENTARY INFORMATION: This action has been reviewed under USDA procedures established by Departmental Regulation 1512-1. These regulations have been reviewed under the procedures established by Departmental Regulations 1512-1 as to the need, currency, clarity, and effectiveness of these regulations. The sunset review date established for the regulations in the Safflower Endorsement is February 1, 1994.

John Marshall, Manager, FCIC, (1) has determined that this action is not a major rule as defined by Executive Order 12291 because it will not result in: (a) an annual effect on the economy of $100 million or more; (b) major increases in costs or prices for consumers, individual industries, federal, State, or local governments, or a geographical region; or (c) significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets; and (2) certifies that this action will not increase the federal paperwork burden for individuals, small businesses, and other persons and will not have a significant economic impact on a substantial number of small entities.

This action is exempt from the provisions of the Regulatory Flexibility Act; therefore, no Regulatory Flexibility Analysis was prepared.

This program is listed in the Catalog of Federal Domestic Assistance under No. 10.450.

This program is not subject to the provisions of Executive Order 12372 which requires intergovernmental consultation with State and local officials. See the Notice related to 7 CFR Part 3015, Subpart V published at 48 FR 29115, June 24, 1983.

This action is not expected to have any significant impact on the quality of the human environment, health, and safety. Therefore, neither an Environmental Assessment nor an Environmental Impact Statement is needed.

The present safflower crop insurance cancellation and termination date is April 15 for all states and the contract change date is the previous December 31. Safflower plantings in California are generally done in January or February and are growing and well established by April 15.

In order to provide that contract changes are filed timely before the sales period begins, and allow an appropriate amount of time for applications to be accepted before the end of the sales period, it is necessary to change the sales closing date to February 15 and to change the date by which contract changes are to be filed in the service office in California to the previous November 30. Since the sales closing date is almost always the same date as the cancellation and termination date, the changing of the sales closing date will require that the cancellation and termination date in California also be changed to February 15.

On Thursday, May 11, 1989, FCIC published a notice of proposed rulemaking in the **Federal Register** at 54 FR 20391, to provide cancellation, termination, and filing dates appropriate to the California safflower crop and to establish a new sunset review date. The public was given 30 days in which to submit written comments, data, and opinions on the proposed rule, but none were received.

In the published notice of proposed rulemaking, the effective year in the Summary of the rule incorrectly indicated that the rule would be "effective for the 1989 and succeeding crop years. This should have read effective for the 1990 and succeeding crop years. This error is corrected herein.

Therefore, with the exception of the effective crop year corrected in the Summary as indicated above, FCIC herewith adopts the rule published at 54 FR 20391, as a final rule with no changes.

List of Subjects in 7 CFR 401

General Crop Insurance Regulations, Safflowers.

Final Rule

Accordingly, pursuant to the authority contained in the Federal Crop Insurance Act, as amended (7 U.S.C. 1501 et seq.), the Federal Crop Insurance Corporation amends the General Crop Insurance Regulations (7 CFR Part 401), effective for the 1990 and succeeding crop years, in the following instances:

PART 401—[AMENDED]

1. The authority citation for 7 CFR Part 401 continues to read as follows:

Authority: 7 U.S.C. 1506, 1516.

2. The Safflower Seed Crop Insurance Regulations (7 CFR § 401.123), are amended by revising subsections 8 and 9 to read as follows:

§ 401.123 Safflower Seed Crop Endorsement

Safflower Seed Crop Endorsement

8. Cancellation and Termination Date. The cancellation and termination date for California is February 15. For all other states, the cancellation and termination date is April 15.

9. Contract Changes. Contract changes will be available at your service office by December 31 prior to the cancellation date for counties with an April 15 cancellation date and by November 30 prior to the cancellation date for all other counties.

Done in Washington, DC on June 22, 1989.

John Marshall,

Manager, Federal Crop Insurance Corporation.

[FR Doc. 89-16124 Filed 7-7-89; 8:45 am]

BILLING CODE 3410-08-M

Agricultural Marketing Service

7 CFR Part 910

[Lemon Reg. 673]

Lemons Grown in California and Arizona; Limitation of Handling

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: Regulation 673 establishes the quantity of fresh California-Arizona lemons that may be shipped to market at 380,000 cartons during the period July 9 through July 15, 1989. Such action is needed to balance the supply of fresh lemons with market demand for the period specified, due to the marketing situation confronting the lemon industry.

DATES: Regulations 673 (§ 910.973) is effective for the period July 9 through July 15, 1989.

FOR FURTHER INFORMATION CONTACT: Beatriz Rodriguez, Marketing Specialist, Marketing Order Administration Branch, F&V AMS, USDA, Room 2523, South Building, P.O. Box 96456, Washington, DC 20090-6456; telephone: (202) 475-3861.

SUPPLEMENTARY INFORMATION: This final rule has been reviewed under Executive Order 12291 and Departmental Regulation 1512-1 and has been determined to be a "non-major" rule under criteria contained therein.

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA), the Administrator of the Agricultural Marketing Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

The purpose of the RFA is to fit regulatory action to the scale of business subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Agricultural Marketing Agreement Act, and rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf. Thus, both statutes have small entity orientation and compatibility.

There are approximately 85 handlers of lemons grown in California and Arizona subject to regulation under the lemon marketing order and approximately 2500 producers in the regulated area. Small agricultural producers have been defined by the Small Business Administration (13 CFR 121.2) as those having annual gross revenues for the last three years of less than $500,000, and small agricultural service firms are defined as those whose gross annual receipts are less than $3,500,000. The majority of handlers and producers of California-Arizona lemons may be classified as small entities.

This regulation is issued under Marketing Order No. 910, as amended (7 CFR Part 910), regulating the handling of lemons grown in California and Arizona. The order is effective under the Agricultural Marketing Agreement Act (the Act, 7 U.S.C. 601-674), as amended. This action is based upon the recommendation and information submitted by the Lemon Administrative Committee (Committee) and upon other available information. It is found that this action will tend to effectuate the declared policy of the Act.

This regulation is consistent with the California-Arizona lemon marketing policy for 1988-89. The Committee met publicly on July 5, 1989, in Los Angeles, California, to consider the current and prospective conditions of supply and demand and unanimously recommended a quantity of lemons deemed advisable to be handled during the specified week. The Committee reports that overall demand for lemons is good.

Pursuant to 5 U.S.C. 553, it is further found that it is impracticable, unnecessary, and contrary to the public interest to give preliminary notice and engage in further public procedure with respect to this action and that good cause exists for not postponing the effective date of this action until 30 days after publication in the **Federal Register** because of insufficient time between the date when information became available upon which this regulation is based and the effective date necessary to effectuate the declared purposes of the Act. Interested persons were given an opportunity to submit information and views on the regulation at an open meeting. It is necessary, in order to effectuate the declared purposes of the Act, to make these regulatory provisions effective as specified, and handlers have been apprised of such provisions and the effective time.

List of Subjects in 7 CFR Part 910

Marketing agreements and orders, California, Arizona, Lemons.

For the reasons set forth in the preamble, 7 CFR Part 910 is amended as follows:

PART 910—LEMONS GROWN IN CALIFORNIA AND ARIZONA

1. The authority citation for 7 CFR Part 910 continues to read as follows:

Authority: Secs. 1-19, 48 Stat. 31, as amended; 7 U.S.C. 601-674.

2. Section 910.973 is added to read as follows:

Note: This section will not appear in the Code of Federal Regulations.

§ 910.973 Lemon Regulation 673.

The quantity of lemons grown in California and Arizona which may be handled during the period July 9, 1989, through July 15, 1989, is established at 380,000 cartons.

Dated: July 6, 1989.

Charles R. Brader,

Director, Fruit and Vegetable Division.

[FR Doc. 89-16252 Filed 7-7-89; 8:45 am]

BILLING CODE 3410-02-M

SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 200

[Rel. No. 34-26986]

Delegation of Authority to the Director of the Division of Market Regulation

AGENCY: Securities and Exchange Commission.

ACTION: Final rule amendment.

SUMMARY: The Commission is amending its Rules of Practice to delegate authority to the Director of the Division of Market Regulation to grant exemptions from Rule 15c2-12 under the Securities Exchange Act of 1934 pursuant to paragraph (d) of that Rule.

EFFECTIVE DATE: July 10, 1989.

FOR FURTHER INFORMATION CONTACT: Robert L.D. Colby, Esq., Chief Counsel, or Edward L. Pittman Esq., Assistant Chief Counsel (202-272-2848), Division of Market Regulation, Mail Stop 5-1, Securities and Exchange Commission, 450 5th Street, NW Washington, DC 20549.

SUPPLEMENTARY INFORMATION: The Securities and Exchange Commission today announced an amendment to its Rules of Practice governing Delegation of Authority to the Director of the Division of Market Regulation (17 CFR 200.30-3). The amendment adds to Rule 30-3, new paragraph (a)(48), authorizing the Director of the Division of Market Regulation to grant exemptions, where appropriate, pursuant to paragraph (d) of Rule 15c2-12 under the Securities Exchange Act of 1934 (17 CFR 240.15c2-12), which the Commission adopted on June 28, 1989.[1]

Paragraph (d) of Rule 15c2-12 provides that:

> The Commission, upon written request, or upon its own motion, may exempt any Participating Underwriter that is a participant in a transaction or class of transactions from any requirement of this rule, either unconditionally or on specified terms and conditions, if the Commission determines that such an exemption is consistent with the public interest and the protection of investors.

The delegation of authority is intended to conserve Commission resources by permitting the staff to accommodate requests on a more expedited basis. Nevertheless, the staff may submit matters to the Commission for consideration as it deems appropriate. Moreover, in light of the exemptions already present in Rule 15c2-12, and the fact that the Rule codifies, to a great degree, responsible industry practice, the Commission does not expect that exemptions will be routinely granted. Requests for exemptive relief should be addressed to the Chief Counsel, Division of Market Regulation, Mail Stop 5-1, Securities and Exchange Commission, Washington, DC 20549.

The Commission finds, in accordance with section 553(b)(A) of the Administrative Procedure Act,[2] that this amendment relates solely to agency organization, procedure, or practice, and does not relate to a substantive rule. Accordingly, notice, opportunity for public comment, and publication of the amendment prior to its effective date are unnecessary.

List of Subjects in 17 CFR Part 200

Administrative practice and procedure, Securities.

Text of Amendment

The Commission hereby amends Title 17 Chapter II of the Code of Federal Regulations as follows:

Securities Exchange Act Release No. 26985 (June 28, 1989).

5 U.S.C. 553(b)(A).

PART 200—ORGANIZATION; CONDUCT AND ETHICS; AND INFORMATION AND REQUESTS

Subpart A—Organization and Program Management

1. The authority citation for Part 200, Subpart A, continues to read in part as follows:

Authority: Secs. 19, 23, 48 Stat. 85, 901, as amended, sec. 20, 49 Stat. 833, sec. 319, 53 Stat. 1173, secs. 38, 211, 54 Stat. 841, 855, 15 U.S.C. 77s, 78w, 79t, 77sss, 80a-37 80b-11

2. Title 17 CFR 200.30-3 is amended by adding new paragraph (a)(48) to read as follows:

§ 200.30-3 Delegation of authority to Director of Division of Market Regulation.

(a)

(48) Pursuant to paragraph (d) of Rule 15c2-12 (17 CFR 15c2-12), to grant or deny exemptions, either unconditionally or on specified terms and conditions, from Rule 15c2-12.

By the Commission.

Dated: June 28, 1989.

Jonathan G. Katz,

Secretary.

[FR Doc. 89-16040 Filed 7-7-89; 8:45 am]

BILLING CODE 8010-01-M

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17 CFR Part 201

[Rel. No. 34-26994]

Applications for Bounty Awards on Civil Penalties Imposed in Insider Trading Litigation

AGENCY: Securities and Exchange Commission.

ACTION: Final Rules.

SUMMARY: The Commission has adopted rules setting forth the procedures by which persons providing information that leads to the imposition of civil penalties in insider trading cases may apply for the award of a bounty. The rules implement the bounty provisions of the Insider Trading and Securities Fraud Enforcement Act of 1988.

EFFECTIVE DATE: July 10, 1989.

ADDRESSES: A pamphlet entitled "Information on Bounties" explains Commission policies and procedures on bounty payments and may be obtained by contacting the Office of Public Affairs, Securities and Exchange Commission, 450 Fifth Street NW Washington, DC 20549.

FOR FURTHER INFORMATION CONTACT: Kenneth H. Hall (202 272-2253), Senior Counsel, Division of Enforcement, Securities and Exchange Commission, 450 Fifth Street NW., Washington, DC 20549.

SUPPLEMENTARY INFORMATION:

I. Bounty Payments Under Section 21A(e)

Section 21A(e) of the Securities Exchange Act of 1934 (the "Exchange Act")[1] authorizes the Commission to award bounties to persons who provide information that leads to the imposition of a civil penalty in insider trading litigation.[2] To implement the bounty provisions of section 21A(e), the Commission has added new Subpart C to its Rules of Practice. Subpart C is intended to inform the public of the possibility of bounty payments; to encourage those who may have information indicating violations of the federal securities laws to provide that information to the Commission; and to provide the structure for an orderly administration of the process of making bounty payments.[3]

Under section 21A(e), all Commission determinations regarding bounties, including whether to make a payment, to whom a payment shall be made, and the amount of a payment (if any), are in the sole discretion of the Commission. Any such determination is final and not subject to judicial review. Nothing in Subpart C is intended to limit the Commission's discretion with respect to bounties.

Section 21A(e) contains a number of limitations on the Commission s ability to award bounties. Bounties may only be awarded from amounts that are imposed as civil penalties in insider trading litigation under section 21A of the Exchange Act and that are recovered by the Commission or by the Attorney General on behalf of the

15 U.S.C. 78u-1(e). Section 21A(e), which became effective on November 19, 1988, was added to the Exchange Act by the Insider Trading and Securities Fraud Enforcement Act of 1988. Pub. L. No. 100-704, 102 Stat. 4677

[2] In general, section 21A authorizes courts to impose civil penalties against any person who has violated the Exchange Act by purchasing or selling security while in possession of material, nonpublic information in, or has violated [the Exchange Act] by communicating such information in connection with, a transaction on or through the facilities of national securities exchange or from or through broker or dealer.

Section 21A(a)(1). In addition, section 21A(a)(1)(B) authorizes imposition of civil penalties against persons who directly or indirectly control such violators.

While the new rules are procedural in nature and do not require notice and comment rulemaking, any interested person may provide comments on the rules to the individual named and at the address provided under the caption "For Further Information Contact.

Commission. The total amount of bounties that may be paid from a penalty may not exceed ten percent of that penalty. In addition, bounty payments may be made only to the person or persons who provided information leading to the imposition of the penalty. Finally, section 21A provides that no bounty may be paid to "any member, officer, or employee of any appropriate regulatory agency, the Department of Justice, or a self-regulatory organization. [4]

In making determinations regarding bounty applications, the Commission will be guided both by the purposes of the Congress in enacting Section 21A and by the limitations contained in section 21A(e). The Commission will also consider whatever other factors it deems relevant, including, as examples, the importance of the information provided by an applicant, whether that information was provided voluntarily, other applications in the matter, and the amount of the penalty from which bounties may be paid.

II. Description of Subpart C

Subpart C consists of eight new rules, Rules 61–68. Rule 61 sets forth the general scope of Subpart C, refers to the statutory premises of the bounty procedures, and provides that nothing contained in the subpart limits the Commission's discretion regarding bounty determinations or subjects those determinations to judicial review.

Rule 62 provides procedures relating to bounty applications. Written applications that conform to the provisions of Subpart C are required before a bounty payment may be made. Upon request of the Commission or its staff, persons seeking bounties must also provide other relevant information. This provision is designed to permit the Commission to be certain that its bounty payments are in accordance with law and to assure that the Commission has all relevant information needed to make informed decisions regarding applications for bounties. The Commission anticipates that the classes of information that may be relevant may include: the employment and affiliations of the applicant; the conduct of the applicant in connection with the violative activity and the relationship of the applicant to other persons and entities involved in the matter; the means by which the applicant came into possession of the information for which an award is sought; and any action taken by the applicant to mitigate the effects of violative conduct or to prevent further violative conduct in the matter.

Rule 63 specifies the time and place of filing for applications for bounties. Applications must be filed no later than 180 days after entry of the court order requiring the payment of the penalty that is subject to the application.

Rule 64 governs the form of bounty applications and requires a detailed statement of the information upon which a bounty may be based, i.e., the information that the applicant believes led or may lead to the imposition of a penalty under Section 21A of the Exchange Act. Where the application is not the means by which a bounty applicant initially provides information to the Commission, the application must also specify the dates and times when the information was previously provided; to whom the information was provided; how the information was provided (*e.g.*, by telephone call or in person); and, when information was initially provided anonymously, sufficient other information to confirm that the applicant is the person who provided the information to the Commission.

Any person who desires to provide information to the Commission that may result in the payment of a bounty may do so by any means desired. However, the Commission wishes to emphasize the utility of providing such information in writing as soon as possible, either in the form of an application for a bounty or otherwise. Providing information in writing reduces the possibility of error, helps assure that appropriate action will be taken, and minimizes subsequent burdens and the possibility of factual disputes.

The Commission recognizes that there may be instances when a bounty applicant wishes to remain temporarily anonymous.[5] Rule 65 takes into account these instances. All applications must identify and be signed by the applicant, and must provide the applicant's mailing address. However, that information may be omitted provided that it is submitted by an amendment to the application. The amendment must be filed within 180 days after the entry of the court order requiring the payment of the penalty upon which the bounty is based.

Rule 66 provides that the Commission will notify an applicant of its determination on the application. Normally, determinations will not be made until a payment of a penalty is both ordered by a court and recovered. The Commission wishes to emphasize that anonymous applicants (and those who fail to make written applications) will not receive the notice provided by Rule 66. Thus, they will bear the risk of losing eligibility for a bounty award through lapse of time or ignorance of the fact that a penalty has been recovered.

Rule 67 contains provisions for filing an application by an executor, administrator or other legal representative of a person who provided information that led or may lead to imposition of a civil penalty, or by the parent or guardian of such a person if that person is a minor. Rule 68 provides that no person is authorized by the new rules to make any offer or promise or otherwise to bind the Commission with respect to bounty payments or their amounts.

The Commission has determined that the final rules relate solely to agency organization, procedure or practice. Therefore, the provisions of the Administrative Procedure Act ("APA") regarding notice of proposed rulemaking and opportunities for public participation, 5 U.S.C. 553, are not applicable. Similarly, the provisions of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, which apply only when notice and comment rulemaking are required by the APA or other law, are not applicable. The Commission finds that the rules will not impose any burden on competition. The Commission further finds, because of the procedural nature of the rules, that the APA requirement with respect to delay in the effective date of substantive rules, 5 U.S.C. 553(d), is also inapplicable.

List of Subjects in 17 CFR Part 201

Rules of practice.

Depending upon the circumstances, the term "appropriate regulatory agency" may include federal bank regulatory authorities as well as the Commission. Section 3(a)(34) of the Exchange Act, 15 U.S.C. 78c(a)(34). "Self-regulatory organizations" include national securities exchanges, registered securities associations, and registered clearing agencies. Section 3(a)(26) of the Exchange Act, 15 U.S.C. 78c(a)(26).

Individuals who provide information to the Commission often request that their identities be held in confidence. Absent compelling cause, the Commission ordinarily does not disclose the identities of these persons. The Freedom of Information Act (5 U.S.C. 552(b)(7)(D)), and the Privacy Act of 1974 (5 U.S.C. 552a(k)(5)) permit agencies to withhold the identity of confidential source. However, there may be circumstances in which disclosure will nonetheless be legally required or will be essential for the protection of the public interest. For example, in litigation court may order disclosure, or the Commission may have to present bounty claimant as a witness in order to assure the success of an enforcement action. Thus, while the Commission and its staff will give serious consideration to requests for confidentiality of identity, no guarantees of confidentiality are possible.

PART 201—[AMENDED]

For the reasons set out in the preamble, Title 17 Part 201 of the Code of Federal Regulations, is amended by adding Subpart C as set forth below:

Subpart C—Procedures Pertaining to the Payment of Bounties Pursuant to Subsection 21A(e) of the Securities Exchange Act of 1934

Sec.
201.61 Scope of subpart.
201.62 Application required.
201.63 Time and place of filing.
201.64 Form of application and information required.
201.65 Identity and signature.
201.66 Notice to applicants.
201.67 Applications by legal guardians.
201.68 No promises of payment.

Authority: Sec. 21A, 102 Stat. 4679, sec. 23, 48 Stat. 901, as amended, 15 U.S.C. 78u-1, 78w.

Subpart C—Procedures Pertaining to the Payment of Bounties Pursuant to Subsection 21A(e) of the Securities Exchange Act of 1934

§ 201.61 Scope of subpart.

Section 21A of the Securities Exchange Act of 1934 authorizes the courts to impose civil penalties for certain violations of that Act. Subsection 21A(e) permits the Commission to award bounties to persons who provide information that leads to the imposition of such penalties. Any such determination, including whether, to whom, or in what amount to make payments, is in the sole discretion of the Commission. This subpart sets forth procedures regarding applications for the award of bounties pursuant to subsection 21A(e). Nothing in this subpart shall be deemed to limit the discretion of the Commission with respect to determinations under subsection 21A(e) or to subject any such determination to judicial review.

§ 201.62 Application required.

No person shall be eligible for the payment of a bounty under subsection 21A(e) of the Securities Exchange Act of 1934 unless such person has filed a written application that meets the requirements of this subpart and, upon request, provides such other information as the Commission or its staff deems relevant to the application.

§ 201.63 Time and place of filing.

Each application pursuant to this subpart and each amendment thereto must be filed within one hundred and eighty days after the entry of the court order requiring the payment of the penalty that is subject to the application. Such applications and amendments shall be addressed to: Office of the Secretary, Securities and Exchange Commission, 450 Fifth Street NW Washington, DC 20549.

§ 201.64 Form of application and information required.

Each application pursuant to this subpart shall be identified as an Application for Award of a Bounty and shall contain a detailed statement of the information provided by the applicant that the applicant believes led or may lead to the imposition of a penalty. Except as provided by Rule 65 of this subpart, each application shall state the identity and mailing address of, and be signed by, the applicant. When the application is not the means by which the applicant initially provides such information, the application shall contain: the dates and times upon which, and the means by which, the information was provided; the identity of the Commission staff members to whom the information was provided; and, if the information was provided anonymously, sufficient further information to confirm that the person filing the application is the same person who provided the information to the Commission.

§ 201.65 Identity and signature.

Applications pursuant to this subpart may omit the identity, mailing address, and signature of the applicant; *provided,* that such identity, mailing address and signature are submitted by an amendment to the application. Any such amendment must be filed within one hundred and eighty days after the entry of the court order requiring the payment of the penalty that is subject to the application.

§ 201.66 Notice to applicants.

The Commission will notify each person who files an application that meets the requirements of this subpart, at the address specified in such application, of the Commission's determination with respect to such person s application. Nothing in this subpart shall be deemed to entitle any person to any other notice from the Commission or its staff.

§ 201.67 Applications by legal guardians.

An application pursuant to this subpart may be filed by an executor, administrator, or other legal representative of a person who provides information that may be subject to a bounty payment, or by the parent or guardian of such a person if that person is a minor. Certified copies of the letters testamentary, letters of administration, or other similar evidence showing the authority of the legal representative to file the application must be annexed to the application.

§ 201.68 No promises of payment.

No person is authorized under this subpart to make any offer or promise, or otherwise to bind the Commission with respect to the payment of any bounty or the amount thereof.

By the Commission.

Jonathan G. Katz,

Secretary.

June 30, 1989.

[FR Doc. 89-16039 Filed 7-7-89; 8:45 am]

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17 CFR Parts 240 and 241

RIN 3235-AD58

[Rel. No. 34-26985, File No. S7-20-88]

Municipal Securities Disclosure

AGENCY: Securities and Exchange Commission

ACTION: Final rule.

SUMMARY: The Securities and Exchange Commission today announced the adoption of Rule 15c2-12, which requires underwriters participating in primary offerings of municipal securities of $1,000,000 or more to obtain, review, and distribute to investors copies of the issuer's disclosure documents. Under the rule, in a primary offering of municipal securities the underwriter will be required: (1) to obtain and review a copy of an official statement deemed final by an issuer of the securities, except for the omission of specified information; (2) in non-competitively bid offerings, to make available, upon request, the most recent preliminary official statement, if any; (3) to contract with an issuer of the securities, or its agent, to receive, within specified time periods, sufficient copies of the issuer s final official statement, both to comply with this rule and any rules of the Municipal Securities Rulemaking Board; and (4) to provide, for a specified period of time, copies of final official statements to any potential customer upon request. The rule contains exemptions for underwriters participating in certain offerings of municipal securities issued in large denominations that are sold to no more than 35 sophisticated investors, have short-term maturities, or have short-term tender or put features. The release also modifies, in limited respects, a previously published interpretation of the legal obligations of municipal securities underwriters.

EFFECTIVE DATE: Rule 15c2-12 is effective on January 1, 1990. The

modification of the intepretation of the legal obligations of municipal underwriters is effective June 28, 1989.

FOR FURTHER INFORMAITION CONTACT: Catherine McGuire, Special Assistant to the Director (202) 272-2790 (prior to the effective date); Robert L.D. Colby, Chief Counsel, or Edward L. Pittman, Assistant Chief Counsel, (202) 272-2848 (concerning the rule and release generally); or Christine A. Sakach, Branch Chief—Market Structure (202) 272-2857 (concerning interpretation of the term "nationally recognized municipal securities information repository"), Division of Market Regulation, Mail Stop 5-1, Securities and Exchange Commission, Washington, DC 20549.

I. Introduction

On September 22, 1988, the Commission released to Congress the results of an extensive investigation into the default of the Washington Public Power Supply System ("Supply System").[1] At the same time, it published Securities Exchange Act Release No. 26100 ("Release"),[2] which requested comment on several initiatives that were designed to improve the quality, timing, and dissemination of disclosure in the Municipal securities markets. The Release proposed for adoption Rule 15c2-12 ("Proposed Rule") under the Securities Exchange Act of 1934 [3] ("Exchange Act"), provided an interpretation of underwriter's responsibilities in municipal offerings ("Interpretation"), and solicited comment on proposals advanced by the Municipal Securities Rulemaking Board ("MSRB") and other members of the industury to create a repository for municipal disclosure documents.

Comment was requested on each aspect of the Proposed Rule, Interpretation, and the creation of a central repository for municipal disclosure documents. In response to the request for comments, the Commission received over sixty letters from all segments of the industry, including issuers, underwriters, institutional investors, bond counsel, analysts, financial advisers, insurance providers, disclosure services, the MSRB, and state securities regulators. The comment letters presented a variety of thoughtful views on the major issues raised by the Release, as well as the commentators' assessment of the general adequacy of disclosure in the municipal markets and current letters, the Commission has determined to adopt Rule 15c2-12 ("Rule"), with certain modifications that are designed to address the concerns expressed by commentators.[4] The Commission also is amending portions of its Interpretation in light of the comments.

II. Rule 15c2-12

The Commission proposed Rule 15c2-12, in part, under its authority in section 15(c) of the Exchange Act to adopt rules and regulations "reasonably designed to prevent [] such acts and practices as are fraudulent, deceptive, or manipulative" [5] As indicated in the Release, the Proposed Rule was designed to establish standards for the procurement and dissemination by underwriters of disclosure documents as a means of enhancing the accuracy and timeliness of disclosure to investors in municipal securities. Specific provisions of the Proposed Rule also were intended to assist underwriters in meeting their responsibilities under the general antifraud provisions of the federal securities laws, by providing them with a mandatory opportunity to review the issuer's disclosure documents before commencing sales to investors.

In proposing Rule 15c2-12, the Commission recognized that, as a result of efforts by the industry to improve disclosure, most issuers in offerings above $1 million prepare offering documents that are available to investors. The Government Finance Officers Association ("GFOA") Disclosure Guidelines [6] state, however, that "[i]ssuers of municipal securities should, in addition to preparing official statements, take appropriate steps to further the avilability to the public of the information therein. Among other things, the GFOA's Disclosure Guidelines encourage the dissemination of official statements to investors "as early as possible. [7]

In responding to the Commission's request for comments, numerous issuers confirmed that it was their practice to produce preliminary and final official statements in connection with an offering of bonds. Moreover, among frequent issuers, the quality of disclosure was reported to be quite good. The Public Securities Association ("PSA") noted, for example, that most of those responding to its survey of current disclosure practices in the municipal markets [8] had rated disclosure in new issues as "satisfactory" and "very good" [9] It pointed out that 94% of those responding to the survey rated "content and completeness" of disclosure documents in new issues as "satisfactory" to "excellent" Nevertheless, the PSA reported that this very positive assessment of disclosure practices dropped sharply when the availability of disclosure was considered. Forty-five percent of those responding to its survey rated "availability of documents (preliminary and final) in a timely fashion" as less than "satisfactory"

The views of the PSA generally correspond to the comments received from issuers, underwriters, and investors. While most issuers are conscientious about providing adequate quantities of official statements in a timely fashion, commentators indicated that there was a range of practices. Investors, in particular, have complained about the ability to obtain disclosure documents prepared by issuers at a time that would permit review prior to making an investment decision.[10]

Securities and Exchange Commission Staff Report on the Investigation in the Matter of Transactions in Washington Public Power Supply System Securities (1988) ("Supply System Report"). The Commission's investigation of the Supply System default revealed serious problems in the disclosure practices observed by securities professionals particiapting in the Supply System's bond offerings.

Securities Exchange Act Release No. 26100 (Sept. 22, 1988), 53 FR 37778.

15 U.S.C. 78a et. seq.

The comment letters and summary of the comment letters prepared by the staff of the Division of Market Regulation are contained in Public File No. S7-20-88.

Rule 15c2-12, although denominated under Section 15(c) of the Exchange Act (15 U.S.C. 78o), also was proposed, and is herein adopted, under the Commission's authority in Sections 2, 3, 10, 15B, 17, and 23 of the Exchange Act, 15 U.S.C. 78b, 78c, 78j, 78o-4, 78q, and 78w.

GFOA, *Disclosure Guidelines for State and Local Government Securities* (January 1988) (hereinafter "GFOA Disclosure Guidelines").

See Procedural Statement No. 3, "Availability of Official Statements to the Public and Delivery of Official Statements to Underwriters, Id. at 83.

Public Securities Association, Municipal Disclousure Task Force Report: Initial Analysis of Current Disclosure Practices in the Municipal Securities Market, (June 1988) (hereinafter "PSA Task Force Report").

Letter from Austin V. Koenen, Chairman, Municipal Securities Division, PSA, to Jonathan G. Katz, Secretary, SEC (Dec. 23, 1988).

[10] *See e.g.,* Letter from Peter J.D. Gordon, Vice President and Director, Municipal Bond Division, T. Rowe Price, to Jonathan G. Katz, Secretary, SEC (Dec. 27, 1988). The PSA's survey also indicates that when disclosure documents are prepared, they are furnished to dealers prior to settlement of the transaction only 41% of the time. Respondents to the PSA's survey reported that official statements are furnished to underwriters and dealers after settlement of the transaction approximately 30% of the time. *PSA Task Force Report, supra* note 8 at III-14, 15.

In addition, there is concern among underwriters that, in light of their responsibilities under the general antifraud provisions of the federal securities laws, greater opportunity should be afforded to review the disclosure of infrequent issuers, so that any problems in the disclosure documents may be detected before recommendations are made to investors. One association, representing bank municipal securities dealers, commented, for example, that in some geographic areas underwriters are able to examine official statements a week prior to the bid date for competitive offerings, while in other geographic areas the preliminary official statements are not available, if at all, until after the bids are due.[11]

The Commission believes that Rule 15c2–12 will promote greater industry professionalism and confidence in the integrity of the municipal markets without unnecessarily burdening issuers. As suggested in the Release, and reflected in the comment letters, it has generally been the view of state and local governments that regulation intended to enhance disclosure in the municipal markets is beneficial, so long as it does not adversely affect the capital-raising function of responsible issuers. In determining to adopt the Rule, the Commission is sensitive to the impact that the Rule may have on efficient financing practices developed in the municipal market. In this regard, the Commission has attempted to take into account commentators' concerns that the use of certain financing techniques, including tax-exempt commercial paper, variable rate offerings, and multi-mode issues,[12] as well as limited placements to sophisticated investors, might be unduly restricted if the Rule is adopted as proposed. Accordingly, the Commission has provided exemptions in the Rule to facilitate such offerings, which generally do not raise the concerns sought to be addressed by the Rule. Although the Commission has chosen to adopt Rule 15c2–12 at this time, it encourages a continuing dialogue with members of all segments of the municipal industry. The Commission has specifically provided in paragraph (d) of the Rule, discussed later, that exemptions from any of the provisions of the Rule may be granted, upon written request, where the exemption is consistent with the public interest and the protection of investors. The exemptive provisions in paragraph (d) are designed to afford immediate flexibility to correct unforeseen burdens.

A. Scope of the Rule

As indicated above, Rule 15c2–12 is being promulgated under the Commission's authority in section 15(c) of the Exchange Act as a means reasonably designed to prevent fraud. The Rule applies only to underwriters participating in "a primary offering of municipal securities with an aggregate principal amount of $1,000,000 or more" In addition, the Rule contains exemptions for underwriters participating in offerings of municipal securities in large denominations that are sold to no more than 35 sophisticated investors, or have short-term maturities, or have short-term tender or put features.

1. Thresholds

Proposed Rule 15c2–12 would have applied to underwriters participating in an offering of municipal securities with an aggregate offering price in excess of $10 million. The Commission proposed an initial threshold of $10 million in an effort to assure that any costs that the Rule might impose would be offset by the potential protection to the largest number of investors. Data supplied by the PSA indicated that if the proposed threshold were implemented, 25% of long-term bond offerings, accounting for 86% of the total dollar volume of such offerings, would be subject to the Proposed Rule. The Commission also requested comment on whether some alternative level was more appropriate, including $1 million, $5 million, $20 million, or $50 million.[13]

Thirty-nine commentators expressed a view on the appropriate theshold for the Rule. The alternative suggestions ranged from no threshold to $50 million. Eight commentators generally favored a higher threshold, while 29 suggested lower thresholds, usually at the $1 million level.[14] In particular, the PSA and the MSRB strongly recommended that the Commission move the Rule's threshold to $1 million dollars.

The comment letters expressed a strong sentiment that a substantial portion of both defaults and disclosure dissemination problems in the municipal securities markets occurred in offerings below the proposed threshold. The Bond Investors Association, for example, noted that of the defaults occurring in bonds issued between 1981 and 1985, 79% of issues and 40% of the dollar amount of defaults were in issues below $10 million.[15] While there is not a direct correlation between economic defaults and the adequacy of disclosure, many of the offerings below the proposed $10 million threshold are in types of securities that present higher risks to investors that should be highlighted in a complete disclosure document. In addition, a greater portion of offerings below $10 million are by infrequent issuers, with whom the market is unfamiliar. The PSA, along with other commentators, noted that the quality of disclosure correlates directly with the size of the bond issue. Generally, the larger the bond issue, the better the disclosure.[16] Thus, the Commission is persuaded that the structural safeguards contained in Rule 15c2–12 will have added significance in offerings below $10 million.

Apart from the actual quality of disclosure in offerings below $10 million, there was also concern about the

[11] Letter from Richard L. DeCair, Executive Director, Bank Capital Markets Association, to Jonathan G. Katz, Secretary, SEC (Jan. 12, 1989). Similar comments were received from individual underwriters who stated that even when preliminary official statements are distributed to potential bidders in competitive offerings, they may not arrive in sufficient time to permit an appropriate review. *See, e.g.* Letter from Susan V. Dushock, First Vice President, Municipal Bond Department, and Walter J. Peters, Vice President and Associate General Counsel, Shearson Lehman Hutton, to Jonathan G. Katz, Secretary, SEC (Dec. 27, 1988).

[12] See discussion *infra* at note 81 concerning variable rate demand notes and multi-mode offerings. *See generally*, Amdrusky, *Creative State and Local Financing Techniques*, in *State and Local Government Financing* (Gelfand ed. 1987).

[13] The Commission inquired about the costs that issuers and underwriters would experience if the threshold were set at alternative offering amounts, and invited comment about the quality and timeliness of disclosure provided at the alternative offering amounts. In addition, the Commission requested comment on whether the threshold should be based upon the type of issuer, maturity, or complexity of the bonds being offered.

[14] Many of the commentators conditioned their support for lower thresholds on appropriate exemptions for certain types of offerings. Some commentators, including the GFOA, that supported higher thresholds for governmental issuers, also indicated that lower, or no thresholds, would be appropriate for conduit offerings, which they reported have shown the greatest degree of disclosure problems. Two commentators supported the proposed threshold.

[15] Letter from C. Richard Lehman, President, Bond Investors Association, to Jonathan G. Katz, Secretary, SEC (Nov. 22, 1988). The Bond Investors Association indicated that it selected the five year period from 1981 to 1985 to avoid most of the distortion created by the Supply System default in pre-1981 statistics. The period chosen also ignores the last three years in which the Association indicated that defaults are future event for the most part.

[16] The PSA Task Force Report on municipal securities stated that only 5% of the 264 dealers responding to its survey found that the adequacy of disclosure was below satisfactory in negotiated offerings above $50 million. In contrast, 20% of the respondents found disclosure to be less than satisfactory in negotiated offerings of $10 million or less. *PSA Task Force Report, supra* note 8, Table 11A. *See also*, Forbes & McGrath, *Disclosure Practices in Tax-Exempt General Obligation Bonds: An Update*, 7 *Mun. Fin. J.* 207 (1986).

perception that a high threshold would create among investors.

Specifically, some commentators conjectured that if a $10 million threshold were utilized, it would result in a "tiering" of the municipal markets.[17] They indicated that investors might view all offerings below the $10 million threshold as lacking the same quality of disclosure as those subject to the Rule, and may have discriminated against such offerings. Accordingly, issuers offering securities in amounts below the threshold may have been required to pay increased underwriting spreads compared to securities subject to the Rule's safeguards.

While the Commission has determined to lower the threshold to one million dollars, it is sensitive to concerns that the Rule not impose unnecessary costs on municipal issuers.[18] Recent studies indicate that the large majority of issuers, 84% of municipal securities offerings, including both competitive and negotiated offerings, provide official statements.[19] Even with the lower threshold, many commentators, including the MSRB and PSA, indicated that the Rule, as adopted, will not impose unnecessary costs or force a majority of responsible issuers to depart from their current practices. The commentators suggested that the Rule should, however, encourage more effective disclosure practices among those issuers that do not currently provide adequate and timely information to the market. In this connection, support for a one million dollar threshold also was found in the comment letters from some issuers and issuer trade associations.[20]

In addition to requesting comment on whether the proposed threshold should be revised, the Commission also invited comment on whether thresholds should be implemented that distinguish among different types of offerings. A number of the commentators suggested that most of the problems in municipal disclosure had occurred in conduit offerings. In light of the low default rate of general obligation bonds, they argued that some distinction should be made according to the type of debt being offered.

The GFOA, among others, recommended that governmental purpose bonds should alternatively be exempt from the Rule's requirements or subject to a $25 million threshold.[21] In contrast, an almost equal number of commentators, including issuers,[22] objected to any distinction in applying the Rule. One issuer noted, for example, "if disclosure is good and most responsible issuers are currently complying with reasonable guidelines, no harm is done in requiring the 9% of government issuer's [sic] who are not making adequate disclosure (according to the PSA Survey) to comply with the proposed rule, and therefore strengthen acceptance for all of us in the market. [23]

After reviewing the comment letters, the Commission has decided not to draw a distinction between types of offerings in the Rule. In reaching this decision, the Commission is mindful that there is a range of creditworthiness and risk associated with both governmental and conduit bonds that may vary significantly according to the issuer.[24] Moreover, while defaults may have the most severe impact on the value of a security, investors are more likely to be affected by the exercise of call provisions or other terms of the offering. The MSRB, in its comment letter, emphasized that as offerings have become more complex, information concerning the structure of the offering has acquired increased significance to investors. Thus, notwithstanding the relatively low default rate enjoyed by general obligation debt, the Commission believes that it is equally important for investors to receive timely and complete information about terms of the offering in all types of issues.[25]

2. Primary Offerings

The Commission also modified the Rule to clarify that it applies only to "primary offerings" a term that is defined in paragraph (e)(7).[26] The Commission determined to restrict the scope of the Rule to primary offerings in response to concerns expressed by commentators that broader language in the Proposed Rule may have incorporated concepts concerning the registration of secondary offerings of securities under the Securities Act of 1933 ("Securities Act").[27] While, as discussed later, the Rule will apply to certain reofferings of municipal securities conducted pursuant to the conversion of a multi-mode issue,[28] the Rule does not generally apply to secondary distributions.

B. Requirements of the Rule

1. Obtain and Review "Near Final" Official Statement

The Proposed Rule would have required that underwriters receive a copy of a "near final" official statement

[17] *See, e.g.*, Letter from John W. Rowe, Chairman, MSRB, to Jonathan G. Katz, Secretary, SEC (Nov. 8, 1988); Letter from PSA.

[18] At the one million dollar threshold, the Rule will apply to 79% of all long-term bond issues, accounting for 99% of the total dollar amount of long-term municipal offerings. Release 53 FR at 37783. In 1988, approximately $23,358 million in short-term debt (less than 13 months) was offered. At the current threshold of $1 million, 99% of the dollar amount and 71% of short-term debt issues would be subject to the Rule. Source: IDD/PSA Database.

[19] *PSA Task Force Report, supra* note 8, at 84.

[20] Letter from Earle E. Morris, Jr., President, National Association of State Auditors, Comptrollers and Treasurers ("NASACT") to Jonathan G. Katz, Secretary, SEC (Jan. 12, 1989); Letter from Janet C. Rzewnicki, President, National Association of State Treasurers, to Jonathan G. Katz, Secretary, SEC (Jan. 18, 1989); Letter from Carl W. Reidy, Jr. and Roy T. Deaton, National Council of State Housing Agencies, to Jonathan G. Katz, Secretary, SEC (Dec. 22, 1988).

[21] Letter from Jeffrey L. Esser, Executive Director, GFOA, to Jonathan G. Katz, Secretary, SEC, (Jan. 12, 1989).

[22] *See*, e.g. Letter from John M. Gunyou, City Finance Officer, Minneapolis, Minnesota, to Jonathan G. Katz, Secretary, SEC (Feb. 16, 1989); Letter from Max R. Bohnstedt, Director of Finance, Montgomery County, Maryland, to Jonathan G. Katz, Secretary, SEC (Dec. 27, 1988); Letter from NASACT; and, Letter from National Council of State Housing Agencies.

[23] Letter from John M. Gunyou.

[24] One commentator noted, for example, that only the general obligation of an issuer of meaningful size, with full governmental powers, is likely to produce a distinct level of security to investors. Similarly, a "conduit" bond of a reporting company may have more in common with the general obligation debt of major city than either does with the bonds of an irrigation district or conduit bonds for a start-up retirement facility. Moreover, a government hospital may have the identical credit risk as a hospital owned by not-for-profit organization. Letter from Robert Dean Pope, Partner, Hunton & Williams, to Jonathan G. Katz, Secretary, SEC (Jan. 31, 1989).

[25] Although the Proposed Rule was published for comment at the same time that the Commission released the *Supply System Report* to Congress, the Proposed Rule was not aimed at preventing municipal defaults. While defaults may pose the most serious economic threat to investors, the Commission noted in the Release that "no amount of increased review of offering materials by municipal underwriters will prevent municipal defaults totally. 53 FR at 37781. The Commission is aware that municipal securities, particularly general obligation bonds, have enjoyed relatively low default rate, when compared to corporate offerings. In addition, as discussed in the Release, efforts by the industry have improved greatly the quality of disclosure provided to investors in municipal securities.

Several commentators provided statistics on the current default ratios for municipal securities by type of issuer. The GFOA stated that the default rate, by type of issuer, was as follows: conduit securities—1.2%; governmental obligations (Supply System default included)—0.5%; governmental obligations (Supply System default excluded)—0.1%. It compared municipal default rates to corporate default rate of 1.1%.

[26] The term "primary offering, for purposes of Rule 15c2-12, is defined in paragraph (e)(7) to mean an offering of municipal securities directly or indirectly by or on behalf of an issuer of such securities, including any remarketing of municipal securities that is accompanied by decrease in the authorized denominations of the securities to less than $100,000 or by an increase in the maturity of such securities to more than nine months.

[27] 15 U.S.C. 77a et seq.

[28] See discussion *infra* at note 81 and accompanying text.

before bidding for or purchasing an offering of municipal securities. The Release states that the purpose of this provision was to assure that underwriters have received and availed themselves of an opportunity to review an official statement containing "complete" disclosure about the issuer and the basic structure of the financing, before becoming obligated to purchase a large issue of securities. The Proposed Rule identified specific information that could be excluded from the official statement at the time that the underwriter bid for or purchased the securities. Specifically, the "near-final" official statement need not have contained information regarding the "offering price, interest rate, selling compensation, amount of proceeds, delivery dates, other terms depending on such factors, and the identity of the underwriter.

Paragraph (b)(1) of the Rule requires any underwriter that bids for, purchases, offers, or sells, whether as principal or as agent, municipal securities in a primary offering, to obtain and review an official statement that is deemed final by the issuer, except for the omission of certain information. Thus, in a competitive offering, an underwriter will need to receive a copy of disclosure documents prepared in conjunction with the offering by the issuer, or on its behalf, before bidding on the issuer's securities.

The Commission recognizes that in most negotiated offerings the underwriter has a much closer relationship with the issuer and generally participates in drafting the issuer's official statement. In negotiated offerings, the Rule would require the underwriter to obtain a copy of the official statement, deemed final by the issuer, prior to the earlier of the time it executes the bond purchase agreement or the first sale of the bonds. Generally, in negotiated offerings, bonds are offered to investors immediately following the pricing of the securities and the bond purchase agreement is executed a few days later. Consequently, for practical purposes, the underwriter would need to have a copy of a "near-final" official statement at the time of pricing.[29]

As adopted, paragraph (b)(1) contains modifications from the Proposed Rule that are designed to reflect the views of commentators. In response to commentators' suggestions, the Rule specifies that any determination concerning whether the official statement provided to underwriters should be deemed final for purposes of satisfying the terms of the paragraph is made by the issure. In changing this provision from the Proposed Rule, the Commission was persuaded that allowing the issuer to determine whether the official statement would be deemed final for purposes of paragraph (b)(1) will eliminate uncertainty as to how, and in what manner, an underwriter should ascertain that the disclosure document is "complete" [30] prior to its review of the document.[31]

Although paragraph (b)(1) requires the underwriter to obtain a copy of an official statement that is deemed final by the issuer, the Commission recognizes that certain information frequently is omitted from preliminary official statements. As provided in the Rule, the official statement required by paragraph (b)(1) need not include the offering price(s), interest rate(s), selling compensation, aggregate principal amount, principal amount per maturity, delivery dates, other terms or provisions required by an issuer of such securities to be specified in a competitive bid, ratings, other terms of the securities depending on such matters, and the identity of the underwriter(s). The types of information that can be omitted also has been modified based on comment letters that suggested a need for greater flexibility with respect to disclosure concerning ratings, as well as credit enhancements and other information that may be specified by the underwriter in a competitively bid offering.

The GFOA's Disclosure Guidelines suggest that "the preliminary official statement should be as complete and accurate as possible" [32] The absence of the information specified above should not prevent the underwriter from soliciting indications of interest, so long as material information is supplied to potential investors prior to the time that an investment decision is made. In this regard, the Commission wishes to emphasize that, while the Rule requires that the underwriter obtain official statements which are deemed final by the issuer, except for the omission of certain information, disclosure is a dynamic process and even substantial changes to the document required by paragraph (b)(1) may be necessary to comply with the federal securities laws at the time of sale to investors.[33]

By requiring the underwriter to receive information concerning the offering at the time that it will most actively be engaged in selling efforts, the Rule is intended to assist the underwriter in satisfying its responsibilities under the antifraud provisions of the federal securities laws. As emphasized in the Interpretation, by participating in an offering, an underwriter makes an implied recommendation about the securities. This recommendation implies that the underwriter has a reasonable basis for belief in truthfulness and completeness of the key representations contained in the official statement. Once the underwriter has received and reviewed the official statement, it will be in a better position to assess the accuracy of the disclosure and to make informed recommendations to investors. Moreover, since the issuer is responsible for the disclosure in the final official statement, it is the ultimate beneficiary of any objective review of its disclosure prior to sale.[34] In this regard, it is

[29] Furthermore, an underwriter in best efforts offering or remarketing that meets the definition of "primary offering" also would have to comply with the provisions of the paragraph, unless it could take advantage of one of the exemptions discussed below.

[30] Reference to final official statement as a complete document has been moved to the definition of "final official statement" and, accordingly, will be applicable only to the final disclosure documents required to be contracted for under paragraph (b)(3) and disseminated to potential customers upon request under paragraph (b)(4).

[31] Some commentators suggested that use of the term "complete" in the Proposed Rule implied substantive disclosure obligations concerning the offering documents. The Rule was not intended to govern the content of the offering documents. The Commission is aware that efforts by the industry have produced disclosure guidelines that are widely followed in the preparation of municipal official statements. The GFOA's Disclosure Guidelines were first exposed for comment in 1975 and have been revised on several occasions, most recently in January of 1988. In addition, the National Federation of Municipal Analysts has recently proposed draft disclosure guidelines that would provide guidance on disclosure for 17 separate sectors of municipal securities. The Commission believes that both of these guidelines will assist issuers in fulfilling their current obligations under the general antifraud provisions of the federal securities laws. Moreover, these guidelines, in conjunction with the underwriter's own disclosure experience, aid the underwriter in satisfying its own obligation to assess the accuracy and completeness of key representations contained in the issuer s disclosure documents.

[32] Procedural Statement No. 2, "Use of Preliminary and Final Official Statements" *GFOA Disclosure Guidelines, supra* note 6 at 81.

[33] Although the Rule does not require the highlighting of changes that occur between the preliminary official statement and final official statement, some commentators have suggested that this practice is desirable. Hunton & Williams, for example, recommended that alterations and amendments suggested by the winning syndicate could more easily be brought to the attention of investors by (a) noting information in the final official statement not appearing in the preliminary or (b) providing special section that makes reference to such information in the final official statement (other than ordinary completion of pricing data). The Commission believes that these practices are beneficial to investors and would encourage their use.

[34] The GFOA Disclosure Guidelines recognize the importance of objective review of the issuer s

Continued

important to note that paragraph (b)(1) of the Rule need not prevent an underwriter from bidding on an issuer's securities in a competitive offering, even when it determines that disclosure problems exist, so long as the underwriter receives assurances that the disclosure will be corrected.[35]

The comment letters indicate that many issuers routinely provide potential bidders with preliminary official statements that would satisfy the requirements of paragraph (b)(1). Nevertheless, some commentators were concerned that the requirement in paragraph (b)(1) might conflict with certain practices used in connection with refundings and other interest rate sensitive offerings. While the Rule requires that the underwriter have disclosure documents before it bids for, purchases, offers or sells the securities, the Commission has changed the definition of a "final official statement" in paragraph (e)(3), discussed below, to reflect the fact that adequate disclosure may be made through the use of multiple documents. A similar philosophy would apply to the official statement required by paragraph (b)(1). Frequent issuers, for example, may be able to meet market windows for refundings or other types of offerings by supplying a recent official statement, together with supplementary information that contains the terms of the current offering and highlights any material changes from the previous offering materials. Nevertheless, the Commission expects that the Rule will require greater planning and discipline by some issuers.

2. Distribute Copies of Preliminary Official Statements in Non-Competitive Offerings

Paragraph (b)(2) of the Rule requires that, except in competitively bid offerings, an underwiter must send a single copy of the most recent preliminary official statement, no later than next business day, to any potential customer, on request. As proposed, paragraph (b)(2) would have required that the underwriter distribute copies of any preliminary official statement that is prepared by the issuer, to any person upon request. The purpose of the requirement is to provide potential investors with access to any preliminary official statement prepared by the issuer, at a time when it may be of use in making their investment decision. The Release noted that preliminary official statements frequently are used as selling documents to large investors, but that practices among underwriters may vary. Commentators confirmed that the current practice of providing preliminary official statements to investors varies from firm to firm and may depend, in great measure, upon a number of factors, including the issuer, whether the offering is conducted on a competitive or negotiated basis, and the position of the underwriter in the syndicate.

The preliminary official statement is an important disclosure document, even though in some cases the information concerning the precise terms of the offering is incomplete and must be supplemented. Despite the importance of the disclosure provided in preliminary official statements, the Commission has received comment from one major institutional investor which indicates that when preliminary official statements are prepared, only 70% arrive in time for the investor to conduct a professional review prior to the time of purchase.[36] Moreover, potential customers who are not institutional investors may not have access to either a preliminary or final official statement until several days following the sale of the securities.

While the Commission has chosen to require that preliminary official statements be provided by the underwriter, upon request, it has narrowed the original proposal in several respects. As adopted, the Rule requires an underwriter in a negotiated offering to send a single copy of the most recent preliminary official statement to any "potential customer" who requests a copy. Dissemination of preliminary official statements is beneficial for both issuers and investors. Nevertheless, paragraph (b)(2) does not require that issuers prepare a preliminary official statement for delivery to investors. If a preliminary official statement is produced, however, and any potential customer requests a copy, the underwriter would be required to send it by first class mail or another equally prompt means.

In response to concerns expressed in the comment letters that the original proposal would have placed unnecessary costs on underwriters, the Commission decided to limit the scope of persons to whom underwriters would be required to provide copies of the preliminary official statement to potential customers. In many cases, however, the commenters noted that it was their practice, as a matter of course, to honor such requests. The Commission believes that a decision about whether to provide copies of such documents to persons other than potential customers [37] should be left to the business judgment of the underwriter.[38]

The Commission also is modifying the Proposed Rule to except underwriters who participate in competitively bid offerings from the requirements of paragraph (b)(2). Many commentators suggested that the Proposed Rule would have forced underwriters bidding competitively on offerings to incur the cost of reproducing preliminary official statements at a point in the selling process when they may have had only limited access to copies of the preliminary official statement and could not be assured of winning the competition. Moreover, underwriters were concerned about distributing preliminary official statements that they had no role in preparing and had not had a full opportunity to review. By limiting application of the paragraph to negotiated offerings, the underwriter only will have to provide copies of the preliminary official statement in those offerings in which it has had the opportunity to participate in the preparation of the disclosure document and will have the direct ability to recover any expenses incurred in providing copies of preliminary official statements through sales of the issuer's securities.

As stated in the Rule, the underwriter's obligation under paragraph (b)(2) arises "from the time that [it] has reached an understanding with an issuer that it will become an underwriter until a final official statement is available.

disclosure. Procedural Statement No. 5, "Assistance by Issuers to Underwriters and Investors Inquiring about Information" states:

Issuers, underwriters and investors are concerned that information in official statements prepared by issuers be accurate and sufficient in all material respects. It has become common practice for underwriters and investors to assist in this effort by raising questions with issuers based on reviews of official statements and upon other information to which the underwriters and investors have access. Generally, the questions raised will relate to (i) possible information voids in an official statement, (ii) possible inconsistencies within the document, or (iii) possible inconsistencies between the document and other available information.

GFOA Disclosure Guidelines, supra note 6, at 86.

[35] *See* Release, 53 FR at 37790, n. 94 (discussing the need for the underwriter to provide in the underwriting agreement for the ability to correct inaccurate or incomplete disclosure).

[36] Letter from T Rowe Price.

[37] At the suggestion of the PSA, and others, the term "potential customer" is defined in paragraph (e)(4) to mean a person contacted by the participating underwriter concerning the purchase of municipal securities that are intended to be offered or have been sold in the offering; any person who has expressed an interest in purchasing such securities; and any person who has a customer account with the participating underwriter.

[38] Copies of preliminary official statements also frequently are available to anyone, upon request, from the issuer.

Generally, the underwriter's formal contractural obligation to purchase the bonds will arise following pricing, at the time that it signs the bond purchase agreement. Notwithstanding the fact that the underwriter has not signed a document agreeing to purchase the bonds in a negotiated offering, its obligation under the Rule would begin at the time it has reached an understanding with the issuer that it will offer the bonds, either directly, or by agreeing to join a syndicate.[39] In many cases, this would mean that the managing underwriter's obligation to provide copies of preliminary official statements will commence at the point that it is chosen by the issuer pursuant to the request for proposal process. Once the underwriter's obligation is incurred, the Rule requires that the underwriter continue to provide copies of the most recent preliminary official statement, upon request, until the final official statement becomes available.[40]

The Proposed Rule contained no definition of "preliminary official statement, although it suggested that a preliminary official statement was a document "prepared by the issuer for dissemination to potential bidders or purchasers. Commentators expressed confusion about the relationship between a "preliminary official statement" and the official statement required to be reviewed by underwriters pursuant to paragraph (b)(1) of the Rule. The Rule now contains a definition of a preliminary official statement in paragraph (e)(6).

The definition of preliminary official statement contains no description of the disclosure content of the document. Instead, the term preliminary official statement is defined only be reference to the issuer's intention that it be distributed to potential customers. Thus, a document (or set of documents) utilized to comply with paragraph (b)(1) need not be disseminated pursuant to paragraph (b)(2), unless the document also is intended to be, or has been, disseminated to any potential customer.[41] This definition is consistent with the purpose of paragraph (b)(2), the only paragraph in which the term is used, in that paragraph (b)(2) is designed to assure access by all potential customers to information prepared by issuers for dissemination to prospective investors.[42]

3. Receive Copies of Final Official Statements

Paragraph (b)(3) of the Rule requires that an underwriter contract with the issuer, or its agents, to receive sufficient quantities of the final statement to provide them to potential customers upon request and to comply with any rules of the MSRB. The purpose of the provision is to facilitate the prompt distribution of disclosure documents so that investors will have a reference document to guard against misrepresentations that may occur in the selling process. In addition, the paragraph, in conjunction with paragraph (b)(4), will assure that both investors and dealers in the secondary market have greater access to information regarding the terms of the securities.

As noted earlier, while the quality of disclosure has improved greatly in the municipal markets, the PSA Task Force Report reveals that significant problems exist in the distribution of disclosure documents. Currently, the MSRB's rule G-32 requires that, if an official statement is prepared, an underwriter participating in a primary offering of municipal securities must make the official statement available to investors "promptly after the date of sale of the issue but no later than two business days before the date all securities are delivered by the syndicate manager to the syndicate members. In addition, the GFOA's Disclosure Guidelines note that "it is important for the official statement to be made available at such time and in such quantity as will permit the official statement to be mailed expeditiously by the underwriters in time for receipt by investors at or prior to settlement. [43]

Notwithstanding underwriters' current obligations under the MSRB's rules, the MSRB stated its concern that the task of distributing official statements often is relegated to a low priority by underwriters. By adopting paragraph (b)(3), which serves as a foundation for fostering compliance with the requirements of MSRB rule G-32, the Commission wishes to emphasize the importance it places on the prompt distribution of final official statements.

Under pararaph (b)(3), the underwriter would be required to contract with the issuer or its agents to receive copies of the final official statement within the time periods mandated by the Rule. Generally, issuers will state in notices of sale for competitive offerings that the successful bidder will be provided with a "reasonable number" of final official statements. Before bidding on a competitive offering, or as a condition to bidding, the underwriter would need to determine that it can comply with the terms of the Rule.

Because the bond purchase agreement in a negotiated offering typically is not signed until a late point in the offering process, the underwriter would need to be sure that contractural terms meeting the requirements of paragraph (b)(3) are separately negotiated or are otherwise a clear condition to its participation in the offering. Either the issuer or its agent may be the party contractually bound to provide the underwriter sufficient copies of the final official statement. In syndicated offerings, members of the syndicate would need to assure themselves that provision has been made by the managers to comply with the terms of the Rule and may require such an undertaking in the agreement among underwriters.

Generally, the underwriter's responsibility would be satisfied under paragraph (b)(3) if it has arranged for sufficient quantity of the final official statement to be made available from either the issuer or a financial printer within the time periods stated in the Rule. While the Rule does not provide rigid quantitative standards for the minimum number of official statements that would be required, the underwriter would need to obtain copies sufficient to comply with paragraph (b)(4) of the Rule and to satisfy MSRB rule G-32 or any other rules adopted by the MSRB. Under current MSRB rule G-32, therefore, the underwriter would have to provide each investor a copy of the final official statement no later than settlement. Also, as discussed below, paragraph (b)(4) generally requires that the underwriter provide copies of the final official statement, upon request, to any potential customer for a period of at least 25 days, and up to 90 days following the end of the underwriting period.

[39] *Cf.* Rule 10b-6(c)(2)(ii) (17 CFR 240.10b-6(c)(2)(ii)) (defining a "prospective underwriter" to include one "who has reached an understanding, with the issuer or other person on whose behalf distribution is to be made, that he will become an underwriter, whether or not the terms and conditions of the underwriting have been agreed upon").

[40] If a broker, dealer or municipal securities dealer reaches an initial understanding that it will offer an issuer s securities, and later, for example, at pricing, determines not to act as an underwriter, its obligations under paragraph (b)(2) would cease.

[41] The Commission does not expect that an underwriter who determines that the preliminary official statement is inaccurate or contains misleading omissions regarding the issuer, would provide copies to potential customers, upon request, pursuant to paragraph (b)(2).

[42] Whether a document identified by an issuer as preliminary official statement meets the requirements of paragraph (b)(1) depends on whether it is deemed final by an issuer, except for the information specifically permitted to be omitted by that paragraph.

[43] Procedural Statement No. 3, "Availability of Official Statements to the Public and Delivery of Official Statements to Underwriters" *GFOA Disclosure Guidelines, supra* note 6, at 83.

Any contract with the issuer or its agents would have to provide that copies of the final official statement will be delivered, at the latest, within seven business days following the bond purchase agreement, and in sufficient time to accompany or precede any confirmation requesting payment ("money confirmation").[44] Apart from requiring that the underwriter contract to obtain copies of the final official statements within a reasonable period of time, the Commission has chosen to leave the determination of the precise method and timing of delivery to the MSRB. Moreover, if the MSRB determines that specific recordkeeping requirements are necessary to assure compliance with this or other provisions of the Rule, it would be able to use its authority under section 15B(b)(2)(G) of the Exchange Act to adopt such rules.

(a) *Definition of "issuer"* In addition to comments on the mechanical requirements of paragraph (b)(3) of the Rule, the Commission received numerous comments on the content of disclosure required in a final official statement and the persons who would be considered "issuer(s)" for purposes of the Rule. The term "issuer of municipal securities" is used in the Rule to identify the person from whom disclosure documents must be received, for purposes of paragraph (b)(1), and with whom the underwriter must contract to obtain disclosure documents, for purposes of paragraph (b)(3). In response to commentators' concerns that the Proposed Rule did not properly distinguish between governmental issuers and the private borrower in conduit offerings, the Commission has specifically defined the term "issuer of municipal securities" in paragraph (e)(4). Commentators had argued that, among other things, the conduit borrower is the economic beneficiary of the transaction and that review of information by the underwriter for purposes of paragraph (b) of this Rule should be focused on the conduit borrower. In light of these comments,[45] the Commission has determined to clarify the Rule by defining the term "issuer of municipal securities" to account for the multiple credit sources that may be considered issuers for purposes of the Rule.[46] As defined, the term encompasses both the governmental issuer specified in section 3(a)(29) of the Exchange Act,[47] as well as the issuer of any separate security, including a separate security as identified in Rule 240.3b-5(a) of the Exchange Act.[48] Accordingly, underwriters would be free to contract with any issuer, or its agent, that is in a position to supply the documents required by paragraph (b)(3) of the Rule.

(b) *Definition of "final official statement"* The term "final official statement" which is used in both paragraphs (b)(3) and (b)(4), is defined in paragraph (e)(3) to mean a document or set of documents prepared by an issuer of municipal securities, or its agents, setting forth, among other matters, information concerning the issuer of the municipal securities and the proposed issue of securities, that is complete on the date of delivery to the Participating Underwriter. As adopted, the term "final official statement" contains several modifications from the Proposed Rule that are designed to reflect the views of commentators.

The term "complete" is used to indicate that the final official statement should not be in preliminary form or intended by the issuer to be subject to amendment after its delivery to the underwriters, except to take account of subsequent events or to correct any errors that are discovered. Also, in response to suggestions from the American Bar Association,[49] and other commentators, the date as of which the official statement must be complete has been changed from the time of the agreement to purchase the securities, to the time at which the final official statement is to be delivered to the underwriters. This avoids the problem that might otherwise arise if events occur between the time of agreement to purchase the securities and the date on which the final official statement is made available to underwriters for dissemination pursuant to this Rule and the rules of the MSRB.

Another modification to the definition of final official statement in the Proposed Rule relates to the use of multiple documents. In the Proposed Rule, the term final official statement referred to a single document that has generally been viewed by the industry as the final official statement. As noted in the Release, the Commission is aware that in competitive offerings a preliminary official statement may be circulated to potential bidders which omits the information described in paragraph (b)(1). In some cases, the issuer will prepare a final official statement containing all the terms of the offering, while in other cases, pricing, underwriting, and other information is appended to the preliminary official statement, which is then regarded by the issuer as its final official statement.

The revised definition of a final official statement specifically recognizes that the issuer's final official statement may be comprised of one or more documents, "not necessarily bound together in a single booklet. [50] Thus, in the context of competitive offerings described above, the term would encompass a preliminary official statement coupled with pricing information. In addition, the term "final official statement" would incorporate a group of documents, containing disclosure about the offering, that collectively present an accurate description of its terms. Some commentators maintained that if an issuer had prepared a complete disclosure document for a recent offering, underwriters should be permitted to use that document, together with supplemental information updating the disclosure and describing the terms of the current offering, to satisfy the requirements of the Rule. It was suggested that this procedure may be appropriate in the context of certain "wire deals and short-term offerings.[51]

4. Provide Copies of Final Official Statements to Potential Customers

As adopted, paragraph (b)(4) of the Rule requires that underwriters provide copies of any final official statement to any potential customer, on request. Once it receives a request for a copy of the final official statement, the underwriter must send the copy no later than the next business day, by first class

[44] The Commission is aware that in many cases underwriters provide interim confirmations to investors, notifying them of the precise amount of municipal securities purchased and the terms of the purchase. This interim confirmation is followed later by money confirmation requesting payment for the bonds purchased. The Rule requires only that the underwriter contract to receive copies of the final official statement prior to the time that money confimations are sent to customers.

[45] Apart from the mechanical requirements of the Rule, the Commission notes that the actual disclosure responsibilities of the parties under the general antifraud provisions of the federal securities laws will depend on the facts and circumstances in each case.

[46] Under the definition in paragraph (e)(3), the issuer of letter of credit would also be considered an issuer of the securities for purposes of this Rule.

[47] 15 U.S.C. 78c(a)(29).

[48] 17 CFR 240.3b-5(a).

[49] Letter from James H. Cheek, Chairman, Committee on Federal Regulation of Securities, and Robert S. Amdursky, Chairman, Subcommittee on Municipal and Governmental Obligations, American Bar Association, to Jonathan G. Katz, Secretary, SEC (Jan. 26, 1989).

[50] *See* Letter from the American Bar Association.

[51] As defined in paragraph (e)(3), these documents would constitute a final official statement when combined. In order to meet the requirements of paragraph (b)(3), however it would be necessary for the underwriter to contract with the issuer for a sufficient quantity of the combined documents for dissemination to investors.

mail or another equally prompt means. The requirements in this paragraph of the Rule differ from the Proposed Rule in two limited respects.

First, there no longer is a requirement that copies of the final official statement be provided to "any person. Many of the commentators suggested that this requirement was too broad, and would have placed an unnecessary burden on the underwriter. Accordingly, the Commission has limited the obligation of underwriters so that, consistent with paragraph (b)(2), they need respond only to requests for copies from potential customers.[52]

A second modification is the addition of specific time periods during which the underwriter must supply copies of the final official statement. The Proposed Rule would have required underwriters to supply copies of the final official statement, on request, for an indefinite period. Many of the commentators indicated that this requirement would have placed an unreasonable burden on underwriters and suggested that the Commission limit the delivery period. Suggestions for the termination of the delivery obligation ranged from completion of the offering to the maturity or redemption of the bonds. If a municipal disclosure repository were created, commentators argued that the underwriters' obligation to distribute copies of the final official statement should terminate at the time the documents were available from the repository.

After reviewing the comment letters, the Commission has decided to limit the underwriter's delivery obligation to a period commencing with the availability of the final official statement and terminating at a maximum of 90 days following the "end of the underwriting period, a term that is defined in paragraph (e)(2) of the Rules.[53] Moreover, while the underwriter must supply copies of the final official statement to potential customers on request for a period of at least 25 days following the end of the underwriting period,[54] its obligation under paragraph (b)(4) will terminate after the 25-day period, if the final official statement is made available to any person from a nationally recognized municipal securities information repository ("NRMSIR").[55] If the final official statement is not available from a NRMSIR, the underwriter's obligation to deliver copies of the final official statements, upon request, would continue for the full 90-day period.

(a) *Nationally Recognized Municipal Securities Information Repository.* In the Release, the Commission solicited comment on the creation of a central repository for municipal disclosure documents.[56] Of the more than 60 comment letters the Commission received, 45 commentators expressed a view on the concept of a central repository. Forty commentators supported some form of a central repository.[57] The primary reason given for supporting the creation of one or more central repositories was the need to have a readily accessible central source of information on municipal bonds.

Even among the 40 commentators that supported the development of a central repository, there was a substantial difference of opinion on how it should be implemented, what documents should be filed, and who should file them. A number of commentators argued that competing private organizations that meet government-imposed standards offer a better approach than a single governmental or quasi-governmental service.[58]

The Commission strongly supports the development of one or more central repositories for municipal disclosure documents.[59] The use of such repositories will substantially increase the availability of information on municipal issues and enhance the efficiency of the secondary trading market. In this regard, the Commission welcomes the recent announcement of the MSRB [60] that it is prepared to establish and manage a central repository that would be funded both by the MSRB and user fees, and would provide for the collection and dissemination of official statements and refunding documents.[61] The Commission understands that in conjunction with the adoption of Rule 15c2-12, the MSRB intends to propose an amendment to its rule G-32, that would require underwriters to submit copies of final official statements to the repository. Once the documents are received from the underwriter, the MSRB has indicated that the repository will function like a public library that stores and keeps an index of its documents. Private vendors will be encouraged to utilize the MSRB's repository as a means of collecting documents for dissemination, in complete or summary form, to their customers.

Although the Commission supports the MSRB's recent initiative, it recognizes the benefits that may accrue from the creation of competing private repositories.[62] The Commission, therefore, views positively the recent statements by disclosure services indicating their intention to acquire information from the MSRB's repository,

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[52] As pointed out earlier, underwriters commenting on the Proposed Rule informed the Commission that in many cases they routinely respond to requests for copies of documents, regardless of the source of the request. In addition, copies of final official statements are generally maintained by the issuer. For example, Procedural Statement No. 3 of the GFOA's Disclosure Guidelines, "Availability of Official Statements to the Public and Delivery of Official Statements to Underwriters" states "all parties other than underwriters who contact the issuer should receive, without charge, at least one copy of the official statement. *GFOA Disclosure Guidelines, supra* note 6 at 83.

[53] The term "and of the underwriting period" differs from similar terms utilized in MSRB rules G-11 and G-32. As used in paragraph (b)(4) of the Rule, the term identifies the period from which the underwriter's obligation to provide final official statements to potential customers is measured. For issues that are sold prior to settlement with the issuer, the settlement date (i.e. the date the issuer delivers the securities to the underwriter) would be the "end of the underwriting period" For securities that are not sold by settlement, the underwriting period is defined to end when the underwriter sells its unsold balance of securities. The definition recognizes that generally in municipal securities offerings, until the syndicate breaks, each underwriter is considered responsible for a portion of the unsold syndicate balance.

[54] During the underwriting period, the underwriter must remain sensitive to developments that impact the accuracy and completeness of the key representations contained in the final official statement. If there are material changes, the final official statement should be amended or "stickered" to provide complete and accurate disclosure.

[55] The elements the Commission would consider in determining whether a particular entity is a NRMSIR are discussed in *infra* note 65.

[56] The concept of a central repository for municipal official statements has been discussed by the industry for a number of years and was specifically presented to the Commission in a proposal by the MSRB. *See* Letter from James B.G. Hearty, Chairman, MSRB, to David S. Ruder, Chairman, SEC (Dec. 17, 1987). As initially envisioned by the MSRB, participation in the repository by municipal issuers would have been mandatory and information concerning new issues would have been made available of interested persons for a fee.

[57] The Commission received comments from a broad spectrum of entities on this issue. As indicated earlier, a detailed description of the comments is included in the comment summary, which is available in the Commission s Public File No. S7-20-88.

[58] *See, e.g.,* Letter from J. Kevin Kenny, Chairman and Chief Executive Officer, J.J. Kenny Co., Inc., to Jonathan G. Katz, Secretary, SEC (Dec. 27, 1988).

[59] The Commission notes that the creation of multiple repositories should be accompanied by the development of an information linkage among these repositories. The advent of a linked repository system would afford the widest retrieval and dissemination of information to the secondary markets.

[60] Letter from John W Rowe, Chairman, MSRB, to Jonathan G. Katz, Secretary, SEC (June 1, 1989).

[61] Under section 15B(b)(2)(J) of the Exchange Act, 15 U.S.C. 78o-4(b)(2)(J), any fees charged by the MSRB must be reasonable

[62] For example, the Bond Buyer maintains repository for municipal securities information under the name "Munifiche.

once created.[63] Regardless of whether private vendors choose to utilize the services of the MSRB's proposed repository, or to gather information independently, the creation of central sources for municipal offering documents is an important first step that may eventually encourage widespread use of repositories to disseminate annual reports and other current information about issuers to the secondary markets.[64]

The Commission believes that paragraph (b)(4) of Rule 15c2–12 provides an important incentive to underwriters that will further encourage the development of one or more central repositories. By submitting copies of final official statements to any NRMSIR,[65] the underwriter avoids the responsibility to deliver, upon request, copies of final official statements to any potential customer for the full 90 day period specified in the Rule. In this regard, the provisions of paragraph (b)(4) are consistent with the views of a significant number of commentators who suggested that an underwriter's responsibility to distribute copies of the final official statement should terminate upon deposit of the documents in a central repository. At the same time, the Commission believes that investors will benefit by having access to information directly from underwriters during the twenty-five days after the end of the underwriting period, when the issuer's securities are most likely to be traded actively.

C. Exemptions.

In addition to inviting comments about the specific provisions of the Proposed Rule, the Release noted that there may be a range of credit risks and disclosure concerns that vary according to the type of municipal bonds being offered, the presence of unusual or complex financing techniques, and the maturity of the securities. Moreover, the Release recognized that many offerings of municipal securities are conducted in a manner that is akin to a "private placement. In light of this practice, the Commission requested the views of commentators on whether exemptions from the Rule should be created for, among other things, offerings made to a limited number of sophisticated investors or offerings of securities with short maturities.

While the Rule is designated to emphasize the implemenation of responsible disclosure practices, it is not intended to restrict access to the capital markets by any issuer. Many of the commentators stated that, as a general matter, the Proposed rule would not have affected significantly the manner in which they conduct offerings currently. There were, however, suggestions that some provisions of the Proposed Rule should be modified, or exemptions created, in order to accommodate certain offerings where application of the Proposed Rule would have created unnecessary hardships.

The National Association of Bond Lawyers ("NABL"), along with others, commented that if the Rule were adopted as proposed, it may have impeded the use of certain efficient market practices.[66] The exemptions contained in the Rule are designed to facilitate certain of those offerings where the Commission believes that, given the sophistication of the investors and the alternative mechanisms developed by the industry to facilitate disclosure in connection with such offerings,[67] the specific requirements of the Rule are not necessary to prevent fraud and encourage the dissemination of disclosure into the secondary market.

After reviewing the comment letter, the Commission has determined to provide exemptions from the Rule for offerings of municipal securities in authorized denominations of $100,000, (1) that are sold in "limited placements, (2) that have maturities of less than nine months, or (3) that contain provisions that allow the investor to redeem or sell to the issuer or its agent the securities at least as frequently as every nine months. In addition, the Rule would permit the Commission to grant exemptions that are consistent with the public interest and the protection of investors. The Commission wishes to emphasize that underwriters participating in offerings that are able to utilize an exemption from the Rule, nevertheless remain subject to the general antifraud provisions of the federal securities laws.[68] Moreover, any participating underwriter in a remarketing of securities initially offered in reliance upon the exemptions contained in paragraph (c)(3), when the remarketing is a primary offering as that term is defined in paragraph (e)(7), would be subject to the Rule, unless that primary offering qualified for exemptions under paragraph (c)(1) or (c)(2).

A condition of each of the exemptions discussed below is the requirement that the municipal securities be offered in authorized denominations of $100,000 or more. In choosing the $100,000 minimum denomination, the Commission was persuaded by the comments of NABL and others that, in this context, minimum denominations on the securities would not unnecessarily interfere with the ability of underwriters to sell securities to sophisticated investors in situations where the investors currently obtain adequate information.[69]

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[63] *See e.g.*, Letter from J. Kevin Kenny, Chairman and Chief Executive Officer, J.J. Kenny Co., Inc. to Jonathan G. Katz, Secretary, SEC (June 6, 1989).

[64] The Commission notes that the GFOA Disclosure Guidelines currently state: "Submission of documents to public or private central repository may be used as one part of accomplishing the purposes of disseminating and preserving official statements, annual reports, information statements, releases, and escrow arrangements. [. .] Issuers are strongly urged to send, promptly upon availability, a copy of each document to a repository. Procedural Statement No. 8, "Dissemination of Information and Providing Statements, Reports, and Releases to a Central Repository, *GFOA Disclosure Guidelines, supra* note 6, at 91.

[65] In determining whether particular entity is a NRMSIR, the Commission will look, among other things, at whether the repository: (1) is national in scope; (2) maintains current, accurate information about municipal offerings in the form of official statements; (3) has effective retrieval and dissemination systems; (4) places no limits on the issuers from which it will accept official statements or related information; (5) provides access to the documents deposited with it to anyone willing and able to pay the applicable fees; and (6) charges reasonable fees.

[66] Letter from Paul S. Maco, Chairman, Special Committee on Securities Law and Disclosure, NABL, to Jonathan G. Katz, Secretary, SEC (Jan 31, 1989). Specifically, NABL noted that the Proposed Rule may have effectively eliminated: (1) tax-exempt commercial paper programs; (2) flexible mode and variable rate issues; (3) municipal short-term note issues used as cash management techniques; (4) competitive bid local issues whose only purchases are local banks and institutions, where bidding practice is mandated by statute; (5) underwritten sales limited to sophisticated investors and privately placed issues where purchasers conduct their own credit investigation; and (6) "subject to delivery of paper deals or "wire deals, where an advantageous rate may be achieved if satisfactory disclosure and other documents are delivered prior to closing.

[67] For example, the Commission notes that issues of tax-exempt commerical paper generally prepare a commerical paper memorandum, containing disclosure about the issuer, that is then used in subsequent roll-overs. A "10b-5 certificate" is usually obtained from the issuer's chief financial officer on each roll-over date to assure the accuracy of the the issuer's disclosure. Similarly, commentators indicated that in traditional municipal private placements, many investors condition their purchases upon receipt of placement memorandum containing complete disclosure about the securities being sold.

[68] Underwriters also must be aware that separate MSRB provisions may be applicable, as well as state securities laws. For example, even where the provisions of the Rule are not applicable, the MSRB may require dissemination of final official statements, if they are prepared by the issuer. *See, e.g., Disclosure Requirements for New Issue Securties: Rule G–31, MSRB Reports.* (Sept. 1986) at 17 (indicating that rule G–32 applies to both private and public offerings).

[69] NABL suggested that use of a $100,000 minimum denomination would assure that only sophisticated purchasers are sold bonds in offerings

Continued

The term "authorized denomination of $100,000 or more" is defined in paragraph (e)(1) of the Rule. The definition recognizes that municipal securities currently are issued in registered form and that instructions to the transfer agent are necessary to assure that securities sold in denominations of $100,000 are not resold in smaller amounts. At the suggestion of the commentators, the definition also is tailored to address the offering of securities with original issue discount, such as zero coupon securities, by making the reference to the purchase price, rather than the principal amount of the securtities.[70]

1. Limited Placements

The Release requested comment on whether the Rule should contain some type of "private placement" exemption.[71] The Release noted that the primary intent of the Proposed Rule was to focus on those offerings that involve the general public and are likely to be actively traded in the secondary market. The absence of a limited placement exemption in the Proposed Rule reflected the Commission's concern that, without transfer restrictions, municipal securities initially sold on a limited basis to sophisticated investors could be resold to numerous secondary market investors, who lacked the sophistication of the initial purchasers.

Comment was requested on whether, and in what manner, the Rule should distinguish between offerings sold to a limited number of investors and those involving broader sales and related efforts. The Commission inquired whether the Rule should contain an exemption for offerings sold to no more than 10, 25, 35 or 50 investors, and whether the exemption should look at the institutional nature or sophistication of the investors. To avoid having securities that are sold to sophisticated investors pursuant to a limited placement exemption immediately be resold in the retail market, the Commission inquired about whether the underwriter should be required to assure that initial investors purchase with investment intent, or whether holding periods or transfer restrictions should be required.

Commentators discussing the issue almost unanimously favored an exemption from the requirements of the Rule for offerings that are similar to traditional municipal private placements. Nevertheless, there were a variety of opinions given on how the exemption should be structured. Among other things, commentators drew analogies to concepts developed under the Securities Act, including proposed Rule 144A.[72]

As some of the commentators noted, the federal securities laws have traditionally distinguished between sales of securities to the general public and limited offerings made to sophisticated investors. In general, offerings of securities to sophisticated investors are not required to comply with the more formal disclosure regimen applicable to registered offerings, because of the investors' perceived ability to "fend for themselves" by demanding the disclosure necessary to make an informed investment decision, and by having such knowledge and experience to be capable of evaluating the merits of the prospective investment. Based in part on similar reasoning, the Commission has determined to incorporate a conditional exemption in the Rule for offerings of securities that are sold to a limited number of sophisticated investors in denominations of $100,000 or more.

Paragraph (c)(1) provides an exemption from the Rule for offerings sold to no more than 35 investors, each of whom the underwriter reasonably believes is not purchasing for more than one account and has such knowledge and experience in financial and business matters that it is capable of evaluating the merits and risks of the prospective investment. As discussed above, the Commission was concerned that any securities offered pursuant to a limited placement exemption could immediately be resold to public investors without the benefit of the Rule's requirements. Accordingly, the Commission requested comment on whether, in conjunction with a limited offering exemption, any specific terms or restrictions, such as minimum holding periods, should be imposed on securities offered in reliance on the exemption. A number of commentators, including the PSA and NASACT, suggested that some limitations on resales may be appropriate. Commentators also indicated that current practice in many municipal private placements is to require letters of investment intent.[73]

The Commission is aware that restrictions on resales of securities are of concern even to institutional investors who initially purchase securities as part of a buy and hold strategy, because they limited the institution's ability to resell securities in changing market conditions. Rather than imposing specific transfer restrictions, the Commission has chosen to require that the securities be issued in relatively large denominations and that the underwriter have a reasonable belief that the securities are being acquired by the purchaser for investment.

Consistent with current practice, the Commission believes that an underwriter will satisfy its obligation under paragraph (c)(1) if it obtains a statement indicating that the investor has purchased the securities with investment intent. Furthermore, as suggested by the American Bar Association, in order to maintain the integrity of the 35 person limit, the Rule requires that each of the purchasers acquire securities for only one account. Finally, the Rule requires that the underwriter make a subjective determination that each investor have the knowledge and experience required to evaluate the merits and risks of the prospective investment.[74] The Commission believes that this procedure also is consistent with the current practice in the municipal securities markets, where limited placements are generally made only to institutional purchasers.

(a) *Definition of Underwriter.* Some commentators suggested that since the term "underwriter" in the Proposed

not subject to the Rule and would have the benefit of: (1) not interfering with cost-savings financing programs using commerical paper, variable rate demand notes, multimode securities and cash flow borrowings: (2) not requrie elaborate development of concepts such as accredited investor, safe harbor, restricted resale, etc.; (3) not adversely affect the institutional market, where investors are often loath to purchase (or are prohibited from purchasing) restricted or legended securities; (4) set the focus of the exemption on the type of investors to be protected, not on the type or volume the issue (thus avoiding a complicated scheme of districtions among issuer type); (5) be applied easily in both the initial issueance and secondary market context; and (6) preserve existing avenues of funding for municipal issuers, without imposing unnecessary costs.

[70] For zero coupon and deep discount securities, the term authorized denomination is defined in paragraph (e)(1) based on the market value of the security.

[71] In 1988, approximately $2,716 million in municipal private placements were reported, amounting to 2.3% of total long-term bond offerings. These figures, however, are considered to underestimate the actual issuance of municipal securities through private placements. Source: IDD/PSA Database.

[72] *See* Securities Act Release No. 6806 (October 21, 1988) 53 FR 44016 (proposing Rule 144A).

[73] *See also,* Procedural Statement No. 6, "Practices in Note and Bond Sales; Private Placements" *GFOA Disclosure Guidelines, supra* note 6, at 88 (indicating that the issuer should receive assurances that the transaction is in fact direct placement).

[74] This differs from Regulation D under the Securities Act, which provides that the issuer in private placements may presume that accredited investors meet the purchaser qualifications.

Rule [75] was defined as a broker, dealer, or municipal securities dealer who participated in a "distribution" the Commission had created an implicit private placement exception.[76] Specifically, they noted that persons selling securities in an offering that did not involve a distribution would not be subject to the Rule. The word "distribution" which was used in the definition of "underwriter" in the Proposed Rule, has been replaced with the term "offering" This change is intended to clarify that a broker, dealer or municipal securities dealer may be acting as underwriter, for purposes of the Rule, in connection with a private offering. Unless the offering meets the requirements of paragraph (c)(1), the underwriter would be subject to the requirements of the Rule.

2. Short-Term Securities

Another issue on which the Commission requested comment was whether an exemption should be provided for short-term debt. Of the commentators who responded to this issue, many distinguished between traditional short-term debt, such as bond, tax, and revenue anticipation notes, which may be sold to a variety of investors, and tax-exempt commercial paper, which primarily is sold in large denominations to institutional investors.[77] Commentators argued that imposition of the requirements of the Rule to tax-exempt commercial paper would seriously impact an issuer s ability to enter the market. The MSRB, along with others, also compared short-term municipal debt to corporate commercial paper that is exempt from the registration provisions of the Securities Act.[78] The MSRB noted that its own rule G–32 contains a specific exemption for tax-exempt commercial paper.

After reviewing the comment letters, the Commission has determined to provide an exemption for offerings of short-term debt with fixed maturities of less than nine months.[79] As with the other exemptions, underwriters would only be able to use the exemption in those offerings in which the securities are issued in authorized denominations of $100,000 or more. The Commission believes that the philosophy of the exemption is consistent with the exemption in section 3(a)(3) of the Securities Act.[80] Nevertheless, the Commission does not want to imply a direct correlation between tax-exempt commercial paper, as the term is used frequently in the municipal markets, and commercial paper offered pursuant to Section 3(a)(3).

3. Securities With Demand Features

In addition to traditional short-term debt issues with fixed maturities of less than nine months, many issuers have utilized multi-mode bonds and variable rate demand notes as a means of efficiently financing their operations. Variable rate demand notes have fixed maturities equivalent to long-term bonds, but provide the purchaser with the opportunity to tender the bonds to the issuer or a third-party liquidity facility at preset tender dates that may be weekly, monthly, or annually. By offering variable rate demand notes, or tender option bonds, the investor is able to reduce interest rate risk, while the issuer can offer short-term yields on long-term bonds.

Variable rate demand notes, as well as tax-exempt commercial paper, may be a component of multi-mode offerings that permit the issuer to convert outstanding debt from short-term variable rates to long-term fixed rates. Investors are notified of the issuer's determination to exercise its conversion option and typically are given the opportunity to redeem their securities at par or retain the securities in their converted form. Bonds that are redeemed upon conversion are generally offered pursuant to a remarketing agreement, with liquidity support typically provided by a third-party financial institution.

Although the use of variable rate financing has declined in recent years in response to a flattening of the yield curve, the Commission recognizes that variable rate debt remains an important method of financing for many issuers.[81] Some commentators expressed concern that applying the provisions of the Proposed Rule to variable rate demand notes, or similar securities, might unnecessarily hinder the operation of this market, if underwriters were required to comply with the provisions of the Proposed Rule on each tender or reset date. To assure that these means of financing are not unnecessarily affected, the Commission has provided an exemption in Rule 15c2–12 that permits sales of variable rate demand notes and other flexible mode securities with effective maturities of less than nine months.

Paragraph (c)(3) provides an exemption for securities issued in authorized denominations of $100,000 or more that, at the option of the holder, may be tendered to an issuer of such securities, or its designated agent, for redemption or purchase at par value or more, at least as frequently as every nine months until maturity, or earlier redemption, or until such securities are remarketed in a primary offering. Thus, variable rate demand notes, tax-exempt commercial paper with an automatic roll-over feature, and tender option bonds with maturities or reset dates of less than nine months, would be eligible for the exemption. In multi-mode offerings, upon conversion to a fixed maturity of greater than nine months, the exemption would no longer be applicable and any primary offering of the securities by a remarketing agent would be subject to the Rule.

D. Exemptive Authority

In addition to the express exemptions contained in paragraphs (c)(1), (2) and (3) of the Rule, paragraph (d) provides that the Commission may, upon written request, or upon its own motion, exempt any participating underwriter from any

[75] The Proposed Rule defined "underwriter" to include "any person who has purchased from an issuer with view to, or offers or sells to, an issuer in connection with the distribution of, any security " The definition in the Proposed Rule paralleled the definition in section 2(11) of the Securities Act, 15 U.S.C. 77b(11), with one modification to more clearly reflect the terminology used in the municipal securities industry for a customary distributor's or seller's commission. *See* Release, 53 FR at 37786, n. 58.

[76] *See generally* Securities Act Release No. 6806 (October 21, 1988) 53 FR 44016, at n.145 (discussing the term "distribution" in the context of the definition of "underwriter" found in section 2(11) of the Securities Act). *But see* Rule 10b–6(c)(5) of the Exchange Act, 17 CFR 10b–6(c)(5) (defining for purposes of that rule, the term distribution to mean an offering of securities that is distinguished from ordinary trading by the magnitude of the offering and special selling efforts and selling methods).

[77] The Commission understands that concerns about reissuance problems under the federal tax laws have reduced true tax-exempt commercial paper offerings in recent years. In 1988, for example, only 16 issues of tax-exempt commercial paper, amounting to $1,142 million were offered. This figure is up from 6 offerings in 1987, amounting to $65 million. Source: IDD/PSA Database.

[78] Section 3(a) (3) of the Securities Act, 15 U.S.C. 77c(a)(3) exempts from registration "[a]ny note, draft, bill of exchange, or bankers acceptance which arises out of a current transaction or the proceeds of which have been or are to be used for current transactions, and which has a maturity at the time of issuance of not exceeding nine months, exclusive of days of grace, or any renewal thereof the maturity of which is likewise limited"

[79] In 1988, 1,482 short-term bond issues (less than 13 months), totaling $23,125 million, were offered with par amounts exceeding $1 million. Four hundred ninety offerings above one million, with a total par amount of 6,246.9 million, had final maturities of less than nine months. Source: IDD/PSA Database.

[80] *See generally*, Securities Act Release 4412 (Sept. 20, 1961) 26 FR 9158 (discussing short-term corporate debt).

[81] Issuance of variable rate demand obligations peaked in 1985, at $66,855 million (based on issues with par amount exceeding $5 million). In 1988, 903 issues were offered, with total volume of $21,622 million. Source: IDD/PSA Database.

requirement of the Rule. The Commission recognizes that there is a continuing evolution in financial products and the means of selling securities. While the Commission believes that the exemptions contained in the Rule will accommodate those offerings in which current practice is appropriate, without the need for the additional requirements of the Rule, it is also aware that instances may arise where the objectives of the Rule can be achieved without strict compliance with its provisions.

Paragraph (d) permits the Commission to exempt from the Rule underwriters participating in particular primary offerings of municipal securities, or classes of transactions, either unconditionally, or upon specified terms and conditions. In determining whether any exemption is appropriate, the Commission would consider whether such an exemption is consistent with the public interest and the protection of investors. Among other things, the Commission would, in some cases, expect persons requesting an exemption to demonstrate that the objectives of the Rule can be achieved using alternative procedures. In light of the fact that the Rule codifies, to a great degree, responsible industry practice, and the fact that the current exemptions are designed to adequately accommodate financing techniques where departure from the specific provisions of the Rule is appropriate, the Commission does not expect that exemptions will be granted routinely.[82]

E. Transitional Provision

Paragraph (f) of the Rule provides an exemption from the provisions of the Rule relating to the dissemination of the final official statements, for remarketings of securities that were initially issued prior to July 28, 1989, and where the underwriter has a contractual commitment to act as remarketing agent. The transition period applies only to paragraphs (b)(3) and (b)(4) of the Rule. The Commission does not believe there is a need for an exemption from the other paragraphs of the Rule, since dissemination of a preliminary official statement is only required if one is prepared and the information needed to comply with paragraph (b)(1) of the Rule is information reasonably foreseeable as necessary to facilitate compliance with the anti-fraud provisions of the Federal securities laws that were in effect at the time of the contract. In this regard, the Commission understands that it is common to provide in remarketing agreements that the remarketing agent will have access to the information necessary to comply with the federal securities laws.

III. Interpretation of Underwriter Responsibilities

In the Release, the Commission also included an interpretation of the responsibilities of underwriters of municipal securities under the general antifraud provisions of the federal securities laws.[83] In light of the practices revealed in the staff's investigation of the Supply System default, the Commission determined it was appropriate to articulate clearly the obligations of underwriters participating in municipal offerings. While the focus of the Interpretation was on activities of underwriters, the Commission recognizes that the primary responsibility for disclosure rests with the issuer.[84]

The Interpretation applies to all offerings of municipal securities, regardless of whether the offering is subject to the provisions of Rule 15c2-12. The Interpretation emphasized the obligation of underwriters under the general antifraud provisions of the federal securities laws to have a reasonable basis for recommending any municipal securities. The Interpretation noted that when the underwriter provides disclosure documents to investors, it makes an implied representation that it has a reasonable basis for belief in the accuracy and completeness of the key representations contained in the documents.

The Interpretation stated that the extent of review necessary for the underwriter to attain a reasonable basis for its belief in the accuracy and completeness of key representations in the final official statement will depend upon all the circumstances. The factors enumerated in the Interpretation were: the extent to which the underwriter relied upon municipal officials, employees, experts and other persons whose duties have given them special knowledge of particular facts; the type of underwriting arrangement (*e.g.* firm commitment or best efforts); the role of the underwriter (manager, syndicate member, or selected dealer); the type of bonds being offered (general obligation, revenue, or private activity); the past familiarity of the underwriter with the issuer; the length of time to maturity of the bonds; the presence or absence of credit enhancements; and whether the bonds are competitively bid or are distributed in a negotiated offering. The Interpretation stated that, at a minimum, the Commission expects that in all offerings underwriters will review the issuer's disclosure document(s) in a professional manner for possible inaccuracies and omissions.[85]

The Interpretation presented the Commission's view of the current responsibilities of underwriters of municipal securities under the federal securities laws. It did not create new standards of liability.[86] Moreover, although the Interpretation was based on judicial decisions and previous administrative actions, the Commission sought comment on the extent to which underwriters currently meet the standards articulated in the Interpretation, and whether alternative

[82] In conjunction with the adoption of the Rule, the Commission also is adopting Rule 30-3(a)(48) of the Rules of Practice, 17 CFR 241.30-3(a)(48), which delegates to the Division of Market Regulation, the authority to grant exemptive requests under Rule 15c2-12. Securities Exchange Act Release No. 26986 (June 28, 1989). The Commission expects that the Division will consider any exemptive requests in light of the goals of the Rule and will submit such matters to the Commission for consideration as appropriate. Requests for exemptive relief, as well as interpretive and no-action advice concerning the Rule, should conform with the Commission's published procedures and should be addressed to the Chief Counsel, Division of Market Regulation, Mail Stop 5-1, Securities and Exchange Commission, Washington, DC 20549. The procedures to be followed in requesting no-action or exemptive relief are outlined in Securities Act Release No. 5127, 36 FR 2600 (Jan. 25, 1971); *see generally*, Lemke, *The SEC No-Action Letter Process*, 42 *Bus. Law.* 1019 (1987).

[83] The Interpretation was based on judicial and administrative decisions applying the federal securities laws and did not address the responsibilities of underwriters under the MSRB's rules or the provisions of state securities laws. Underwriters should be aware that their responsibilities under state securities laws may be different from those articulated in the Commission's Interpretation.

[84] Although the focus of the Commission's Interpretation was on underwriter practices, issuers are primarily responsible for the content of their disclosure documents and may be held liable under the federal securities laws for misleading disclosure. *See, e.g. In re Washington Public Power Supply System Securities Litigation*, 623 F. Supp 1466, 1478-1480 (W.D.Wa. 1985), *aff'd*, 823 F.2d 1349 (9th Cir. 1987); *In re Citisource, Inc. Securities Litigation*, 694 F. Supp. 1069, 1072-1075 (S.D.NY 1988); *In re New York City Municipal Securities Litigation*, 507 F Supp. 169, 184-185 (S.D.N.Y. 1980). Because they are ultimately liable for the content of their disclosure, issuers should insist that any persons retained to assist in the preparation of their disclosure documents have professional understanding of the disclosure requirements under the federal securities laws.

[85] In offerings where the issuer has not produced disclosure documents, including those that are exempted from Rule 15c2-12, the underwriter must take other measures to develop reasonable basis for its recommendation.

[86] The Commission explained in the Release that the factors set forth in the Interpretation do not change the applicable legal standards against which the underwriter's conduct must be measured, or attempt to set an objective standard against which to measure recklessness for purposes of any scienter requirement under specific antifraud provisions. Release 53 FR at 37789, n. 84.

formulations of the Interpretation would be more appropriate.

The Commission received comments on the Interpretation from all segments of the municipal industry. Most comments addressing the issue agreed that the Interpretation accurately reflected practices currently employed by responsible underwriters of municipal securities. In light of the comments, the Commission remains convinced that the Interpretation correctly articulates the legal responsibilities of underwriters of municipal securities under the federal securities laws. Nevertheless, the Commission has determined to clarify and modify limited portions of the Interpretation to address concerns raised by commentators.

Some commentators suggested additional factors that should be included among those enumerated in the Interpretation, while others disputed the relevance of some factors that were cited. In this regard, the Commission wishes to further emphasize that the factors enumerated in the Interpretation were not intended to be an exclusive list of factors bearing upon the reasonableness of the underwriter's investigation. While the Commission believes that, as modified below, the factors cited generally will be relevant in most offerings, any determination about the reasonableness of the underwriter's investigation in a particular offering "will depend upon all the circumstances" and will likely include factors not enumerated in the Interpretation as modified.[87]

Similarly, certain factors specificially enumerated in the Interpretation may not be relevant in some offerings.[88] In this regard, the Commission had determined that the comments generated in response to two of the factors enumerated in the Interpretation suggest that these factors are sufficiently ambiguous so as not to be relevant in most offerings. Thus, the Interpretation is modified to the extent that it indicates that the nature of the underwriting arrangement (*e.g.*, best efforts or firm commitment) would generally be a signficant factor in assessing the reasonableness of the underwriter's investigation in muncipal offerings. In addition, although the Commission included the presence or absence of credit enhancements as a consideration that might be relevant in gauging the underwriter's investigation, it is apparent, based upon the comments, that there is a diversity of opinion among participants in the municipal markets regarding the protection actually provided by credit enhancements.

In the Commission's view, the presence of credit enhancements generally would not be a substitute for material disclosure concerning the primary obligor on municipal bonds.[89] Several commentators, including analysts, investors, and insurers, have indicated that even in credit enhanced offerings they rely upon disclosure concerning the primary obligor. In credit enhanced offerings, there is event risk, including default or the primary obligor, that may impair the value of the municipal bonds. Empirical evidence was provided by the Assocration of Financial Guarantors illustrating the discount imposed by the market on credit enhanced offerings, compared to offerings with similar ratings without credit enhancements.[90] In light of these comments, the Commission wishes to emphasize that the presence of credit enhancement does not foreclose the need for a reasonable investigation of the accuracy and completeness of key representations concerning the primary obligor. Accordingly, the Interpretation is modified to the extent that it suggests the presence or absence of credit enhancements generally would be a significant factor in assessing the reasonableness of the underwriter s investigation.

The Commission's Interpretation is modified in accordance with the discussion presented above.

IV Effects on Competition and Regulatory Flexibility Act Considerations

Section 23(a)(2) of the Exchange Act [91] requires that the Commission, in adopting rules under the Act, consider the anticompetitive effects of such rules, if any, and balance any anticompetitive impact against the regulatory benefits gained in terms of furthering the purposes of the Exchange Act. The Commission is of the view that Rule 15c2–12 will not result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Exchange Act.

In addition, the Commission has prepared a Final Regulatory Flexibility Analysis ("FRFA"), pursuant to the requirements of the Regulatory Flexibility Act,[92] regarding the Rule. Commentators were invited in the Release to provide data concerning the costs and benefits of the Proposed Rule. The FRFA indicates that Rule 15c2–12 could impose some additional costs on small broker-dealers and municipal issuers. Nevertheless, the Commission believes that many of the substantive requirements of the Rule already are observed by underwriters and issuers as a matter of good business practice, or to fulfill their existing obligations under the general antifraud provisions of the federal securities laws. Morever, in the Commission's view, any costs are substantially outweighed by the benefits of improved disclosure and access to information that are provided by the Rule.

A copy of the FRFA may be obtained from Edward L. Pittman, Assistant Chief Counsel, Division of Market Regulation, Securities and Exchange Commission, 450 Fifth Street, NW Mail Stop 5–1, Washington, DC 20549, (202) 272–2848.

V Statutory Basis and Text of Amendments

The Commission proposes to adopt § 240.15c2–12 in Chapter II of Title 17 of the Code of Federal Regulations as follows: (List of Subjects in 17 CFR Part 240) Reporting and recordkeeping requirements, securities.

[87] Indeed, the factors that have been withdrawn below may be relevant in particular circumstances.

[88] For example, the Commission stated in the Interpretation that the fact an offering is nominally classified as competitively bid would not be relevant to the scope of an underwriter's review, where there is little uncertainty about the choice of underwriters or where other factors are present that would command closer examination.

[89] The Commission noted in 1987, in the context of an examination of the financial guarantee markets, that:

[w]hile the presence of a guarantor is a material factor that investors may wish to consider in determining whether to invest in particular debt issue, the Commission does not believe that it can, in general, serve as substitute for disclosure of material information regarding the offering.

Investors in public offerings of securities backed by insurance policies have an interest in information allowing them to assess the financial resources of both the issuer and the insurer. Investors also have an interest in assessing other material matters in addition to the solvency of the issuer and its guarantor. Thus, the Commission observes that the presence of an insurance policy may not, in general, serve as an adequate substitute for disclosure of material terms of the proposed transaction.

Report of the United States Securities and Exchange Commission on the Financial Guarantee Market: The Use of the Exemption in Section 3(a)(2) of the Securities Act of 1933 for Securities Guaranteed by Banks and the Use of Insurance Policies to Guarantee Debt Securities (1987) at 82, 83.

[90] Letter from Phillip R. Kastellec, Chairman, Disclosure Committee, Association of Financial Guaranty Insurors, to Jonathan G. Katz, Secretary, SEC (Dec. 22, 1988).

[91] 15 U.S.C. 78w(a)(2).

[92] 5 U.S.C. 604.

PART 240—GENERAL RULES AND REGULATIONS, SECURITIES EXCHANGE ACT OF 1934

1. The authority citation for Part 240 is amended by adding the following citation:

Authority: Sec. 23, 48 Stat. 901, as amended; 15 U.S.C. 78w. § 240.15c2-12 also issued under 15 U.S.C. 78b, 78c, 78j, 78*o*, 78*o*-4 and 78q.

2. By adding § 240.15c-12 as follows:

§ 240.15c2-12 Municipal securities disclosure.

(a) *General.* As a means reasonably designed to prevent fraudulent, deceptive, or manipulative acts or practices, it shall be unlawful for any broker, dealer, or municipal securities dealer (hereinafter "Participating Underwriter") to act as an underwriter in a primary offering of municipal securities with an aggregate principal amount of $1,000,000 or more (hereinafter "Offering") unless the Participating Underwriter complies with the requirements of this rule or is exempted from the provisions of this rule.

(b) *Requirements.* (1) Prior to the time the Participating Underwriter bids for, purchases, offers, or sells municipal securities in an Offering, the Participating Underwriter shall obtain and review an official statement that an issuer of such securities deems final as of its date, except for the omission of no more than the following information: The offering price(s), interest rate(s), selling compensation, aggregate principal amount, principal amount per maturity, delivery dates, any other terms or provisions required by an issuer of such securities to be specified in a competitive bid, ratings, other terms of the securities depending on such matters, and the identity of the underwriter(s).

(2) Except in competitively bid offerings, from the time the Participating Underwriter has reached an understanding with an issuer of municipal securities that it will become a Participating Underwriter in an Offering until a final official statement is available, the Participating Underwriter shall send no later than the next business day, by first-class mail or other equally prompt means, to any potential customer, on request, a single copy of the most recent preliminary official statement, if any.

(3) The Participating Underwriter shall contract with an issuer of municipal securities or its designated agent to receive, within seven business days after any final agreement to purchase, offer, or sell the municipal securities in an Offering and in sufficient time to accompany any confirmation that requests payment from any customer, copies of a final official statement in sufficient quantity to comply with paragraph (b)(4) of this rule and the rules of the Municipal Securities Rulemaking Board.

(4) From the time the final official statement becomes available until the earlier of—

(i) Ninety days from the end of the underwriting period or

(ii) The time when the official statement is available to any person from a nationally recognized municipal securities information repository, but in no case less than twenty-five days following the end of the underwriting period, the Participating Underwriter in an Offering shall send no later than the next business day, by first-class mail or other equally prompt means, to any potential customer, on request, a single copy of the final official statement.

(c) *Exemptions.* This rule shall not apply to a primary offering of municipal securities in authorized denominations of $100,000 or more, if such securities:

(1) Are sold to no more than thirty-five persons each of whom the Participating Underwriter reasonably believes (i) has such knowledge and experience in financial and business matters that it is capable of evaluating the merits and risks of the prospective investment and (ii) is not purchasing for more than one account or with a view to distributing the securities; or

(2) Have a maturity of nine months or less; or

(3) At the option of the holder thereof may be tendered to an issuer of such securities or its designated agent for redemption or purchase at par value or more at least as frequently as every nine months until maturity, earlier redemption, or purchase by an issuer or its designated agent.

(d) *Transactional Exemptions.* The Commission, upon written request, or upon its own motion, may exempt any Participating Underwriter that is a participant in a transaction or class of transactions from any requirement of this rule, either unconditionally or on specified terms and conditions, if the Commission determines that such an exemption is consistent with the public interest and the protection of investors.

(e) *Definitions.* For the purposes of this rule—(1) The term "authorized denominations of $100,000 or more means municipal securities with a principal amount of $100,000 or more and with restrictions that prevent the sale or transfer of such securities in principal amounts of less than $100,000 other than through a primary offering; except that, for municipal securities with an original issue discount of 10 percent or more, the term means municipal securities with a minimum purchase price of $100,000 or more and with restrictions that prevent the sale or transfer of such securities, in principal amounts that are less than the original principal amount at the time of the primary offering, other than through a primary offering.

(2) The term "end of the underwriting period" means the later of such time as

(i) the issuer of municipal securities delivers the securities to the Participating Underwriters or

(ii) the Participating Underwriter does not retain, directly or as a member or an underwriting syndicate, an unsold balance of the securities for sale to the public.

(3) The term "final official statement" means a document or set of documents prepared by an issuer of municipal securities or its representatives seeting forth, among other matters, information concerning the issuer(s) of such municipal securities and the proposed issue of securities that is complete as of the date of delivery of the document or set of documents to the Participating Underwriter.

(4) The term "issuer of municipal securities" means the governmental issuer specified in section 3(a)(29) of the Act and the issuer of any separate security, including a sepatate security as defined in rule 3b-5(a) under the Act.

(5) The term "potential customer" means (i) Any person contacted by the Participating Underwriter concerning the purchase of municipal securities that are intended to be offered or have been sold in an offering, (ii) Any person who has expressed an interest to the Participating Underwriter in possibly purchasing such municipal securities, and (iii) Any person who has a customer account with the Participating Underwriter.

(6) The term "preliminary official statement" means an official statement prepared by or for an issuer of municipal securities for dissemination to potential customers prior to the availability of the final official statement.

(7) The term "primary offering means an offering of municipal securities directly or indirectly by or on behalf of an issuer of such securities, including any remarketing of municipal securities.

(i) That is accompanied by a change in the authorized denomination of such securities from $100,000 or more to less than $100,000, or

(ii) That is accompanied by a change in the period during which such securities may be tendered to an issuer of such securities or its designated agent for redemption or purchase from a period of nine months or less to a period of more than nine months.

(8) The term "underwriter" means any person who has purchased from an issuer of municipal securities with a view to, or offers or sells for an issuer of municipal securities in connection with, the offering of any municipal security, or participates or has a direct or indirect participation in any such undertaking, or participates or has a participation in the direct or indirect underwriting of any such undertaking; except, that such term shall not include a person whose interest is limited to a commission, concession, or allowance from an underwriter, broker, dealer, or municipal securities dealer not in excess of the usual and customary distributors' or sellers' commission, concession, or allowance.

(f) *Transitional Provision.* If on July 28, 1989 a Participating Underwriter was contractually committed to act as underwriter in an Offering of municipal securities originally issued before July 29, 1989, the requirements of paragraphs (b)(3) and (b)(4) shall not apply to the Participating Underwriter in connection with such an Offering.

List of Subjects in 17 CFR Part 241

Reporting and recordkeeping Requirements, Securities, Issuers, Broker-Dealers, Fraud.

PART 241—INTERPRETIVE RELEASES RELATING TO THE SECURITIES EXCHANGE ACT OF 1934 AND GENERAL RULES AND REGULATIONS THEREUNDER

Part 241 of Title 17 of the Code of Federal Regulations is amended by adding Securities Exchange Act Release No. 26100 (53 FR 37778) concerning "Municipal Securities Underwriter Responsibilities" and this Release "Modifying and confirming the Interpretation of Municipal Underwriter Securities Responsibilities" to the list of interpretive releases set forth thereunder.

By the Commission.

Dated: June 28, 1989.

Jonathan G. Katz,

Secretary.

[FR Doc. 89-16038 Filed 7-7-89; 8:45 am]

BILLING CODE 8010-01-M

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 100

[CGD 05-89-61]

Special Local Regulations for Marine Events; Seventh Annual Intra-Harbor Powerboat Regatta, Elizabeth River, Norfolk, VA and Portsmouth, VA

AGENCY: Coast Guard, DOT.

ACTION: Notice of implementation of 33 CFR 100.501.

SUMMARY: This notice implements 33 CFR 100.501 for the Seventh Annual Intra-Harbor Powerboat Regatta. The event will be held on the Elizabeth River between the Norfolk and Portsmouth downtown areas. The special local regulations are necessary to control vessel traffic in the immediate vicinity of this event. The effect will be to restrict general navigation in the regulated area for the safety of spectators and participants.

EFFECTIVE DATES: The regulations in 33 CFR 100.501 are effective from 11:30 a.m. to 6:00 p.m., July 16, 1989. If inclement weather causes the postponement of the event, the regulations will be effective from 11:30 a.m. to 6:00 p.m., September 17 1989.

FOR FURTHER INFORMATION CONTACT: Mr. Billy J. Stephenson, Chief, Boating Affairs Branch, Fifth Coast Guard District, 431 Crawford Street, Portsmouth, Virginia 23704-5004, (804) 398-6204.

SUPPLEMENTARY INFORMATION:

Drafting Information

The drafters of this notice are Billy J. Stephenson, project officer, Chief, Boating Affairs Branch, Boating Safety Division, Fifth Coast Guard District, and Lieutenant Commander Robin K. Kutz, project attorney, Fifth Coast Guard District Legal Staff.

Discussion of Regulations

The Portsmouth Powerboat Association has submitted an application to hold the Seventh Annual Intra-Harbor Powerboat Regatta on July 16, 1989, in the vicinity of the "Waterside" area of downtown Norfolk, Virginia, and the "Portside" area of downtown Portsmouth, Virginia. This area area is covered by 33 CFR 100.501 and generally includes the waters of the Elizabeth River between Town Point Park, Norfolk, Virginia, the mouth of the Eastern Branch of the Elizabeth River, and Hospital Point, Portsmouth, Virginia. Since this event is of the type contemplated by this regulation and the safety of the participants and spectators viewing this event will be enhanced by the implementation of special local regulations for the Elizabeth River, 33 CFR 100.501 will be in effect. Because commercial vessels will be permitted to transit the regulated area between heats, commercial traffic should not be severely disrupted.

In addition to regulating the area for the safety of life and property, this notice of implementation also authorizes the Patrol Commander to regulate the operation of the Berkley drawbridge in accordance with 33 CFR 117.1007 and authorizes spectators to anchor in the special anchorage areas described in 33 CFR 110.72aa. The implementation of 33 CFR 100.501 also implements regulations in 33 CFR 110.72aa and 117.1007 33 CFR 110.72aa establishes the spectator anchorages in 33 CFR 100.501 as special anchorage areas under Inland Navigation Rule 30, 33 U.S.C. 2030(g). 33 CFR 117.1007 closes the draw of the Berkley Bridge to vessels during and for one hour before and after the effective period under 33 CFR 100.501.

These regulations are implemented by publication of this implementing notice in the **Federal Register** and a notice in the Local Notice to Mariners.

Date: June 27 1989.

A.D. Breed,

Rear Admiral, U.S. Coast Guard, Commander, Fifth Coast Guard District.

[FR Doc. 89-16064 Filed 7-7-89; 8:45 am]

BILLING CODE 4910-14-M

33 CFR Part 165

[COTP San Diego Reg. 89-06]

Safety Zone; San Diego Bay, California, Pacific Ocean

AGENCY: Coast Guard, DOT.

ACTION: Emergency rule.

SUMMARY: The Coast Guard is establishing a moving safety zone in San Diego Bay, San Diego, California. This safety zone consists of the water area within five hundred (500) yards ahead and three hundred (300) yards off each side and astern of the M/V Exxon Valdez as it transits San Diego Bay from sea to National Steel and Shipbuilding berth #6. The M/V Exxon Valdez is scheduled to transit San Diego Bay between 11-13 July 1989. The actual date and time will be announced in a Broadcast Notice to Mariners. The safety zone is needed to protect the M/V Exxon Valdez from hazards associated with the possibility of

spectators or other vessel traffic impeding her transit to the shipyard. Entry into this zone is prohibited during this operation unless authorized by the Captain of the Port.

EFFECTIVE DATE: This regulation becomes effective at 0500 Pacific Daylight Time (p.d.t.) on 11 July 1989 and terminates upon the vessel arriving at National Steel, or sooner if terminated by the Captain of the Port.

FOR FURTHER INFORMATION CONTACT: LT Tom S. Orzech, USCG, C/O U. S. Coast Guard Captain of the Port, 2710 N. Harbor Drive, San Diego, CA 92101-1064, telephone (619) 557-5860.

SUPPLEMENTARY INFORMATION: A notice of proposed rulemaking (NPRM) was not published for this regulation and it is being made effective in less than 30 days from the date of publication. Following the normal rulemaking process would have been contrary to the public interest since immediate action is needed to respond to potential hazards to vessels and persons in the area.

Drafting Information

The drafters of this notice are LT Tom S. Orzech, project officer for the Captain of the Port, and CDR Samuel E. Burton, project attorney, Eleventh Coast Guard District Legal Office.

Since the impact of these regulations is expected to be minimal, the Coast Guard certifies that they will not have a significant economic impact on a substantial number of small entities.

Discussion of Regulation

This safety zone consists of the water area within five hundred (500) yards ahead of the M/V Exxon Valdez and three hundred (300) yards off each side and astern as it transits San Diego Bay on the published date. This safety zone moves with the M/V Exxon Valdez as it transits San Diego Bay from the San Diego sea buoy #1 through the ship channel to National Steel and Shipbuilding in San Diego. This regulation is needed to provide a safe, clear passage for the M/V Exxon Valdez on its way to the drydock and to protect vessels and persons which may impede her transit. Positive control during the movement of the M/V Exxon Valdez is necessary to prevent injury and property damage during her transit.

This regulation is issued pursuant to 33 U.S.C. 1225 and 1231 as set out in the authority citation for all of Part 165.

List of Subjects in 33 CFR Part 165:

Harbors, Marine safety, Navigation (water), Security measures, Vessels, Waterways.

Final Regulation

In consideration of the foregoing, Part 165 of Title 33, Code of Federal Regulations is amended as follows:

PART 165—[AMENDED]

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

Authority: 33 U.S.C. 1225 and 1231: 50 U.S.C. 191; 49 CFR 1.46 and 33 CFR 1.05-1(g), 6.04-1, 6.04-6, and 33 CFR 160.5.

2. In Part 165, a new § 165.T1104 is added, to read as follows:

§ 165.T1104—Safety Zone: San Diego Bay, California, Pacific Ocean.

(a) *Location.* This safety zone consists of the water area within five hundred (500) yards ahead of the M/V Exxon Valdez and 300 yards off each side and astern as she transits San Diego Bay inbound from San Diego sea buoy #1 to National Steel and Shipbuilding in San Diego, California, berth #6.

(b) *Effective Dates.* This regulation becomes effective at 0500 Pacific Daylight Time (PDT) on 11 July 1989 and terminates upon the arrival of the M/V Exxon Valdez at National Steel and Shipbuilding or sooner if terminated by the Captain of the Port.

(c) *Regulations.* (1) In accordance with the general regulations in § 165.23 of this part, entry into the area of this zone is prohibited unless authorized by the Captain of the Port, San Diego, California.

(2) Section 165.23 also contains other general requirements.

Dated: June 29, 1989.

D. P Montoro,

Commander, U.S. Coast Guard, Alternate Captain of the Port, San Diego, California.

[FR Doc. 89-16063 Filed 7-7-89; 8:45 am]

BILLING CODE 4910-14-M

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 22

[CC Docket No. 86-495; FCC 89-163]

Basic Exchange Telecommunications Radio Service; Order on Reconsideration

AGENCY: Federal Communications Commission.

ACTION: Final rule; Order on reconsideration.

SUMMARY: The Commission has determined that no additional spectrum will be allocated to Basic Exchange Telecommunications Service in the Public Land Mobile Service. The Commission also declined to change its standards for determining waivers of the 100-mile boundary from Metropolitan Statistical Areas for private radio frequencies available to BETRS licensees. In addition, the Commission declined to change its processing for BETRS applications for private radio frequencies. Finally, the Commission decided to codify its ruling in the Report and Order that existing Rural Radio Service licensees must provide frequency coordination information to *bona fide* potential co-channel and adjacent channel applicants. The purpose of this action is to ensure that no unwarranted filing delays are encountered by applicants for Public Land Mobile Radio Services, Rural Radio Services, and Basic Exchange Telecommunications Radio Service.

EFFECTIVE DATE: August 9, 1989. For the rule promulgated in the Order, the effective date will be announced by public notice in the **Federal Register** after the requisite approval of the Office of Management and Budget is received.

FOR FURTHER INFORMATION CONTACT: Susan E. Magnotti, Mobile Services Division, Common Carrier Bureau, (202) 632-6450.

SUPPLEMENTARY INFORMATION: CFR Part Amended: 47 CFR, Part 22, "Public Mobile Service. Public reporting burden for this collection of information is estimated to average 1 hour per response, including the 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 this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to the Federal Communications Commission, Office of Managing Director, Washington, DC 20554, and to the Office of Management and Budget, Office of Information and Regulatory Affairs, Washington, DC 20503.

This is a summary of the Commission's order on Reconsideration, CC Docket No. 86-495, adopted May 22, 1989, and released June 21, 1989.

The full text of Commission decisions is available for inspection and copying during normal business hours in the FCC Dockets Branch (Room 230), 1919 M Street, Northwest, Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, International Transcription Service, (202) 857-3800, 2100 M Street, Northwest, Suite 140, Washington, DC 20037

Summary of Order on Reconsideration

The Commission has determined that no additional spectrum will be allocated to Basic Exchange Telecommunications Service in the Public Land Mobile Service. In this Order, the Commission states that adequate spectrum appears to be available in rural areas in the VHF and UHF common carrier mobile allocation. Moreover, the Commission's recent order Amendment of Parts 2 and 22 of the Commission's Rules to Permit Liberalization of Technology and Auxiliary Service Offerings in the Domestic Public Cellular Radio Telecommunications Service, Report and Order, 3 FCC Rcd. 7033 (1988) (the Auxiliary Cellular Services Order") permits cellular frequencies to be used for fixed basic exchange service. There are an abundant number of frequencies available in the cellular allocation, and the Commission found that radio basic exchange service may draw from them.

The Commission also declined to change its standards for determining waivers of the 100-mile boundary from Metropolitan Statistical Areas for private radio frequencies available to BETRS licensees. Two parties had proposed different waiver standards from those contained in Section 22.19 of the Commission's Rules. The Commission found that its present standards are such that all relevant factors would be taken into account on a case by case basis should a waiver of the 100-mile rule be requested.

In addition, the Commission declined to change its processing for BETRS applications for private radio frequencies. Parties had argued that processing would be delayed for such frequency requests because it is necessary for two Commission bureaus to coordinate processing the applications. The Commission stated that it does not anticipate a substantial increase in processing time.

The Commission also decided to codify its ruling in the Report and Order that existing Rural Radio Service licensees must provide frequency coordination information to *bona fide* potential co-channel and adjacent channel applicants. The purpose of this action is to ensure that no unwarranted filing delays are encountered by applicants for Rural Radio Services and Basic Exchange Telecommunications Radio Service. The Report and Order had found that Rural Radio Licensees should have co-primary access to common carrier mobile frequencies with licensees in the Public Land Mobile Radio Service. Thus, the same frequency coordination information required of PLMRS licensees must also be required of RRS licensees.

Ordering Clauses:

Wherefore, the foregoing premises considered, IT IS ORDERED that the Petition for Reconsideration filed by United States Telephone Association is denied.

It is further ordered that the Petition for Reconsideration filed by Pacific Bell and Nevada Bell is denied.

The effective date of the rule promulgated herein will be announced by public notice in the **Federal Register** after the requisite approval of the Office of Management and Budget is received.

List of Subjects in 47 CFR Part 22

Reporting and recordkeeping requirements.

Federal Communications Commission.

Donna R. Searcy,

Secretary.

Appendix

Part 22 of Title 47 of the Code of Federal Regulations is amended as follows:

PART 22—PUBLIC MOBILE SERVICE

1. The authority citation for Part 22 continues to read as follows:

Authority: Secs. 4, 303, 48 Stat. 1066, 1082, as amended (47 U.S.C. 154, 303), sec. 553 of the Administrative Procedure Act (5 U.S.C. 553), unless otherwise noted.

2. Section 22.609 is amended by adding new paragraph (e) as follows:

§ 22.609 Supplementary showing required with applications for rural radio facilities.

*

(e) All licensees in the Rural Radio Service, must, upon request by a *bona fide* prospective applicant, provide to such applicant the information in paragraph (d) of this part regarding the portion of the licensee's operations which potentially affects, or potentially is affected by, the prospective applicant's proposed system, if such information is not already on file with the Commission. This information must be given to the *bona fide* prospective applicant within thirty days of receipt of the information request.

[FR Doc. 89-15973 Filed 7-7-89; 8:45 am]

BILLING CODE 6712-01-M

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47 CFR Part 22

[CC Docket No. 88-135; FCC 89-126]

Public Mobile Services

AGENCY: Federal Communications Commission (FCC).

ACTION: Final rule.

SUMMARY: The Commission has authorized Public Mobile Service (PMS) licensees to increase the effective radiated power (ERP) of their stations in the 35 MHz, 152 MHz, and 450 MHz bands, when their interference contours do not exceed the existing interference contours of co-channel stations operating under the control of the same licensee. This change will enhance the efficiency of PMS operations because fewer transmitters will be needed to cover the same geographic area, building penetration will be increased and the system's ability to overcome man-made noise will be improved. This, in turn, will permit more economical and efficient use of the spectrum, without creating interference to other licensees. Previously, PMS stations were limited to a maximum ERP of 500 watts at a maximum antenna height of 500 feet above average terrain for stations operating in the 35, 43, 152 and 450 MHz frequency bands. This Report and Order adopts an increase in permissible power to 600 watts in the 35 MHz band, and increase to 1400 watts in the 150 MHz band and an increase to 3500 watts in the 450 MHz band. Additionally, the Report and Order retains the present power limitations for 4 adjacent channels in the 150 MHz band and from the one channel adjacent to the Petroleum Radio Service in the 450 MHz band because an increase in radiated power at these frequencies might cause interference to private radio services. The Commission retains the present power limitations in the 43 MHz band because any further increase in power would cause TV interference. The Commission declined to increase height limitations because serious questions were raised concerning the accuracy of the propagation curves used to calculate interference contours for the common carrier public mobile service for antenna heights greater than 500 feet. Lastly, the Commission permitted the three nationwide paging channels in the 931 MHz band to operate without height restrictions since the channels are controlled nationwide by the same entity and will not cause interference to other licensees.

EFFECTIVE DATE: August 14, 1989.

ADDRESS: Federal Communications Commission, 1919 M Street, NW Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Linda Dubroof, Mobile Services Division, Common Carrier Bureau, (202) 632-6450.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Report and Order adopted April 26, 1989, and released June 29, 1989. The full text of this action is available for inspection and copying during normal business hours in the FCC Dockets Branch (Room 230), 1919 M Street, NW., Washington, DC. The complete text of this action may also be purchased from the Commission's copy contractors, International Transcription Services (ITS), (202) 857-3800, 2100 M Street, NW Suite 140, Washington, DC 20037

Summary of Report and Order

1. This Order adopts an increase in radiated power for Public Mobile Service licensees in the 35, 150 and 450 MHz bands, when their interference contours do not exceed the existing interference contours of co-channel stations operating under the control of the same licensees, and retains the current rules for height-power limitations in the remaining frequency bands. Because each frequency band is affected uniquely by changes in radiated power and antenna height, the Order adopts an increase in permissible power to 600 watts in the 35 MHz band, and increase to 1400 watts in the 150 MHz band and an increase to 3500 watts in the 450 MHz band. The increases in radiated power adopted in this Order will permit more economical and efficient use of the spectrum, without creating interference to other licensees. The changes incorporated in this Order will also enhance the efficiency of service operations, increase signal penetration in buildings and further enable public mobile service systems to overcome man-made noise.

Additionally, the Order retains the present power limitations for four adjacent channels in the 150 MHz band and for the one channel adjacent to the Petroleum Radio Service in the 450 MHz band because an increase in radiated power at these frequencies might cause interference to private radio services. Moreover, the Order retains the present power limitations in the 43 MHz band because any further increase in power would cause TV interference.

Similarly, the Order declines to increase height limitations because of the inability to determine co-channel interference with other Commission licensees. The Order does allow the three nationwide paging channels in the 931 MHz band to operate without height restrictions since the channels are controlled nationwide by the same entity and will not cause interference to other licensees.

2. *Final Regulatory Flexibility Analysis.* The rulemaking will enhance the efficiency of PMS operations because fewer transmitters will be needed to cover the same geographic area. In addition, building penetration will be increased and the PMS systems' ability to overcome man-made noise will be improved. Our objective is to provide service to the public with greater speed and efficiency.

The Order takes into consideration the various issues raised by the public concerning the proposed rules. As a result of these comments, whenever possible, we have modified our proposal so as to permit both economical and efficient spectrum use but without creating interference to other services. We have determined no specific alternatives which could accomplish the objective achieved in this rulemaking Order.

3. *Paperwork Reduction.* This proposal has been analyzed with respect to the Paperwork Reduction Act of 1980 and found not to impose a new or modified information collection requirement on the public.

Ordering Clauses

4. Authority for this Rulemaking is contained in Sections 1, 4(i) and (j), 301, 303 and 309 of the Communications Act of 1934, as amended, and Section 503 of the Administrative Procedure Act;

5. Wherefore, for the foregoing reasons, Part 22 of the Commission's Rules are hereby amended as specified in the Rules Section appended to this summary. The amendments adopted in this Order for Part 22 licensees will become effective August 14, 1989.

List of Subjects in 47 CFR Part 22

Radio.

Federal Communications Commission.

Donna R. Searcy,

Secretary.

Rules Section

Part 22 of Title 47 of the Code of Federal Regulations is amended as follows:

PART 22—PUBLIC MOBILE SERVICE

1. The authority citation for Part 22 continues to read as follows:

Authority: Secs. 4, 303, 48 Stat. 1066, 1082, as amended (47 U.S.C. 154, 303), sec. 553 of the Administrative Procedure Act (5 U.S.C. 553), unless otherwise noted.

2. Section 22.100 is amended by adding paragraph (e) to read as follows:

§22.100 Frequencies, Interference.

(e) *Blanketing.* Areas adjacent to the transmitting antenna that receive a signal strength of 115 dBu or greater will be assumed to be blanketed. In determining the blanketed area, the 115 dBu contour is determined by calculating the inverse distance field using the maximum radiated lobe of the antenna without considering its vertical radiation pattern or height. For directional antennas, the effective radiated power in the pertinent bearing shall be used.

(1) The distance to the 115 dBu contour is determined using the following equation:

$$D \text{ (in miles)} = 0.245 \times (P)^{1/2}$$

Where P is the maximum effective radiated power (ERP), measured in kilowatts, of the maximum radiated lobe.

(2) Licensees of new or modified stations ("licensee(s)"); must resolve all complaints of blanketing interference (as defined in this Section) which are received by licensee within one year of filing a "Notification of Status of Facilities, FCC Form 489. Resolution of complaints shall be at no cost to the complainant. These requirements specifically do not include interference complaints resulting from malfunctioning or mistuned receivers, improperly installed antenna systems, or the use of high gain antennas or antenna booster amplifiers. Mobile receivers and non-RF devices are also excluded.

(3) A licensee co-locating with one or more existing licensees must assume full financial responsibility for remedying new complaints of blanketing interference for a period of one year. Two or more licensees concurrently co-locating facilities are jointly responsible for remedying blanketing interference unless the commission can readily determine the offending station and then that station shall assume full responsibility.

(4) Following the one year period of full financial responsibility to satisfy blanketing complaints, licensees shall provide technical information to complainants on remedies for blanketing interference.

3. Section 22.505 is amended by adding paragraph (c) to read as follows:

§ 22.505 Antenna height-power limit.

(c) Base stations in the 35, 43, 152, and 454 MHz bands that exceed a maximum effective radiated power of 500 watts, pursuant to section 22.506(f), may not exceed 500 watts in any radial direction where the height above average terrain exceeds 500 feet. Base stations on 931.8875, 931.9125, and 931.9375 MHz are

exempt from the height limits of this section.

4. Section 22.506 is amended by adding paragraph (f) to read as follows:

§ 22.506 Power.

(f) Proposed base stations, other than in the air-ground radio service, the 43 MHz band, 152.24, 152.84, 158.10, 158.70 and 454.025 MHz, the 470–512 MHz band, and the 931 MHz Band, whose interference contours do not exceed the interference contours(s) of existing co-channel station(s), which are operated under the control of the same licensee, may operate with the following power limits:

Frequency band (MHz)	Maximum effective radiated power (in Watts)
35	600
152	1,400
454	3,500

[FR Doc. 89–15972 Filed 7–7–89; 8:45 am]

BILLING CODE 6712-01-M

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

49 CFR Parts 390, 391, and 393

[FHWA Docket No. MC-88-18]

RIN 2125-AC21

Federal Motor Carrier Safety; General; Exempt Intracity Zone; Foreign Motor Carriers

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Reopening of comment period.

SUMMARY: On March 24, 1989, the FHWA published in the **Federal Register** a final rule and request for comments (54 FR 1200). In the final rule, the FHWA amended Parts 390, 391, and 393 of the Federal Motor Carrier Safety Regulation (FMCSRs). Particularly, the applicability of Part 393 was delayed until November 18, 1989, for certain foreign motor carriers operating commercial motor vehicles in the United States. The FHWA requested comments from all interested parties regarding the issue of the exemption of certain foreign motor carriers from the provisions of 49 CFR Part 393. The comment period for this final rule closed on June 22, 1989. The FHWA has received a formal request from the Rio Grande Valley Trucking Coalition (RGV) and the Border Trade Alliance (BTA) for extension of the comment period because they are encountering difficulty in obtaining specific information they believe to be relevant. The FHWA is granting the request for an extension by reopening the docket.

The comment period, therefore, is being reopened until July 24, 1989. No further requests for extensions will be considered where this rulemaking action is concerned.

DATE: Comments must be received on or before July 24, 1989.

ADDRESS: Submit written, signed comments to FHWA Docket No. MC–88–18, Room 4232, HCC–10, Office of the Chief Counsel, Federal Highway Administration, 400 Seventh Street, SW., Washington, DC. 20590. Commenters may, in addition to submitting "hard copies" of their comments, submit a floppy disk (either 1.2Mb or 360Kb density) in a format that is compatible with either word processing programs, Word Perfect or WordStar. All comments received will be available for examination at the above address from 8:30 a.m. to 3:30 p.m. ET, Monday through Friday, except legal holidays. Those desiring notification of receipt of comments must include a self-addressed, stamped postcard.

FOR FURTHER INFORMATION CONTACT: Mr. Thomas P Kozlowski, Office of Motor Carrier Standards, (202) 366–2981, or Mr. Thomas P Holian, Office of the Chief Counsel, (202) 366–1350, Federal Highway Administration, Department of Transportation, 400 Seventh Street, SW., Washington, DC 20590. Office hours are from 7:45 a.m. to 4:15 p.m., e.t., Monday through Friday, except legal holidays.

SUPPLEMENTARY INFORMATION: The RGV and BTA have jointly requested a 30-day extension of the comment period established when the aforementioned final rule was published. Both organizations stated that an extension would provide adequate time to assemble the necessary manufacturing data and information from the Mexican manufacturers of commercial motor vehicles. They also noted that members of the BTA would be meeting in Arizona in June, and in Mexico in early July and that an extension would allow time to thoroughly review the data and provide more meaningful comments to the docket. The FHWA does not anticipate receiving similar requests from other organizations within the transportation industry.

The FHWA, therefore, concludes that the request to extent the comment period has merit. Accordingly, the comment period for this docket is being reopened until Monday, July 24, 1989.

Authority: 49 U.S.C. App. 2503 and 2505; 49 U.S.C. 3102 and 3104; 49 CFR 1.48.

List of Subjects in 49 CFR Parts 390, 391, and 393

Highway safety, Highways and roads, Motor carriers, Drivers, Reporting and recordkeeping requirements, Motor vehicle safety.

(Catalog of Federal Domestic Assistance Program Number 20.217 motor carrier safety.)

Issued on: June 30, 1989.

Eugene R. McCormick,

Deputy Administrator.

[FR Doc. 89–16069 Filed 7–7–89; 8:45 am]

BILLING CODE 4910-22-M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 661

[Docket No. 90515-9115]

Ocean Salmon Fisheries Off the Coasts of Washington, Oregon, and California; Corrections

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

ACTION: Notice of 1989 fishery management measures, modification of the Klamath River fall chinook spawning escapement rate; corrections.

SUMMARY: A notice of 1989 fishery management measures for the commercial and recreational ocean salmon fisheries off Washington, Oregon, and California, was published May 8, 1989 (54 FR 19798), and corrected June 6, 1989 (54 FR 24175 and 24288). This notice makes additional corrections to (1) the seasons for the commercial troll fishery between Horse Mountain and Point Arena to be consistent with the descriptive text in the May 8 notice, and (2) two longitudinal coordinates used to describe the open area in the August commercial troll fishery between the U.S.-Canada border and Carroll Island, Washington.

FOR FURTHER INFORMATION CONTACT: William L. Robinson, 206–526–6140, or Rodney R. McInnis, 213–514–6199.

In rule document 89–10793 beginning on page 19788 in the issue of May 8, 1989, make the following corrections:

1. In Table 1 (pages 19803 and 19804), the seasons for the subarea from Horse Mountain to Point Arena are corrected by changing the following, all on page 19804.

(a) Column for Area and season, entry beginning on line 1 with "Earlier" on

lines 2 and 3, "September 30" should read "June 17"

(b) Immediately after that entry, add a new entry on a new line as follows: Column for Area and season to read "Coho reserve thru June 17 "· column for species to read All except coho."· column for Quota for Chinook to read "None"· and column for Quota for Coho to read "* *"

(c) Column for Area and season, entry beginning on line 7 with "Earlier" lines 8 and 9, "September 30" should read "July 14"

(d) Immediately after that entry, add a new entry on a new line as follows: Column for Area and season to read "Coho reserve thru July 14."· column for species to read "All except coho."· column for Quota for Chinook to read "None"· and column for Quota for Coho to read "* *"

2. On Page 19805, under "C. Special Requirements, Restrictions, and Exceptions" in C-8, in the third line, "125°49'30" W should read "124°49'30" W.; and, in the same line, "125°49'00" W. should read "124°49'00" W.

Dated: July 5, 1989.

James W. Brennan,

Assistant Administrator For Fisheries, National Marine Fisheries Service.

[FR Doc. 89-16112 Filed 7-7-89; 8:45 am]

BILLING CODE 3510-22-M

Proposed Rules

Federal Register
Vol. 54, No. 130
Monday, July 10, 1989

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.

DEPARTMENT OF AGRICULTURE

Federal Crop Insurance Corporation

7 CFR Part 401

[Admt. 40; Docket No. 6750S]

General Crop Insurance Regulations; Raisin Endorsement

AGENCY: Federal Crop Insurance Corporation, USDA.

ACTION: Proposed rule.

SUMMARY: The Federal Crop Insurance Corporation (FCIC) proposes to amend the General Crop Insurance Regulations (7 CFR Part 401), effective for the 1990 and succeeding crop years, by adding a new section, 7 CFR 401.142, the Raisin Endorsement. The intended effect of this rule is to provide the provisions of crop insurance protection on raisins in an endorsement to the general crop insurance policy.

DATE: Written comments, data, and opinions on this proposed rule should be received not later than August 9, 1989, to be sure of consideration.

ADDRESS: Written comments on this proposed rule should be sent to Peter F Cole, Office of the Manager, Federal Crop Insurance Corporation, Room 4090, South Building, U.S. Department of Agriculture, Washington, DC, 20250.

FOR FURTHER INFORMATION CONTACT: Peter F Cole, Secretary, Federal Crop Insurance Corporation, U.S. Department of Agriculture, Washington, DC 20250, telephone (202) 447-3325.

SUPPLEMENTARY INFORMATION: This action has been reviewed under USDA procedures established by Department Regulation 1512-1. This action constitutes a review as to the need, currency, clarity, and effectiveness of these regulations under those procedures. The sunset review date established for these regulations is established as March 1, 1994.

John Marshall Manager, FCIC, (1) has determined that this action is not a major rule as defined by Executive Order 12291 because it will not result in: (a) an annual effect on the economy of $100 million or more; (b) major increases in costs or prices for consumers, individual industries, federal, State, or local governments, or a geographical region; or (c) significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets; and (2) certifies that this action will not increase the federal paperwork burden for individuals, small businesses, and other persons and will not have a significant economic impact on a substantial number of small entities.

This action is exempt from the provisions of the Regulatory Flexibility Act; therefore, no Regulatory Flexibility Analysis was prepared.

This program is listed in the Catalog of Federal Domestic Assistance under No. 10.450.

This program is not subject to the provisions of Executive Order 12372 which requires intergovernmental consultation with State and local officials. See the Notice related to 7 CFR Part 3015, Subpart V published at 48 FR 29115, June 24, 1983.

This action is not expected to have any significant impact on the quality of the human environment, health, and safety. Therefore, neither an Environmental Assessment nor an Environmental Impact Statement is needed.

FCIC proposes to add to the General Crop Insurance Regulations (7 CFR Part 401), a new section to be known as 7 CFR 401.142, the Raisin Endorsement, effective for the 1990 and succeeding crop years, to provide the provisions for insuring raisins.

Upon publication of 7 CFR 401.142 as a final rule, the provisions for insuring raisins contained therein will supersede those provisions contained in 7 CFR Part 402, the Raisin Crop Insurance Regulations, effective with the beginning on the 1990 crop year. The present policy contained in 7 CFR Part 402 will be terminated at the end of the 1989 crop year and later removed and reserved. FCIC will propose to amend the title of 7 CFR Part 402 by separate document so that the provisions therein are effective only through the 1989 crop year.

Minor editorial changes have been made to improve compatibility with the new general crop insurance policy. These changes do not affect meaning or intent of the provisions. In adding the new Raisin Endorsement to 7 CFR Part 401, FCIC makes other changes in the provisions for insuring raisins as follows:

1. Subsection 1.—Add language regarding share in the event of a loss. For purposes of raisin insurance, in case of an indemnity, the share should nor exceed the share when the raisins are removed from the vineyard rather than at the beginning of harvest. Remove language allowing raisin insurance on grapes that have been sized for table grapes. This change was made due to unfavorable loss experience when insuring raisins made from table grapes.

2. Subsection 3.—Change the tonnage to be reported from net tons to delivered tons. Raisin maturity standards have made the use of net tonnage (or net paid tonnage) inappropriate when determining premium amounts.

3. Subsection 9.—Include language to authorize us to obtain records from the Raisin Administrative Committee and other parties who may have such records.

This authorization is needed to allow us to determine insured tonnage when a tonnage report is not submitted.

4. Subsection 7—Unit division provisions are included in this subsection of the endorsement to indicate that additional premium may be required for unit division on noncontiguous land.

5. Subsection 9—Change language regarding the value of undamaged raisins. The new term used is the "insurance price. This change was made because the term "field price" has generally been used in the raisin industry to define only the free tonnage price. Add language to clarify that the number of tons of raisins on which we allow a reconditioning allowance will be the actual (unadjusted) tonnage to be reconditioned. This clarification was made to eliminate inconsistencies in loss adjustment procedure.

6. Subsection 12—Add the definitions of "Delivered ton, "Noncontiguous Land, "Insurance price, and "Substandard.

FCIC is soliciting public comment on this proposed rule for 30 days following publication in the **Federal Register.** Written comment should be sent to Peter F Cole, Office of the Manager,

Federal Crop Insurance Corporation, Room 4090, South Building, U.S. Department of Agriculture, Washington, DC 20250.

All written comments received pursuant to this proposed rule will be available for public inspection and copying in the Office of the Manager, Federal Crop Insurance Corporation, Room 4090, South Building, U.S. Department of Agriculture, Washington, DC 20250, during regular business hours, Monday through Friday.

List of Subjects in 7 CFR Part 401

Crop insurance; Raisin endorsement.

Proposed Rule

Accordingly, pursuant to the authority contained in the Federal Crop Insurance Act, as amended (7 U.S.C. 1501 et seq.), the Federal Crop Insurance Corporation proposes to amend the General Crop Insurance Regulations (7 CFR Part 401), to be effective for the 1990 and succeeding crop years, as follows:

PART 401—[AMENDED]

1. The authority citation for 7 CFR Part 401 continues to read as follows:

Authority: 7 U.S.C. 1506, 1516.

2. Title 7 CFR Part 401 is amended to add a new section to be known as § 401.142, Raisin Endorsement, effective for the 1990 and Succeeding Crop Years, to read as follows:

§ 401.142 Raisin endorsement.

The provisions of the Raisin Crop Insurance Endorsement for the 1990 and subsequent crop years are as follows:

Federal Crop Insurance Corporation

Raisin Endorsement

1. Crop, Tonnage, and Share Insured

a. The crop insured will be raisins of grape varieties designated insurable by the actuarial table.

b. The tonnage insured will be the tonnage in which you have a share (as reported by you or as determined by us, whichever we elect).

c. In lieu of subsection 2.c.(2) of the general crop insurance policy, for the purpose of determining the amount of indemnity, your share will not exceed your share at the time the raisins are removed from the vineyard.

d. In addition to the raisins not insurable under section 2 of the general crop insurance policy, we do not insure any raisins:

(1) laid on trays after September 8 in vineyards with north-south rows in Merced or Stanislaus Counties or after September 20 in all other instances;

(2) made from table grape strippings; or

(3) made from vines that have had manual, mechanical, or chemical treatment to produce table grape sizing.

2. Causes of Loss

The insurance provided is against the unavoidable loss of production resulting from rain, occurring within the insurance period, while raisins are in the vineyard, on trays or in rolls, for drying unless limited by the actuarial table.

3. Report of Tray Count, Tonnage, and Share (Tonnage Report)

In lieu of section 3 of the general crop insurance policy, you must report on our farm:

a. For all raisins which are not damaged, the delivered tons of insured raisins produced in the county in which you have a share and your share as soon as delivery records are available, but in any event no later than March 1 following the crop year;

b. For insured raisins which are damaged:

(1) the variety;

(2) the location of the vineyard;

(3) the number of trays upon which the raisins have been placed for drying; and

(4) your share.

By execution of the application for insurance you authorize us to determine or verify the insured tonnage from records maintained by the Raisin Administrative Committee of the United States Department of Agriculture or any other person who may have such records. You must report separately any tonnage that is not insurable. You must report if you do not have a share in any insurable tonnage in the county. This report must be submitted annually on or before March 1 of the year following the crop year. Indemnities may be determined on the basis of information you have submitted on this report. If you do not submit this report by the reporting date, we may determine by unit the insured tonnage and share or we may deny liability on any unit. Any report submitted by you may be revised only upon our approval. Errors in reporting units may be corrected by us to conform to applicable guidelines at the time of adjusting a loss.

4. Amounts of Insurance and Production Reporting

a. The amount of insurance for the unit will be determined by multiplying the insured tonnage times the amount of insurance per ton, times your share. Insured tonnage is determined for raisins:

(1) not damaged by rain, by the raisins delivered (delivered tons); or

(2) damaged by rain, by adding raisins delivered (delivered tons), if any, to any verifiable loss of production due to rain damage in the vineyard. Tray weights will be used to establish raisin tonnage not removed from the vineyard.

b. Subsection 4.d. of the general crop insurance policy is not applicable to this crop.

5. Annual Premium

a. The annual premium amount is computed by mulitplying the amount of insurance per ton times the premum rate, times the insured tonnage, times your share on the date insurance attaches.

b. If you are eligible for a premium reduction in excess of 5 percent based on your insuring experience through the 1983 crop year under the terms of the experience table contained in the raisin policy in effect for the 1984 crop year, you will continue to receive the benefit of that reduction subject to the following conditions:

(1) no premium reduction will be retained after the 1991 crop year;

(2) the premium reduction will not increase because of favorable experience;

(3) the premium reduction will decrease becasue of unfavorable experience in accordance with the terms of the policy in effect for the 1984 crop year;

(4) once the loss ration exceeds .80, no further premium reduction will apply; and

(5) participation must be continuous.

6. Insurance Period

In lieu of section 7 of the general crop insurance policy, insurance attaches at the time the raisins are placed on trays for drying and ends the earlier of:

a. October 20;

b. the date the raisins are boxed; or

c. the date the raisins are removed from the vineyard.

7 Unit Division

a. Raisin acreage that would otherwise be one unit, as defined in section 17 of the general crop insurance policy, may be divided into units by grape variety.

b. Raisin acreage that would otherwise be one unit as defined in section 17 of the general crop insurance policy and subsection 7.a. above may be divided into more than one unit if you agree to pay additional premium if required by the actuarial table and if, for each proposed (optional) unit:

(1) you maintain written, verifiable records of raisin production for at least the previous crop year; and

(2) the acreage of insured raisins is located on noncontiguous land.

If you have a loss on any unit, production records for all harvested units must be provided. Production that is commingled between optional units will cause those units to be combined.

8. Notice of Damage or Loss

In lieu of section 8 of the general crop insurance policy, if you are going to claim an indemnity on any unit, we must be given notice within 72 hours of the time the rain fell on the raisins. We may reject any claim for indemnity if such damage is not reported within 72 hours.

9. Claim for Indemnity

a. In lieu of subsection 9.a. of the general crop insurance policy any claim for indemnity must be submitted to us on our form not later than March 31 after the calendar date for the end of the insurance period.

b. In addition to the requirements in subsection 9.b. of the general crop insurance policy, we will not pay any indemnity unless you authorize us in writing to examine and obtain any records pertaining to the production and marketing of any raisins in which you have a share from the raisin packer, raisin reconditioner, Raisin Administrative Committee established under order of the United States Department of Agriculture, or any other party who may have such records.

c. The indemnity will be determined on each unit by:

(1) multiplying the insured tonnage of raisins by the amount of insurance per ton;

(2) subtracting therefrom the total value of all insured damaged and undamaged raisins; and

(3) multiplying this result by your share.

d. Undamaged raisins or raisins damaged solely by uninsured causes will be valued at the insurance price (see subsection 12.c.).

e. Raisins damaged partially by rain and partially by uninsured causes will be valued at the highest price obtainable, subject to an adjustment for any reduction in value due to uninsured causes.

f. Raisins damaged by rain, but which are reconditioned and meet the Raisin Administrative Committee (RAC) standards for raisins, will be valued at the insurance price. An allowance for reconditioning will be deducted from the value only if you obtained our written consent prior to reconditioning. The allowance for reconditioning will be made only when the raisins have been inspected by the USDA and, due to rain damage while on the tray are found to contain mold, embedded sand, excessive moisture, or micro/organisms in excess of RAC tolerances.

The reconditioning allowance will be made based on the actual (unadjusted) weight of raisins to be reconditioned. Additionally, when raisins contain excessive moisture due to rain, the reconditioning allowance will be made only when the moisture is determined to be in excess of 18.0 percent and the raisins are wash-and-dry reconditioned. The meximum allowance for reconditioning is contained in the actuarial table, but the total reconditioning allowance will not exceed the value of the raisins after reconditioning. We may require you to recondition a representative sample of not more than 10 tons of raisins to determine if they meet RAC standards for marketable raisins. On the basis of determinations made after such sampling, we may require you to recondition all raisins, or we may value such raisins at the insurance price. If the representative sample does not meet RAC standards for marketable raisins, the cost of reconditioning the sample will be deducted from the total value of the raisins for the unit.

g. The value to count for any raisins produced on the unit and not removed from the vineyard will be the larger of the appraised salvage value of $35.00 per ton. You must box and deliver any raisins that can be removed from the vineyard.

h. We may acquire all the rights and title to your share of any raisins damaged by rain. In such event, the raisins will be valued at "zero" in determining the amount of loss and we will have the right of ingress or egress to the extent necessary to take possession of, care for, and removed such raisins.

i. Raisins destroyed without USDA inspection or put to another use without our consent will be valued at the amount of insurance

10. Cancellation and Termination Dates

The cancellation and termination dates are July 31.

11. Contract Changes

The date by which contract changes will be available in your service office is April 30 preceding the cancellation date.

12. Meaning of Terms

a. *"Crop year"* means the calendar year in which the raisins are placed on trays for drying.

b. *"Delivered ton"* means a ton of raisins or raisin material delivered to a buyer or a reconditioner, adjusted for moisture over 16 percent and adjusted for substandard raisins over 5 percent.

c. *"Insurance price"* means the value established by us for raisin tonnage for the purpose of determining indemnities. This value is shown in the actuarial table.

d. *"Noncontiguous land"* means land which is not touching at any point. Land which is separated by only a public or private right-of-way will be considered to be touching (contiguous).

e. *"Raisins"* means specific varieties of grapes, designated insurable by the actuarial table, which have been laid on trays or are in rolls in the vineyard to dry.

f. *"Raisin tonnage report"* means a form prescribed by us for annually reporting all the tonnage or raisins in the county in which you have a share.

g. *"Substandard"* means a quality of raisins that fail to meet the requirements of U.S. Grade C except that layer or cluster raisins with seeds or Zante Currant raisins will be considered substandard if they fail to meet the requirements of U.S. Grade B.

h. *"Table grapes"* mean grapes which are grown for commercial sales as fresh grapes on acreage where the cultural practices to produce fresh marketable grapes were carried out.

i. *"Ton"* means 2,000 pounds. Raisin tonnage may be computed on the basis of one ton of raisins insured for every four and one-half tons of fresh grapes when first placed on trays for drying.

j. *"USDA inspection"* means the actual determination by a USDA inspector of all defects. Limited inspections or inspections on submitted samples are not considered "USDA inspections.

Done in Washington, DC on June 22, 1989.

John Marshall,

Manager, Federal Crop Insurance Corporation.

[FR Doc. 89-16123 Filed 7-7-89; 8:45am]

BILLING CODE 3410-08-M

NUCLEAR REGULATORY COMMISSION

10 CFR Part 2

RIN 3150-AD17

Informal Hearing Procedures for Nuclear Reactor Operator Licensing Adjudications

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule: Extension of comment period.

SUMMARY: On April 26, 1989, (54 FR 17961), the NRC published for public comment a proposed rule to amend its regulations to provide procedures for the conduct of informal adjudicatory hearings in nuclear reactor operator licensing proceedings. The comment period for this proposed rule was to have expired on June 26, 1989. On June 26, 1989, the Professional Reactor Operator Society requested a thirty-day extension of the comment period and on June 27 1989, Shaw, Pittman, Potts & Trowbridge law firm, on behalf of several of its clients, requested an extension until July 3, 1989. Around this same time, two other individuals requested copies of the rule and indicated that they may file written requests for extensions of time. In view of the importance of the proposed rule, the recent interest of the public in the rule, the amount of time that the requesters suggest is required in order to provide meaningful comments, and the desirability of developing a final rule as soon as practicable, the NRC has decided to extend the comment period for an additional forty-five days. The extended comment period now expires on August 10, 1989.

DATES: The comment period has been extended and now expires August 10, 1989. Comments received after this date will be considered if it is practical to do so but the Commission is able to assure consideration only for comments received before this date.

ADDRESSES: Send written comments or suggestions to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, ATTN: Docketing and Service Branch, Hand deliver comments to Docketing and Service Branch, One White Flint North, 11555 Rockville Pike, Rockville, MD, between 7:30 a.m. and 4:15 p.m. Examine comments received at: The NRC Public Document Room, 2120 L Street NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Karla Smith, Attorney, Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Telephone (301) 492-1606.

Dated at Washington, DC, this 3rd day of July, 1989.

For the Nuclear Regulatory Commission.

Samuel J. Chilk,

Secretary of the Commission.

[FR Doc. 89-16125 Filed 7-7-89; 8:45 am]

BILLING CODE 7590-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 320

[Docket Nos. 77N-0194, 77N-0425, 78N-0178, 79N-0034, 79N-0133, 79N-0464, 79N-0477, 80N-0183, 80N-0191, 80N-0235, 80N-0315]

Bioequivalence Requirements; Withdrawal of Proposed Rules

AGENCY: Food and Drug Administration.

ACTION: Withdrawal of proposed rules.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing 11 proposed rules that would have established bioequivalence requirements for certain drug products. Elsewhere in this issue of the **Federal Register**, FDA is proposing regulations to implement Title I of the Drug Price Competition and Patent Term Restoration Act of 1984. That proposal supersedes the proposals being withdrawn.

DATE: This withdrawal is effective July 10, 1989.

FOR FURTHER INFORMATION CONTACT: Marilyn L. Watson, Center for Drug Evaluation and Research (HFD-360), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857 301-295-8038.

SUPPLEMENTARY INFORMATION: The regulations regarding methods and procedures for in vivo testing to determine the biovailability of drug products (21 CFR 320.22(c)) list specific drug products with known or potential bioequivalence problems for which the agency intended to establish bioequivalence requirements.

On September 24, 1984, the President signed into law the Drug Price Competition and Patent Term Restoration Act. Title I of the new law amended the Federal Food, Drug, and Cosmetic Act to expand the universe of drugs for which FDA may accept abbreviated new drug applications (ANDA s). The new law imposes a bioequivalence requirement on all drug products that are the subject of ANDA s and that refer to and are the same as one of the drug products listed under § 302.22(c). FDA no longer intends to establish separate bioequivalence requirements for those drug products.

Elsewhere in this issue of the **Federal Register**, FDA is proposing regulations to implement Title I of the new law.

Therefore, for the reasons set forth above and under the Federal Food, Drug, and Cosmetic Act (secs. 201(p), 502, 505, 701(a), 52 Stat. 1041-1042 as amended, 1050-1053 as amended, 1055 (21 U.S.C. 321(p), 352, 355, 371(a))) and under 21 CFR 5.11, the agency is withdrawing the following proposed bioequivalence requirements published in the **Federal Register** on the dates indicated:

Drug name	Docket No.	Date of publication
Anticonvulsants	77N-0194	August 5, 1977 (42 FR 39675).
Carbonic anhydrase inhibitors	79N-0477	Februrary 22, 1980 (45 FR 11849).
Cortiocosteroids, oral	79N-0034	April 13, 1979 (44 FR 22111).
Phenothiazine products	80N-0191	August 26, 1980 (45 FR 56832).
Probenecid	80N-0183	July 18, 1980 (45 FR 48160).
Procainamide hydrochloride	78N-0178	August 8, 1978 (43 FR 35056).
Quinidine	80N-0315	October 31, 1980 (45 FR 72200).
Sulfonamide anti-infectives, certain	79N-0133	October 19, 1979 (44 FR 60320).
Sulfones	80N-0235	August 22, 1980 (45 FR 56075).
Tricyclic anti-depressants	77N-0425	February 17 1978 (43 FR 6965).
Vitamin K-type coagulants	79N-0464	March 4, 1980 (45 FR 14063).

Dated: March 2, 1989.

Frank E. Young,

Commissioner of Food and Drugs.

[FR Doc. 89-16025 Filed 7-7-89; 8:45 am]

BILLING CODE 4160-01-M

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 2 and 87

[PR Docket No. 89-295; FCC 89-207; RM-6620, RM-6649]

Aviation Services; Rules To Permit the Aviation Services To Use Frequencies in the 136-137 MHz Band

AGENCY: Federal Communications Commission.

ACTION: Proposed Rule.

SUMMARY: The proposed rule would permit aircraft to use the frequencies in the 136-137 MHz band. This action was initiated in response to two petitions. One petition (RM-6620) was filed by the Aeronautical Radio, Inc. (ARINC) and the other (RM-6649) filed by the American Petroleum Institute (API). The effect of the proposed rule is to permit the aviation community to use additional frequencies in order to alleviate the frequency congestion that currently exists in the aviation services.

DATES: Comments must be received on or before August 11, 1989, and reply comments must be received on or before August 28, 1989.

ADDRESS: Federal Communications Commission, 1919 M Street NW Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: William P Berges, Federal Communications Commission, Private Radio Bureau, Washington, DC 20554, (202) 632-7175.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission s *Notice of Proposed Rule Making*, PR Docket No. 89-295, adopted June 15, 1989, and released June 28, 1989. The full text of this Commission decision including the proposed rule change is available for inspection and copying during normal business hours in the FCC Dockets Branch (Room 230), 1919 M Street NW Washington, DC. The full text of this decision including the proposed rule change may also be purchased from the Commission s copy contractor, International Transcription Services, Inc., (202) 857-3800, 2100 M Street NW Suite 140, Washington, DC 20037

Summary of Notice of Proposed Rulemaking

In response to two petitions for rulemaking, one filed by the Aeronautical Radio, Inc. (ARINC) and the other by the American Petroleum Institute (API), the FCC proposes to amend the rules to authorize the aviation services to use the frequencies in the 136-137 MHz band. Authorization to use these frequencies will help to alleviate the frequency congestion currently being experienced in the aviation services.

Ordering Clauses

This is a non-restricted notice and comment rule making proceeding. *See*

§ 1.1231 of the Commission's Rules, 47 CFR 1.1231, for rules governing permissible *ex parte* contacts.

The Commission hereby certifies pursuant to Section 605(b) of the Regulatory Flexibility Act of 1980 (Pub. L. 96–354), that these rules, if promulgated, will not have a significant economic impact on a substantial number of small entities. Although these proposed changes allow the aviation community greater flexibility in the selection of operating frequencies and result in some expenditures for equipment, these additional optional expenditures should be minimal.

The proposal contained herein has been analyzed with respect to the Paperwork Reduction Act of 1980 and found to contain no new or modified form, information collection and/or record keeping, labeling, disclosure, or record retention requirements; and will not increase or decrease burden hours imposed on the public.

Authority for issuance of this *Notice* is contained in Sections 4(i) and 303(r) of the Communications Act of 1934, as amended, 47 U.S.C. 154(i) and 303(r). Pursuant to applicable procedures set forth in §§ 1.415 and 1.419 of the Commission's Rules, 47 CFR §§ 1.415 and 1.419, interested parties may file comments and reply comments as indicated in the "DATES" paragraph of this document. All relevant and timely comments will be considered by the Commission before final action is taken in this proceeding.

A copy of the Notice of Proposed Rule Making will be served on the Chief Counsel for Advocacy of the Small Business Administration.

List of Subjects

47 CFR Part 2

Frequency allocations, Treaties

47 CFR Part 87

Aviation services, Aeronautical stations.

Federal Communications Commission.

Donna R. Searcy,

Secretary.

Parts 2 and 87 of Chapter I, Title 47 of the Code of Federal Regulations are proposed to be amended as follows:

PART 2—FREQUENCY ALLOCATIONS AND RADIO TREATY MATTERS: GENERAL RULES AND REGULATIONS

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

Authority: Sec. 4, 302, 303, 307 48 Stat. 1066, 1082, as amended; 47 U.S.C. 154, 302, 303, 307 unless otherwise noted.

2. In § 2.106, United States footnote US244 is revised to read as follows:

§ 2.106 Table of frequency allocations.

United States (US) Footnotes

US244 The band 136.000–137.000 MHz is allocated to the non-Government aeronautical mobile (R) service on a primary basis, and is subject to pertinent international treaties and agreements. The frequencies 136.000 MHz, 136.025 MHz, 136.050 MHz, 136.075 MHz, 136.125 MHz, 136.150 MHz, 136.175 MHz, 136.225 MHz, 136.250 MHz, 136.300 MHz, 136.325 MHz, 136.350 MHz, 136.400 MHz, 136.425 MHz and 136.450 MHz are available on a shared basis to the Federal Aviation Administration for air traffic control purposes, such as automatic weather observation services (AWOS), automatic terminal information services (ATIS) and airport control tower communications. Existing stations using the 136–137 MHz band as an alternative allocation to the space operation (space-to-earth), meteorological-satellite service (space-to-earth) and the space research service (space-to-earth) may continue to use this band on a secondary basis to the aeronautical mobile (R) service stations. No new assignments will be made to stations in the above space services.

PART 87—AVIATION SERVICES

1. The authority citation for Part 87 continues to read as follows:

Authority: 48 Stat. 1066, 1082, as amended; 47 U.S.C. 154, 303, unless otherwise noted. Interpret or apply 48 Stat. 1064–1068, 1081–1105, as amended; 47 U.S.C. 151–156, 301–609.

§ 87.137 [Amended]

2. In § 87.137 paragraph (a), footnote 5 is amended by removing the period after § 87.263(a)(1) and adding "and (5).

§ 87.173 [Amended]

3. In § 87.173, the frequency table in paragraph (b) is amended by adding the following four columnar entries in frequency numerical order:

Frequency of frequency band	Subpart	Class of station	Remarks
136.000–136.075 MHz	O, S	MA, FAC, FAW	Air traffic control operations.
136.100 MHz			Reserved for future unicom or AWOS.
136.125–136.175	O, S	MA, FAC, FAW	Air traffic control operations.
136.200 MHz			Reserved for future unicom or AWOS.
136.225–136.250 MHz	O, S	MA, FAC, FAW	Air traffic control operations.
136.275 MHz			Reserved for future unicom or AWOS.
136.300–136.350 MHz	O, S	MA, FAC, FAW	Air traffic control operations.
136.375 MHz			Reserved for future unicom or AWOS.
136.400–136.450 MHz	O, S	MA, FAC, FAW	Air traffic control operations.
136.475 MHz			Reserved for future unicom or AWOS.
136.500–136.600 MHz	I	MA, FAE	Domestic VHF
136.625 MHz	I	MA, FAE	Domestic VHF (special).
136.650 MHz	I	MA, FAE	Domestic VHF
136.675 MHz	I	MA, FAE	Domestic VHF (special).
136.700 MHz	I	MA, FAE	Domestic VHF
136.725 MHz	I	MA, FAE	Domestic VHF (special).
136.750 MHz	I	MA, FAE	Domestic VHF
136.775 MHz	I	MA, FAE	Domestic VHF (special).
136.800 MHz	I	MA, FAE	Domestic VHF
136.825 MHz	I	MA, FAE	Domestic VHF (special).
136.850 MHz	I	MA, FAE	Domestic VHF
136.875 MHz	I	MA, FAE	Domestic VHF (special).
136.900 MHz	I	MA, FAE	Domestic VHF
136.925 MHz	I	MA, FAE	Domestic VHF (special)
136.950 MHz	I	MA, FAE	Domestic VHF
136.975 MHz	I	MA, FAE	Domestic VHF (special).

4. In § 87.263, paragraph (a)(1) is revised and a new paragraph (a)(5) is added to read as follows:

§ 87.263 Frequencies.

(a) *Domestic VHF Service.* (1) The frequencies in the 128.825–132.000 MHz band and the frequencies 136.500 MHz, 136.525 MHz, 136.550 MHz, 136.575 MHz, 136.600 MHz, 136.650 MHz, 136.700 MHz, 136.750 MHz, 136.800 MHz, 136.850 MHz, 136.900 MHz and 136.950 MHz are available to serve domestic routes. Frequency assignments are based on 25 kHz spacing. Proposed operations must be compatible with existing operations. Use of these frequencies must be in accordance with pertinent international treaties and agreements.

(5) The frequencies 136.625 MHz, 136.675 MHz, 136.725 MHz, 136.775 MHz, 136.825 MHz, 136.875 MHz, 136.925 MHz and 136.975 MHz are available for special purpose assignment to aeronautical enroute stations. Frequency assignments will be based on 25 kHz channel spacing, will be coordinated by the Commission and are not subject to the conditions contained in § 87.261 (b), (c) and (d), and paragraph (a)(2) of this section. Use of these frequencies must be in accordance with pertinent international treaties and agreements.

5. In § 87.421, the introductory text is revised to read as follows:

§ 87.421 Frequencies.

The Commission will assign VHF frequencies after coordination with the FAA. Frequencies in the following bands are available to control towers. Channel spacing is 25 kHz.

118.000–121.400 MHz	136.225–136.250 MHz
121.600–121.925 MHz	136.300–136.350 MHz
123.600–128.800 MHz	136.400–136.450 MHz
132.025–136.075 MHz	
136.125–136.175 MHz	

[FR Doc. 89–15979 Filed 7–7–89; 8:45 am]

BILLING CODE 6712-01-M

Notices

Federal Register
Vol. 54, No. 130
Monday, July 10, 1989

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

Agricultural Stabilization and Conservation Service

1989-Crop Peanuts; National Poundage Quota

AGENCY: Agricultural Stabilization and Conservation Service.

ACTION: Notice of determination.

SUMMARY: This notice affirms the determination of the national poundage quota for the 1989 crop of quota peanuts. On December 15, 1988, the Secretary of Agriculture announced that the national poundage quota for the 1989–90 marketing year would be 1,440,000 short tons, 37,800 short tons above last year's quota. That determination was made pursuant to the statutory requirements of the Agricultural Adjustment Act of 1938, as amended (hereinafter referred to as "the Act").

EFFECTIVE DATE: December 15, 1988.

FOR FURTHER INFORMATION CONTACT: Gypsy Banks or Robert Miller, Agricultural Economists, Agricultural Stabilization and Conservation Service, USDA, Room 3734–South Building, P.O. Box 2415, Washington, DC 20013, (202) 447–7477 or (202) 447–8839. The final regulatory impact analysis describing the impact of implementing this determination will be available on request from the above-named individuals.

SUPPLEMENTARY INFORMATION: This notice has been reviewed under USDA procedures established to implement Executive Order 12291 and Departmental Regulation No. 1512–1 and has been classified "not major. The matters under consideration will not result in: (1) An annual effect on the economy of $100 million or more; (2) a major increase in costs or prices for consumers, industries, Federal, State, or local governments or geographical regions: or, (3) 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.

The title and number of the Federal assistance program that this final rule applies to are: Title—Commodity Loans and Purchases: Number 10.051, as found in the Catalog of Federal Domestic Assistance.

This program/activity is not subject to the provisions of Executive Order No. 12372 relating to intergovernmental consultation with State and local officials. See the Notice related to 7 CFR Part 3015, Subpart V published at 48 FR 29115 (June 24, 1983).

It has been determined that the Regulatory Flexibility Act is not applicable to this notice since ASCS is not required by 5 U.S.C. 553 or any other provision of law to publish a notice of proposed rulemaking with respect to the subject matter of this determination.

The Secretary of Agriculture proposed, by a notice published on November 25, 1988 (53 FR 47740), that the quota for the 1989 crop of peanuts be set at 1,440,000 short tons. The 1988-crop quota was 1,402,200 short tons. Under section 358(p) of the Act, quota peanuts are those produced on a farm within the farm's poundage quota as established for the farm under the Act. Section 358(q)(1) of the 1938 Act requires that the national poundage quota for peanuts for each of the 1986 through 1990 marketing years be established by the Secretary at a level that is equal to the quantity of peanuts in tons that the Secretary estimates will be devoted in each such marketing year to domestic edible, seed, and related uses. Section 358(q)(1) further provides that the national poundage quota for any such marketing year shall not be less than 1,100,000 short tons. The marketing year for the 1989 crop of peanuts will run from August 1, 1989 through July 31, 1990. Poundage quotas for the 1986–1990 crops of peanuts were approved by producers in a mail ballot held January 27–31, 1986.

Through December 7 comments were receivd from 18 respondents—one national producer group, two area producer groups, three State producer groups, two producers, one regional sheller association, one shelling firm, two procesor associations and six processors.

One respondent recommended reducing the quota to 1,361,000 short tons, one respondent supported no change in the quota from the 1988-crop quantity, and six supported the proposed quota of 1,440,000 short tons. These eight respondents were concerned that a quota level above the proposed 1,440,000 short tons would produce a surplus of peanuts for domestic edible use resulting in potential losses to the Commodity Credit Corporation. One producer specifically suggested that the crushing residual component used to calculate the proposed quota was excessive and had resulted in a proposed quota that was too high.

Ten respondents recommended an increase in the quota, ranging from an unspecified increase to a quota of 1,525,000 short tons. These respondents suggested that inadequate demand projections, an inadequate crushing residual estimate, and the failure to allow for increased government purchases of peanut butter were the primary reaons that the proposed quota was too low.

On December 15, 1988, the Secretary announced that the quota would be the proposed amount, 1,440,000 short tons. That determination was based on the estimates of domestic edible, seed and related uses set out in the November 25, 1988, notice published in the **Federal Register**. The sources of those estimates were set out in that notice and no better figures were offered in the comments. The demand estimates set out in the notice of proposed determination were determined to be the most reliable available at the time of the final determination. The plans for purchases of peanut butter by the government cited by the respondents as a basis for a higher quota are planned purchases that will affect the 1988 crop, rather than the 1989 crop; in addition, the plans for such purchases are subject to change.

Determination

Accordingly, the national poundage quota for 1989-crop peanuts is 1,440,000 short tons.

Authority: 7 U.S.C. 1358.

Signed at Washington, DC on July 3, 1989.

Keith D. Bjerke,

Administrator, Agricultural Stabilization and Conservation Service.

[FR Doc. 89-16119 Filed 7-7-89; 8:45 am]

BILLING CODE 3410-05-M

Commodity Credit Corporation

1989-Crop Peanuts; Program Determinations Regarding National Average Support Levels for Quota and Additional Peanuts and the Minimum Commodity Credit Corporation Export Edible Sales Price for Additional Loan Peanuts

AGENCY: Commodity Credit Corporation.

ACTION: Notice of determinations.

SUMMARY: This notice affirms determinations announced on February 15, 1989, with respect to the following for the 1989 crop of peanuts: (1) The national average level of price support for quota peanuts shall be $615.87 per short ton; (2) the national average level of support for additional peanuts shall be $149.75 per short ton; and (3) the Commodity Credit Corporation (CCC) minimum sales price for export for edible use of 1989-crop additional peanuts which were pledged as collateral for a price support loan shall be $400.00 per short ton.

FOR FURTHER INFORMATION CONTACT: Gypsy Banks, Agricultural Economist, Agricultural Stabilization and Conservation Service, USDA, Room 3732-South Building, P.O. Box 2415, Washington, DC 20013, (202) 447-7477 The final regulatory impact analysis describing the impact of implementing this determination is available upon request from the above-named individual.

SUPPLEMENTARY INFORMATION: This notice of determination has been reviewed under Department of Agriculture (USDA) procedures established to implement Executive Order 12291 and Department Regulation 1512-1 and has been classified "not major. It has been determined that these program provisions will not 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 governments, or geographical regions; or (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.

The title and number of the Federal Assistance Program to which this notice applies are: Title—Commodity Loans and Purchases, Number—10.051, as found in the Catalog of Federal Domestic Assistance.

It has been determined that the Regulatory Flexibility Act is not applicable to this notice since CCC is not required by 5 U.S.C. 553 or any other provision of law to publish a notice of proposed rulemaking with respect to the subject matter of this notice.

Section 1017 of the Food Security Act of 1985 provides that the Secretary of Agriculture shall determine the rate of loans, payments, and purchases under the 1949 Act for the 1986-90 crops of commodities without regard to the requirements for notice and public participation in rulemaking prescribed in section 553 of title 5 of the United States Code or in any directive of the Secretary.

This program/activity is not subject to the provisions of Executive Order 12372 which requires intergovernmental consultation with State and local officials. See the Notice related to 7 CFR Part 3015, Subpart V published at 48 FR 29115 (June 24, 1983).

The announcement of the national average support level for the 1989 crop of quota and additional peanuts was required to be made by the Secretary of Agriculture no later than February 15, 1989.

1. *Quota Peanut Suport Level.* In accordance with Section 108B(1)(B)(ii) of the 1949 Act, the national average price support level for the 1989 crop of quota peanuts must be the corresponding 1988-crop price support level adjusted to reflect any increase in the national average cost of peanut production (excluding any changes in the cost of land) during the calendar year immediately preceding the marketing year for the 1989 crop. Furthermore, the price support level cannot exceed the 1988 crop support level by more than 6 percent. The 1988-crop quota peanut price support level was $615.27 per short ton.

Based on estimates of the Department of Agriculture's Economic Research Service, it was determined that peanut production costs, as calculated in accordance with the statute had increased $0.60 per short ton. The 1989-crop quota peanut price support level will accordingly be $615.87 per short ton.

2. *Additional Peanut Support Level.* Section 108B(2)(A) of the 1949 Act provides that price support shall be made available for additional peanuts at such level as the Secretary finds appropriate taking into consideration the demand for peanut oil and peanut meal, expected prices of other vegetable oils and protein meals, the demand for peanuts in foreign markets, and that will ensure that there are no losses to CCC on the sale or disposal of such peanuts. CCC supports peanuts through loans. Peanuts pledged as collateral for a price support loan are sold to recover the loan and related costs. Peanuts pledged as collateral for price support loans are accounted for by CCC by "pools.

Depending on peanut supply and demand, it is possible that all peanuts in some pools of additional peanuts may be sold for crushing. The estimated average price expected to be received for 1989-crop peanuts sold for domestic crushing is $214 per ton. Expected CCC handling and storage costs are $63 per short ton, a difference of $151 per short ton.

It was determined that the 1989-crop support level for additional peanuts should, accordingly, remain at the 1988-crop price support level of $149.75 per short ton. That price will provide a cushion against higher than expected handling costs or lower than expected market prices.

3. *CCC Minimum Sales Price for Additional Peanuts Sold for Export Edible Use.* The announcement of a minimum price at which additional peanuts pledged for collateral for a price support loan may be sold for use as edible peanuts in export markets is discretionary. That price is announced at the same time that the quota and additional peanut support levels are announced. It is announced to provide information for producers and handlers contracting for the upcoming crop year for the private sale of additional peanuts.

An overly-high price may create an unrealistic expectation of high price support pool dividends and an excess supply of additional peanuts pledged as collateral for price support loans. If too low, the price will reduce pool revenues.

Because of expected world market conditions for the 1989/90 marketing year, it has been determined with respect to additional peanuts pledged as collateral for a price support loan that the minimum sales price for such peanuts of the 1989 crop which are sold for export for edible use should remain at the 1988-crop level of $400 per short ton.

Determinations

Accordingly, the following determinations, announced by the Secretary of Agriculture on February 15, 1989, are affirmed:

(1) The national average level of price support for the 1989 crop of quota

peanuts shall be $615.87 per short ton. This level of price support is applicable to eligible 1989-crop farmers stock peanuts in bulk or in bags, net weight basis.

(2) The national average level of price support for the 1989 crop of additional peanuts shall be $149.75 per short ton. This level of price support is applicable to eligible 1989-crop farmers stock peanuts in bulk or in bags, net weight basis.

(3) The minimum sales price for additional peanuts of the 1989 crop which are sold for export for edible use is $400 per short ton for peanuts: (1) owned by CCC, or (2) which are pledged as collateral for a price support loan made available by CCC.

Authority: 7 U.S.C. §§ 1359, 1445c-2.

Signed at Washington, DC on July 3, 1989.

Keith D. Bjerke,

Executive Vice President, Commodity Credit Corporation.

[FR Doc. 89-16120 Filed 7-7-89; 8:45 am]

BILLING CODE 3410-05-M

Rural Electrification Administration

Dairyland Power Cooperative; Finding of No Significant Impact

AGENCY: Rural Electrification Administration, USDA.

ACTION: Finding of no significant impact.

SUMMARY: Notice is hereby given that the Rural Electrification Administration (REA), pursuant to the National Environmental Policy Act of 1969, as amended (42 U.S.C. 4321 et seq.), the Council on Environmental Quality Regulations (40 CFR Parts 1500-1508), and REA Environmental Policy and Procedures (7 CFR Part 1794), has made a Finding of No Significant Impact (FONSI) with respect to the construction of the Barron-Apple River 161/69 kV transmission line and associated facilities. Associated facilities include the expansion of the Barron and Apple River Substations to provide space to accommodate terminations of the new 161/69 kV line. Also, space will be provided at the Apple River Substation for the addition of a second 161/69 kV 60 MVA transformer in the future. The proposed facilities will be located in Polk and Barron Counties, Wisconsin. The Barron Substation is located about one-half mile south of the City of Barron in Section 33, Township 34 North, Range 12 West in the Barron Township, Barron County. The Apple River Substation is located about 2 miles southwest of the City of Range in Section 2, Township 33 North, Range 16 West in the Lincoln Township, Polk County. The proposed facilities will be built by the Dairyland Power Cooperative (DPC) of La Crosse, Wisconsin.

FOR FURTHER INFORMATION CONTACT: REA's Environmental Assessment (EA) and FONSI and DPC's Borrower's Environmental Report (BER) may be reviewed at the REA, Office of the Director, Northwest Area-Electric, Room 0230, South Agriculture Building, Washington, DC 20250, telephone (202) 382-1400; or at the Office of DPC, Mr. James W Taylor, Manager, P.O. Box 817 La Crosse, Wisconsin 54602-0817 telephone (608) 788-4000, during regular business hours. Copies of the BER, EA and FONSI can be obtained from either of the contacts listed above. All comments or questions should be directed to the REA contact.

SUPPLEMENTARY INFORMATION: REA reviewed the BER submitted by DPC and determined that it represents an accurate assessment of the environmental impacts of the proposed project. The line consists of a 161/69 kV transmission line approximately 43 kilometers (27 miles) in length and associated facilities. Associated facilities include the expansion of the 161 kV bus at Barron Substation into a breaker-and-a-half scheme and expansion of the 161 kV bus at Apple River Substation to accommodate a new 161 kV line. DPC at a future date also intends to install a second 161/69 kV 60 MVA transformer at the Apple River Substation. The BER and EA adequately consider the potential impacts of the proposed project, and REA has concluded that approval of the project would not result in a major Federal action significantly affecting the quality of the human environment. REA determined that the proposed project will have no significant effect on air quality, water quality, floodplains, wetlands, important farmlands, prime rangelands or prime forest lands, Federal or State listed or proposed threatened or endangered species or their critical habitat, or any property listed or eligible for listing in the *National Register of Historic Places.* REA identified no other matters of potential environmental concern related to the proposed project.

Various alternatives to the proposed project were considered including no action, rebuilding the existing Barron to Apple River 69 kV transmission line, energy conservation, local generation, alternative voltage, alternative sources of power, alternative transmission route, and undergound construction. REA determined that the proposed project is an environmentally acceptable alternative that meets DPC's need with a minimum of adverse environmental impact. REA has concluded that project approval would not constitute a major Federal action significantly affecting the quality of the human environment. Therefore, the preparation of an Environmental Impact Statement is not necessary.

In accordance with REA's Environmental Policies and Procedures, 7 CFR Part 1794, DPC advertised in the area newspapers requesting comments on the environmental aspects of the proposed project. DPC also held three meetings in the project areas to solicit public input. All comments were resolved and incorporated in its BER.

This program is listed in the Catalog of Federal Domestic Assistance under No. 10.850—Rural Electrification Loans and Loan Guarantees. For the reasons set forth in the final rule related notice to 7 CFR Part 3015, Subpart V in 50 FR 47034, November 14, 1985, this program is excluded from the scope of Executive Order 12372 which requires intergovernmental consultation with State and local officials.

Date: June 29, 1989.

John H. Arnesen,

Assistant Administrator—Electric.

[FR Doc. 89-16104 Filed 7-7-89; 8:45 am]

BILLING CODE 3410-15-M

Soil Conservation Service

McCoy Wash Watershed, CA; Intent To Prepare Environmental Impact Statement

AGENCY: Soil Conservation Service, USDA.

ACTION: Notice of intent to prepare an Environmental Impact Statement.

SUMMARY: Pursuant to Section 102(2)(C) of the National Environmental Policy Act of 1969; the Council on Environmental Quality Guidelines (40 CFR Part 1500); and the Soil Conservation Service Guidelines (7 CFR Part 650); the Soil Conservation Service, U.S. Department of Agriculture, gives notice that an environmental impact statement is being prepared for the McCoy Wash Watershed, Riverside County, California.

FOR FURTHER INFORMATION CONTACT: Eugene E. Andreuccetti, State Conservationist, Soil Conservation Service, 2121-C Second Street, Davis, California, 95616, telephone (916) 449-2848.

SUPPLEMENTARY INFORMATION: The environmental evaluation of this federally assisted action indicates that the project may cause significant local,

regional, or national impacts on the environment. As a result of these findings, Eugene E. Andreuccetti, State Conservationist, has determined that the preparation and review of an environemtnal impact statement are needed for this project.

The project concerns a plan for flood prevention. Alternatives under consideration include a diversion structure in the upper watershed; a temporary storage structure (dam); channel enlargement, realignment, or consolidation and channel lining. There will be a land use permit and a possible land exchange between the United States Department of the Interior, Bureau of Land and Mangement, and the local flood district.

A draft environmental impact statement will be prepared and circulated for review by agencies and the public. The Soil Conservation Service invites participation and consultation of agencies and individuals that have special expertise, legal jurisdication or interest in the preparation of the draft environmental impact statemnt. Further information on the proposed action or future meetings may be obtained from Eugene E. Andreauccetti, State Conservationist, at the above address or telephone (916) 449-2848.

(This activity is listed in the Catalog of Federal Domestic Assistance Under No. 10.904—Watershed Protection and Flood Prevention—and is subject to the provisions of Executive Order 12372 which requires intergovernmental consultation with State and local officials.)

Eugene E. Andreauccetti,

State Conservationist.

[FR Doc. 89-16044 Filed 7-7-89; 8:45 am]

BILLING CODE 3410-16-M

DEPARTMENT OF COMMERCE

International Trade Administration

Performance Review Board Membership

This notice announces the appointment by the Department of Commerce Under Secretary for International Trade, J. Michael Farren, of the Performance Review Board. This is a revised list of membership which includes previous members as listed in the August 3, 1988, Federal Register Announcement (52 FR 29248) with additional members added to serve a two year term. The purpose of the International Trade Administration's PRB is to review and make recommendations to the appointing authority on performance recommendations and other issues concerning members of the Senior Executive Service (SES). The members of the PRB are:

Maureen R. Smith, Deputy Assistant Secretary for Japan, International Economic Policy

Joseph Spetrini, Deputy Assistant Secretary for Compliance, Import Administration

Saul Padwo, Director, Office of Trade Promotion, U.S. & Foreign Commercial Service

Marilyn Wagner, Assistant General Counsel for Administration

James C. Lake, Director, Office of Planning and Coordination, Trade Development

Jonathan C. Menes, Director, Office of Industry Assessment, Trade Development

Donald N. De Marino, Deputy Assistant Secretary for Africa, Near East, South Asia, International Economic Policy

Dated: June 29, 1989.

James T. King, Jr.,

Personnel Officer, ITA.

[FR Doc. 89-16115 Filed 7-7-89; 8:45 am]

BILLING CODE 3510-25-M

National Oceanic and Atmospheric Administration

Coastal Zone Management; Federal Consistency Appeal by Exxon Company, USA From an Objection by the New Jersey Department of Environmental Protection

AGENCY: National Oceanic and Atmospheric Administration, Commerce.

ACTION: Notice of decision.

SUMMARY: Exxon Company, USA (Appellant) proposes to construct an automobile service station on a 1.068 acre parcel near Barnegat Bay in Dover Township, Ocean County, New Jersey. Construction of the service station according to the Appellant's design would necessitate the filling of approximately 5,660 square feet of wetlands on the lot. Accordingly, in 1986, the Appellant applied to the U.S. Army Corps of Engineers (Corps) for a permit to fill the wetlands with sand. In conjunction with that Federal permit application, the Appellant submitted to the Corps a consistency certification for the proposed activity for the State of New Jersey's (State) review under Section 307 (c)(3)(A) of the Coastal Zone Management Act of 1982, as amended (CZMA), 16 U.S.C. 1456(c)(3)(A).

In December, 1986, the State objected to the Appellant's consistency certification for the proposed project on the ground that it violates the State Coastal Management Program's prohibition of the filling of wetlands. Pursuant to the CZMA and its implementing regulations, see 15 CFR 930.131 (1988), the State's consistency objection precludes the Corps from issuing any permit or license necessary for the Appellant's proposed activity unless the Secretary of Commerce (Secretary) determines that the activity may be federally approved, notwithstanding the State's objection, because the activity is either (1) consistent with the objectives or purposes of the CZMA (Ground I), or (2) necessary in the interest of national security (Ground II). If the requirements of either Ground I or Ground II are met, the Secretary must overide the State's objection.

In January, 1987 in accordance with CZMA Section 307(c)(3)(A) and 15 CFR Part 930, Subpart H (1988), counsel for the Appellant filed with the Secretary a notice of appeal from the State's objection to the Appellant's consistency certification for the proposed project. The Appellant based its appeal on Ground I. Upon consideration of the information submitted by the Appellant, the State and several Federal agencies, the Under Secretary for Oceans and Atmosphere found, pursuant to 15 CFR 930.121 (1988), that the proposed filling of wetlands to construct the service station does not further the objectives or purposes of the CZMA. Accordingly, the requriements of Ground I are not met, and the Under Secretary, therefore, will not override the State's objection to the Appellant's consistency certification. This decision precludes the Corps and other Federal agencies from issuing any permits for the Appellant's proposed project.

FOR ADDITIONAL INFORMATION CONTACT: Katherine A. Pease, Assistant General Counsel for Ocean Services, National Oceanic and Atmospheric Administration, U.S. Department of Commerce, 1825 Connecticut Avenue, NW Suite 603, Washington, DC 20235, (202) 673-5200.

Date: June 30, 1989.

B. Kent Burton,

Assistant Secretary for Oceans and Atmosphere.

[Federal Domestic Assistance Catalog No. 11.419 Coastal Zone Management Program Assistance]

[FR Doc. 89-16113 Filed 7-7-89; 8:45 am]

BILLING CODE 3510-08-M

Western Pacific Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service, NOAA, Commerce.

The Western Pacific Fishery Management Council will hold its 45th Scientific and Statistical Committee (SSC) meeting on July 20–21, 1989, at 9 a.m., at the National Marine Fisheries Service, Honolulu Laboratory Conference/Seminar Rooms, 2570 Dole Street, Honolulu, HI.

The SSC will review the status of programmatic projects in support of fishery management plans (FMPs) for bottomfish, crustaceans, precious corals, and pelagic species. The Committee will also review reports of the Plan Monitoring Team for each FMP and formulate recommendations for the Council. In particular, the SSC will: (1) Review a draft document outlining the Council's program for 1990–1995; (2) review the revised guidelines for National Standards 1 and 2; (3) review the status of the Fishing Rights for Indigenous People and Limited Entry Project; (4) review the status of annual reports for pelagics, bottomfish, and crustaceans, and (5) discuss reauthorization of the Magnuson Fishery Conservation and Management Act.

For further information contact Kitty M. Simonds, Executive Director, Western Pacific Fishery Management Council, 1164 Bishop Street, Suite 1405, Honolulu, HI 96813; telephone: (808) 532–1368.

Date: July 3, 1989.

Richard H. Schaefer,

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

[FR Doc. 89–16110 Filed 7–7–89; 8:45 am]

BILLING CODE 3510-22-M

Western Pacific Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service, NOAA, Commerce.

The Western Pacific Fishery Management Council and its Standing Committees will hold public meetings on July 24–26, 1989, at the Turtle Bay Hilton Hotel, Kahuku, HI. The Council will begin meeting on July 25 and 26 at 9 a.m. The Council's Standing Committees will meet on July 24 at 9 a.m.

At its 66th meeting, the Council will hear routine fisheries reports from state, territorial, and federal governments' representatives on the Council, as well as from private sector Council members from Hawaii, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands (CNMI). The status of fishery management plans (FMPs) covering crustaceans, bottom fish and seamount groundfish, pelagics, and precious corals will also be discussed. The Council will adopt a program for 1990–1995.

The Council will review the: (1) 1988 annual report for crustaceans; (2) 1988 annual report for bottomfish; (3) first and second annual reports for pelagics; (4) Fishing Rights of Indigenous People and Limited Entry Projects for American Samoa, Guam, and the CNMI; (5) Congressional hearings on reauthorization of the Magnuson Fishery Conservation and Act; (6) status of the North and South Pacific foreign drift gillnet fishing situations, and (7) general administrative matters, including review of the Council's Statement of Organization, Practices and Procedures, and other routine Council business.

For further information contact Kitty M. Simonds, Executive Director, Western Pacific Fishery Management Council, 1164 Bishop Street, Suite 1405, Honolulu, HI 96813; telephone: (808) 532–1368.

Date: July 3, 1989.

Richard H. Schaefer,

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

[FR Doc. 89–16111 Filed 6–7–89; 8:45 am]

BILLING CODE 3510-22-M

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

Adjustment of Import Limits for Certain Cotton, Man-Made Fiber, Silk Blend and Other Vegetable Fiber Textiles and Textile Products Produced or Manufactured in India

June 30, 1989.

AGENCY: Committee for the Implementation of Textile Agreements (CITA).

ACTION: Issuing a directive to the Commissioner of Customs adjusting limits.

EFFECTIVE DATE: July 11, 1989.

FOR FURTHER INFORMATION CONTACT: Jennifer Tallarico, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 377–4212. For information on the quota status of these limits, refer to the Quota Status Reports posted on the bulletin boards of each Customs port or call (202) 343–6494. For information on embargoes and quota re-openings, call (202) 377–3715.

SUPPLEMENTARY INFORMATION:

Authority: Executive Order 11651 of March 3, 1972, as amended; Section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854).

The current limits for Group II and certain categories in Groups I and II are being adjusted, variously, for swing, carryover, carryforward, carryforward used and special allowance provided for under the agreement for 100 percent cotton garments made from handloomed fabrics.

A description of the textile and apparel categories in terms of HTS numbers is available in the CORRELATION: Textile and Apparel Categories with the Harmonized Tariff Schedule of the United States (see **Federal Register** notice 53 FR 44937 published on November 7 1988). Also see 54 FR 50071, published on December 13, 1988.

The letter to the Commissioner of Customs and the actions taken pursuant to it are not designed to implement all of the provisions of the bilateral agreement, but are designed to assist only in the implementation of certain of its provisions.

Auggie D. Tantillo,

Chairman, Committee for the Implementation of Textile Agreements.

Committee for the Implementation of Textile Agreements

June 30, 1989

Commissioner of Customs,
Department of the Treasury, Washington, DC 20229

Dear Mr. Commissioner: This directive amends, but does not cancel, the directive of December 8, 1988, as amended, from the Chairman, Committee for the Implementation of Textile Agreements. That directive establishes restraint limits for certain cotton, man-made fiber, silk blend and other vegetable fiber textiles and textile products, produced or manufactured in India and exported during the twelve-months period which began on January 1, 1989 and extends through December 31, 1989.

Effective on July 11, 1989, you are directed to amend further the December 8, 1988 directive to include the following adjusted limits, as provided under the terms of the current bilateral textile agreements between the Governments of the United States and India:

Category	Adjusted twelve-month limit
Levels in Group I:	
218	7,885,500 square meters
219	30,621,811 square meters
313	21,609,525 square meters
314	4,855,937 square meters
315	8,782,861 square meters
335	206,623 dozen
336/636	535,492 dozen
338/339/340	1,391,651 dozen
341	3,017,128 dozen of which, not more than 1,720,292 dozen shall be in Category 341-Y
342	495,444 dozen
347/348	343,247 dozen
363	25,416,780 numbers
Group II:	
200, 201, 220-229, 237, 239, 300/301, 317, 326, 330-334, 345, 349-352, 359-362, 369-0 369-S 600-607, 611-635, 638-652, 659, 665pt. 666-679 and 831-859, as a group.	102,617,030 square meters equivalent
Sublevels in Group II:	
237	104,476 dozen
369-S	379,839 kilograms
640	158,795 dozen
641	939,468 dozen
642	285,491 dozen

The limits have not been adjusted to account for any imports exported after December 31, 1988.

In Category 341-Y, only HTs numbers 6204.22.3060, 6206.30.3010 and 6206.30.3030.

In Category 369-0, all HTS numbers except 6307.10.2005 in Category 369-S; 6302.60.0010 and 6302.91.0020 in Category 369-D; and rugs exempt from the bilateral agreement in HTS numbers 5702.10.9020, 5702.49.1010 and 5702.99.1010.

In Category 369-S, only HTS number 6307.10.2005.

In Category 665pt., and HTS numbers except rugs exempt from the bilateral agreement in HTS number 5702.10.9030, 5702.42.2010, 5702.92.0010 and 5703.20.1000.

The Committee for the Implementation of Textile Agreements has determined that these actions fall within the foreign affairs exception to the rulemaking provisions of 5 U.S.C. 553(a)(1).

Sincerely,

Auggie D. Tantillo,

Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 89-16103 Filed 7-7-89; 8:45 am]

BILLING CODE 3510-DR-M

Adjustment of Import Limits for Certain Man-Made Fiber Textile Products Produced or Manufactured in the Philippines

June 30, 1989.

AGENCY: Committee for the Implementation of Textile Agreements (CITA).

ACTION: Issuing a directive to the Commissioner of Customs adjusting limits.

EFFECTIVE DATE: July 11, 1989.

FOR FURTHER INFORMATION CONTACT: Kimbang Pham, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 377-4212. For information on the quota status of these limits, refer to the Quota Status Reports posted on the bulletin boards of each Customs port or call (202) 535-6735. For information on embargoes and quota re-openings, call (202) 377-3715.

SUPPLEMENTARY INFORMATION:

Authority: Executive Order 11651 of March 3, 1972, as amended; Section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854).

The current limit for Category 633 is being increased by application of special shift, reducing the limit for Category 634.

A description of the textile and apparel categories in terms of HTS numbers is available in the CORRELATION: Textile and Apparel Categories with the Harmonized Tariff Schedule of the United States (see **Federal Register** notice 53 FR 44937 published on November 7 1988). Also see 53 FR 49343, published on December 7 1988.

The letter to the Commissioner of Customs and the actions taken pursuant to it are not designed to implement all of the provisions of the bilateral agreement, but are designed to assist only in the implementation of certain of its provisions.

Auggie D. Tantillo,

Chairman, Committee for the Implementation of Textile Agreements.

Committee for the Implementation of Textile Agreements

June 30, 1989.

Commissioner of Customs,

Department of the Treasury, Washington, DC 20229

Dear Mr. Commissioner: This directive amends, but does not cancel, the directive issued to you on December 2, 1988 by the Chairman, Committee for the Implementation of Textile Agreements. That directive concerns imports of certain cotton, wool, man-made fiber, silk blend and other vegetable fiber textiles and textile products, produced or manufactured in the Philippines and exported during the period which began on January 1, 1989 and extends through December 31, 1989.

Effective on July 11, 1989, the directive of December 2, 1988 is being amended to adjust the limits for the following categories, under the terms of the current bilateral textile agreement between the Governments of the United States and the Philippines:

Category	Twelve-month limit
Levels in Group I:	
633	26,865 dozen
634	241,628 dozen

The limits have not been adjusted to account for any imports exported after December 31, 1988.

The Committee for the Implementation of Textile Agreements has determined that these actions fall within the foreign affairs exception to the rulemaking provisions of 5 U.S.C. 553(a)(1).

Sincerely,

Auggie D. Tantillo,

Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 89-16102 Filed 7-7-89; 8:45 am]

BILLING CODE 3510-DR-M

COMMITTEE FOR PURCHASE FROM THE BLIND AND OTHER SEVERELY HANDICAPPED

Procurement List 1989; Addition

AGENCY: Committee for Purchase from the Blind and Other Severely Handicapped.

ACTION: Additions to procurement list.

SUMMARY: This action adds to Procurement List 1989 a service to be provided by workshops for the blind or other severely handicapped.

EFFECTIVE DATE: August 8, 1989.

ADDRESSES: Committee for Purchase from the Blind and Other Severely Handicapped, Crystal Square 5, Suite 1107 1755 Jefferson Davis Highway, Arlington, Virginia 22202-3509.

FOR FURTHER INFORMATION CONTACT: Beverly Milkman (703) 557-1145.

SUPPLEMENTARY INFORMATION: On May 5, 1989, the Committee for Purchase from the Blind and Other Severely Handicapped published notice (54 FR 19429) of proposed addition to Procurement List 1989, which was published on November 15, 1988 (53 FR 46018).

No comments were received concerning the proposed addition to the Procurement List. After consideration of the material presented to it concerning capability of qualified workshops to provide the service at fair market prices and impact of the addition on the current or most recent contractors, the Committee has determined that the service listed below is suitable for procurement by the Federal Government under 41 U.S.C. 46-48c and 41 CFR 1-2.6.

I Certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

a. The action will not result in any additional reporting, recordkeeping or other compliance requirements.

b. The action will not have a serious economic impact on any contractors for the service listed.

c. The action will result in authorizing small entities to provide the service procured by the Government.

Accordingly, the following service is hereby added to Procurement List 1989: Janitorial/Custodial for the following locations in Rssellville, Arkansas:

Federal Building, 115 South Denver Street

Henry R. Koen Federal Building, W Main and Fargo Street

Beverly L. Milkman,

Executive Director.

[FR Doc. 89-16116 Filed 7-7-89; 8:45 am]

BILLING CODE 6820-33-M

Procurement List 1989; Proposed Additions

AGENCY: Committee for Purchase from the Blind and Other Severely Handicapped.

ACTION: Proposed additions to procurement list.

SUMMARY: The Committee has received proposals to add to Procurement List 1989 commodities to be produced by workshops for the blind or other severely handicapped.

Comments Must Be Received on or Before: August 8, 1989.

ADDRESSES: Committee for Purchase from the Blind and Other Severely Handicapped, Crystal Square 5, Suite 1107 1755 Jefferson Davis Highway, Arlington, Virginia 22202-3509.

FOR FURTHER INFORMATION CONTACT: Beverly Milkman (703) 557-1145.

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 47(a)(2) and 41 CFR 51-2.6. Its purpose is to provide interested persons an opportunity to submit comments on the possible impact of the proposed actions.

If the Committee approves the proposed additions, all entities of the Federal Government will be required to produce the commodities listed below from workshops for the blind or other severely handicapped.

It is proposed to add the following commodities to Procurement List 1989, which was published on November 15, 1988 (53 FR 46018):

Strap Assembly, Webbing
2540-00-894-9545

Correction Fluid
7510-01-020-2806

Solvent, Correction Fluid
7510-01-013-9215

Beverly L. Milkman,

Executive Director.

[FR Doc. 89-16117 Filed 7-7-89; 8:45 am]

BILLING CODE 6820-33-M

DEPARTMENT OF DEFENSE

Department of the Navy

Federal Information Processing Standards (FIPS)

ACTION: Notice of FIPS waivers.

SUMMARY: Notice is hereby given that, pursuant to a delegation of authority by the Department of Commerce and a redelegation of authority by the Department of Defense, the Department of the Navy has granted waivers from FIPS 60-2, 61-1, 62, 63-1, and 97 (Input/Output Standards) and FIPS 146 (Government Open Systems Interconnection Profile) for an expansion and technology upgrade of computer systems supporting the Navy Headquarters Budgeting System (NHBS) at the Pentagon and other locations. These waivers were necessary because compliance with the FIPS would cause a major adverse financial impact on the operator of the NHBS which is not offset by Government-wide savings, and would adversely affect the accomplishment of the mission of the operator of the NHBS.

FOR FURTHER INFORMATION CONTACT: Dr. James L. Raney, Office of the Director, Department of the Navy Information Resources Management, Washington, DC 20350-1000, telephone (202) 697-7216.

Date: July 5, 1989.

Sandra M. Kay,

Department of the Navy, Alternate Federal Register Liaison Officer.

[FR Doc. 89-16058 Filed 7-7-89; 8:45 am]

BILLING CODE 3810-AE-M

DEPARTMENT OF EDUCATION

Indian Education National Advisory Council; Meeting

AGENCY: National Advisory Council on Indian Education.

ACTION: Notice of meeting.

SUMMARY: This notice sets forth the schedule and proposed agenda of a forthcoming meeting of the Executive Committee of the National Advisory Council on Indian Education. This notice also describes the functions of the Council. Notice of this meeting is required under section 10(a)(2) of the Federal Advisory Commitee Act.

DATES: July 17-18, 1989, 9:00 a.m. until conclusion of business each day.

ADDRESS: Summer House Inn, 7955 La Jolla Shores Drive, La Jolla, California 619/459-0261.

FOR FURTHER INFORMATION CONTACT: Jo Jo Hunt, Executive Director, National Advisory Council on Indian Education, 330 C Street, SW Room 4072, Switzer Building Washington, DC 20202-7556 (212/732-1353).

SUPPLEMENTARY INFORMATION: The National Advisory Council on Indian Education is established under section 5342 of the Indian Education Act of 1988 (25 U.S.C. 2642). The Council is established to, among other things, assist the Secretary of Education in carrying out responsibilities under the Indian Education Act of 1988 (Part C, Title V Public Law 100-297) and to advise Congress and the Secretary of Education with regard to federal education programs in which Indian children or adults participate or from which they can benefit.

The Executive Committee of the Council will meet starting at approximately 9:00 a.m. and will end at the conclusion of business each day at approximately 5:00 p.m. The meeting is open to the public. The agenda includes reports by the Chairman and Executive Director; a review of the updated NACIE Handbook; a planning session for the agenda of the Full Council Meeting to be scheduled in October 1989 in conjunction with the meeting of the National Indian Education Association in Anchorage, Alaska, and planning of any site visits in Alaska; discussion of the staff evaluation process; and approval of the 1990 revised budget proposal and the 1991 proposed budget for the Council.

The public is being given less than 15 days notice due to scheduling problems and delay in permission for an out-of-town meeting.

Date: July 3, 1989. Signed at Washington, DC.

Jo Jo Hunt,

Executive Director, National Advisory Council on Indian Education.

[FR Doc. 89-16033 Filed 7-7-89; 8:45 am]

BILLING CODE 4000-01-M

DEPARTMENT OF ENERGY

Office of the Assistant Secretary for International Affairs and Energy Emergencies

Proposed Subsequent Arrangement Between the United States and Canada

Pursuant to section 131 of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2160), notice is hereby given of a proposed "subsequent arrangement" under the Agreement for Cooperation between the Government of the United States of America and the Government of Canada concerning Civil Uses of Atomic Energy, as amended.

The subsequent arrangement to be carried out under the above-mentioned agreement involves the agreement between the Government of the United States of America and the Government of Canada to the reprocessing of irradiated fuel rods from the NRU research reactor in Canada for the purpose of radioisotope recovery for commercial sale. The recovered uranium and associated transuranic products, including plutonium will be recovered for subsequent return to the United States of America for storage and reprocessing. Approximately 10 fuel rods are to by processed each year. Each fuel rod contains approximately 200 grams of uranium, enriched to 50 percent in the isotope uranium-235, and 0.5 grams of plutonium.

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 and after fifteen days of continuous session of the Congress, beginning the day after the date on which the reports required by section 131(b)(1) of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2160) are submitted to the Committee on Foreign Affairs of the House of Representatives and the Committee on Foreign Relations of the Senate. The two time periods referred to above shall run concurrently.

For the Department of Energy.

Date: July 5, 1989.

Richard W. Williamson,

Deputy Assistant Secretary for International Affairs.

[FR Doc. 89-16121 Filed 7-7-89; 8:45 am]

BILLING CODE 6450-01-M

Federal Energy Regulatory Commission

[Docket No. RP84-13-005 et al.]

Michigan Consolidated Gas Co., et al., Filing of Pipeline Refund Reports

June 30, 1989.

Take notice that the pipelines listed in the Appendix hereto have submitted to the Commission for filing proposed refund reports. The date of filing and docket number are also shown on the Appendix.

Any person wishing to do so may submit comments in writing concerning the subject refund reports. All such comments should be filed with or mailed to the Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, DC 20426, on or before July 20, 1989. Copies of the respective filings are on file with the Commission and available for public inspection.

Lois D. Cashell,

Secretary.

Filing date	Company	Docket No.
6/2/89	Michigan Consolidated Gas Company.	RP84-13-005
6/9/89	Columbia Gas Transmission Corp..	RP78-20-027
6/12/89	Transcontinental Gas Pipe Line Corporation.	RP87-7-054
6/19/89	Northwest Pipeline Corporation.	RP72-154-018
6/26/89	Texas Eastern Transmission Corporation.	RP74-41-045.

[FR Doc. 89-16118 Filed 7-7-89; 8:45 am]

BILLING CODE 6717-01-M

Southwestern Power Administration

Initial Town Bluff Dam Power Rate; Order Confirming, Approving, and Placing Initial Town Bluff Dam Power Rate in Effect on an Interim Basis

AGENCY: Southwestern Power Administration, Department of Energy.

ACTION: Notice of Power Rate Order.

SUMMARY: The Deputy Secretary of Energy, acting under Delegation Order No. 0204-108, as amended, has confirmed, approved and placed in effect on an interim basis, an initial annual power rate of $373,068 for the sale of power and energy by the Southwestern Power Administration (SWPA) from Town Bluff Dam to the Sam Rayburn Municipal Power Agency (SRMA). This rate is the first to be effective for this isolated project and provides for recovery of all annual operating costs, as well as expected future capital additions or replacements. The rate has no original investment amortization component since all design and construction costs were financed by the non-Federal sponsor of the project, SRMA, which has, in essence, prepaid this element in return for receipt of the project's entire output for a period of 50 years.

EFFECTIVE DATES: Rate Order No. SWPA-22 specifies the date of commercial operation (expected about July 1, 1989) through September 30, 1993,

as the effective period of the initial annual rate of $373,068 for the sale of power and energy from Town Bluff Dam.

FOR FURTHER INFORMATION CONTACT: Francis R. Gajan, Director, Power Marketing, Southwestern Power Administration, Department of Energy, P.O. Box 1619, Tulsa, Oklahoma 74101, (918) 581-7529.

SUPPLEMENTARY INFORMATION: The SWPA Administrator has prepared a 1989 Town Bluff Dam Revised Initial Power Repayment Study based on an annual power rate of $373,068, beginning about July 1, 1989 (the expected date of commercial operation). The study indicates that this initial power rate is adequate to satisfy cost recovery criteria for the sale of power and energy from Town Bluff Dam to Sam Rayburn Municipal Power Agency under Contract No. DE-PM75-85SW00117 and will satisfy the provisions of section 5 of the Flood Control Act of 1944 and Department of Energy Order No. RA 6120.2. In this regard, the Administrator has determined that the initial annual rate of $373,068 is the lowest possible rate to the customer consistent with sound business principles. The rate has been approved on an interim basis through September 30, 1993, or until confirmed and approved on a final basis by the FERC.

Issued in Washington, DC, this 28th day of June 1989.

W. Henson Moore,

Deputy Secretary.

[Rate Order No. SWPA-22]

Order Confirming, Approving and Placing Initial Power Rate in Effect on an Interim Basis

In the matter of: Southwestern Power Administration—Town Bluff Dam Rate.

Pursuant to Sections 302(a) and 301(b) of the Department of Energy Organization Act, Public Law 95-91, the functions of the Secretary of the Interior and the Federal Power Commission under Section 5 of the Flood Control Act of 1944, 16 U.S.C. 825s, for the Southwestern Power Administration were transferred to and vested in the Secretary of Energy. By Delegation Order No. 0204-33, effective January 1, 1979, 43 FR 60636 (December 28, 1978), the Secretary of Energy delegated to the Assistant Secretary for Resource Applications the authority to develop power and transmission rates, acting by and through the Administrator, and to confirm, approve and place into effect such rates on an interim basis, and delegated to the Federal Energy Regulatory Commission the authority to confirm and approve on a final basis or to disapprove rates developed by the Assistant under the Delegation. Due to a Department of Energy organizational realignment, Delegation Order No. 0204-33 was amended, effective March 19, 1981, to transfer the authority of the Assistant Secretary for Resource Applications to the Assistant Secretary for Conservation and Renewable Energy. By Delegation Order No. 0204-108, effective December 14, 1983, 48 FR 55664 (December 14, 1983) the Secretary of Energy delegated to the Deputy Secretary of Energy on a non-exclusive basis the authority to confirm, approve and place into effect on an interim basis power and transmission rates, and delegated to the Federal Energy Regulatory Commission on an exclusive basis the authority to confirm, approve and place in effect power and transmission rates on a final basis. Amendment No. 1 to Delegation Order No. 0204-108, effective May 30, 1986, 51 FR 19744 (May 30, 1986), revised the delegation of authority to confirm, approve and place into effect on an interim basis power and transmission rates by delegating such authority to the Under Secretary of Energy rather than the Deputy Secretary of Energy. However, on October 27 1988, the Secretary of Energy issued a notice (DOE N 1110.29) which has the effect of amending Delegation Order No. 0204-108 by transferring the authority to place rates into effect on an interim basis from the Under Secretary of the Department of Energy to the Deputy Secretary of the Department of Energy. This rate order is issued pursuant to the amended Delegation Order to the Deputy Secretary of Energy.

Background

The Town Bluff project is located on the Neches River in eastern Texas downstream from the Sam Rayburn Dam, was originally constructed in 1951 by the U.S. Army Corps of Engineers (Corps) and, now, primarily provides streamflow regulation of releases from the Sam Rayburn Dam. The Lower Neches Valley Authority (LNVA) contributed funds toward construction of both projects and makes established annual payments for the right to withdraw up to 2000 cubic feet of water per second from Town Bluff for its own use. Power was legislatively authorized at the project, but installation of hydroelectric facilities was deferred until justified by economic conditions. A determination of feasibility was made in a 1982 Corps study. In 1983, the SRMA proposed to sponsor the development of hydropower at Town Bluff in return for the output of the project to be delivered to its member municipalities; Jasper, Liberty and Livingston, Texas and Vinton, Louisiana, as well as, the participating member cooperatives of the Sam Rayburn Dam Electric Cooperative, of which the SRMA municipals are also members and through which they receive a portion of the power produced at the Sam Rayburn Dam. SRMA provided non-Federal funds for the entire design and construction of the project which was performed by the Corps at a cost of approximately $18 million. SRMA will pay all annual operating and marketing costs, as well as expected capital replacement costs, through the rate paid to the SWPA, and will receive all power and energy produced at the project for a period of 50 years from the commercial on-line date.

The 1989 Town Bluff Dam Revised Initial Power Repayment Study indicates that an annual rate of $373,068 will be required beginning on the date the project's generators are declared in commercial operation, to recover annual costs of marketing and operation and maintenance (O&M), and to repay the isolated project's investment in additions or replacements in accordance with Department of Energy Order No. RA 6120.2 and Section 5 of the Flood Control Act of 1944. The proposed rate is classified as a minor rate adjustment in accordance with Title 10, Part 903, Subpart A of the code of Federal Regulations (10 CFR Part 903), "Procedures for Public Participation in Power and Transmission Rate Adjustments and Extensions" (50 FR 37837), since it is for establishment of a rate for a new service from a power system with an installed capacity of less than 20 MW.

SWPA published Notice in the **Federal Register** April 6, 1989, announcing a 30-day period for public review and comment concerning a proposed annual rate of $285,444 as required by 10 CFR 903. By letter dated April 11, 1989, SWPA provided a copy of the **Federal Register** Notice and supporting data for the 1989 Power Repayment Study to the customer for information and review. The letter also confirmed a meeting among SRMA, SWPA and the Corps which was held on April 20, 1989, to discuss the rate proposal, among other things. At the meeting, the Corps provided new and more detailed information which significantly increased their previous estimates of annual O&M costs. Further, the Corps indicated that the commercial on-line date for the project would be delayed until about July 1, 1989, rather than June 1 as expected earlier. In accordance with 10 CFR 903.18, SWPA extended the initial comment period by 15 days to announce a revised proposed rate of $373,068 annually, made necessary by the new O&M estimates and on-line date. By letter dated May 5, 1989, SWPA provided a preliminary copy of the **Federal Register** Notice, which was published on May 19, 1989 (54 FR 21929), and a 1989 Revised Initial Power Repayment Study with supporting data to the customer for review and comment. Written comments from the customer and interested parties were accepted through May 23, 1989; and are contained along with SWPA's responses in the Comments and Responses Section of this Rate Order.

Discussion

The 1989 Revised Initial Power Repayment Study tests the adequacy of the revised proposed initial rate based on a cost evaluation period extending from initial commercial operation in FY 1989 through FY 1993, to cover annual expenses for marketing, operation and maintenance, and to amortize additions to plant and major replacement of the generating facilities. Since the project's design and construction were financed in their entirety by the non-Federal sponsor, SRMA, no component for amortization of the original investment of some $18 million is included in the rate determination. The Power Repayment Study is, therefore, presented somewhat differently than normal, and illustrates the collection of revenues in advance of their need for repayment of future replacement investments. Revenues in excess of current year expenses are accumulated as

surpluses, accruing an interest credit as provided by DOE Order RA 6120.2 and Corps accounting procedures, awaiting their use to cover replacement costs as they occur. The original estimates of future project replacements were provided by the Corps in their December 6, 1988, letter to SWPA and were based on 1988 cost data. The 1988 cost estimates were escalated to FY 1989 cost levels by SWPA using "The Handy-Whitman Index of Public Utility Construction Costs" for use in the revised Study and adjusted to show FY 1990 as the first full year of commercial operation instead of FY 1989. The 1989 Initial Power Repayment Study estimated project replacements totaling $1,138,200 for the period FY 1989 through FY 2039. The 1989 Revised Initial Power Repayment Study estimates replacements totaling $1,107,800 for the period.

By letter dated December 6, 1988, the Corps originally provided estimates of Town Bluff Dam O&M expense for the 1989 Initial Power Repayment Study based on FY 1989 cost levels. SWPA adjusted those projections for inflation using Gross National Product Deflators for FY 1990 through FY 1993. The original estimates of Corps O&M expense for the 1989 Initial Power Repayment Study varied from $76,700 in FY 1989 (4 months) to a maximum inflation-adjusted O&M expense figure of $258,100 for FY 1993, which was extended through the end of the repayment period in FY 2039. Based on a more detailed analysis of costs, the Corps provided new estimates of O&M expense by letter dated April 27 1989. The more detailed analysis included a number of assumptions about the costs of operating and maintaining the Town Bluff project in conjunction with the Sam Rayburn Dam project immediately upstream. Town Bluff hydropower will be operated and maintained from Sam Rayburn Dam with the addition of only a few maintenance staff rather than having its own full complement of operators, superintendent, maintenance and clerical support. In developing the estimated O&M costs for Town Bluff, the Corps assumed the operators' time and labor costs would be shared equally (50/50) between Sam Rayburn and Town Bluff, while two man-years of labor would be necessary to maintain Town Bluff. Supervisory and clerical staff would spend one-fourth and one-eight of their time, respectively, on Town Bluff work. Further, about 45 percent of the supervisor's time assigned to Town Bluff (25 percent of time) is assumed to relate to operations while 55 percent relates to maintenance. Clerical support assigned to Town Bluff (12.5 percent of time) is assumed to relate 50 percent to operations and 50 percent to maintenance. Until some actual experience in these areas is obtained and a detailed efforts analysis can be made, these assumptions appear reasonable. The assumptions utilized produce an end result that about 60 percent of the total cost of operations (as distinct from maintenance) of the two projects is assigned to Sam Rayburn Dam and about 40 percent to Town Bluff. The resulting estimates of O&M for Town Bluff were used for the 1989 Revised Initial Power Repayment Study and vary from $94,587 in FY 1989 (3 months) to a maximum inflation-adjusted O&M expense figure of $346,124 for FY 1993 and thereafter.

Estimates of General Administrative and Overhead (GA&O) expense for both the 1989 Initial and Revised Initial Power Repayment Studies were based on SWPA's FY 1989 Department of Energy Internal Review Budget for FY 1989–1993. The FY 1993 amount is used for each subsequent year of the Power Repayment Study. GA&O Expense is assigned to isolated projects, including both the Town Bluff and the Sam Rayburn Dam projects, based on the capital investment in the Southwestern Federal Power System (SWFPS) excluding transmission investment, as a percentage of total capital investment in the SWFPS, and the installed hydroelectric capacity of the project as a percent of the total installed hydroelectric capacity in the SWFPS. A five year average (FY 1984–FY 1988) of actual Transmission and GA&O Expense for the SWFPS indicates that GA&O Expense comprises 45.6 percent and Transmission Expense 54.4 percent of the total Transmission and GA&O Expense. Transmission Expense is not chargeable to the Town Bluff Dam project. The project was expected to have 6 MW of installed capacity (two 3 MW generators) according to the Corps' plan for development of the most economical project. However, during construction, a decision was made to substitute two 4 MW units for the two 3 MW units originally planned, based on "off-the-shelf" availability at no more than an equivalent price. Consequently, 8 MW of installed capacity was used instead of 6 MW in the assignment of GA&O costs to the project in both the Initial and Revised Initial Power Repayment Studies. The 1989 Initial Power Repayment Study estimated GA&O expense assignable to the Town Bluff Dam Project to be $6,500 in FY 1989 (4 months), while the 1989 Revised Initial Power Repayment Study estimates the GA&O expense to be $4,900 for FY 1989 (3 months). Both the Initial and Revised Initial Studies show the assignable GA&O costs to increase to $21,800 in FY 1993, which was carried through the end of the repayment period.

Comments & Responses

The Southwestern Power Administration received two written replies by letters dated May 4 and May 22, 1989, both from the customer, SRMA, concerning the Notices published in the Federal Register April 6, 1989, and May 19, 1989, which announced the proposed and revised proposed Town Bluff Dam power rates respectively, scheduled for implementation upon commercial operation of the project. A summary of the four major comments and SWPA's responses to those comments follows:

Use of 6 MW Vs. 8 MW Installed Capacity to Assign GA&O

Comment: SRMA believes it would be inequitable to utilize 8 MW based on the installed capacity of units not originally designed for the project to assign SWPA General Administration and Overhead (GA&O) costs to the Town Bluff Dam in the Power Repayment Study, if the units are in fact able to produce only 6 MW, or some other rating. Since the actual capacity will soon be determined during testing, SRMA suggests the 6 MW contemplated in the power sales contract be used in the initial rate to assign GA&O costs.

Response: SWPA agrees that the correct capacity quantity should be used to establish the GA&O assignment to Town Bluff and that testing will soon determine whether each unit is able to produce the rated 4 MW of installed capacity at the design head. However, the original 6 MW was chosen for installation at the project because that capacity produced the greatest net economic benefits, not necessarily because it was the optimum project design capacity. In fact a variety of installed capacities ranging from 2 to 11 MW were evaluated, with unit numbers and sizes including one 2 MW unit (2 MW installed); two 3 MW units (6 MW installed); four 2.5 MW units (10 MW installed); and two 3 MW units with two 2.5 MW units (11 MW installed). Since economics (lowest cost construction) was the driving factor in the use of two 4 MW unit as opposed to the planned two 3 MW units, and it is likely that the units will generate at their design capacity of 4 MW, SWPA has elected to stay with the name plate capacity of 8 MW until testing confirms this or determines another rating. As a point of interest, the larger units may increase the expected project energy production of the project by some 15 percent. Certainly, if the units will produce only at a level commensurate with the expected production from the two 3 MW units, since the two substituted 4 MW units are specified to have operating characteristics no less than those of the 3 MW units, the GA&O assignment will be modified and the rate adjusted accordingly at the next practical time following the development of the next annual Power Repayment Study, expected in January 1990.

Estimated Corps O&M Costs

Comment: SRMA believes, given that Town Bluff will be remotely operated from the Sam Rayburn Dam power house, the Corps' proposal to share power house operators' costs equally between Sam Rayburn and Town Bluff Dams would be unfair, and has proposed that such costs could be distributed based on installed plant capacity (approximately 85/15 percent respectively) or in such a way that the split of operation costs reflects the power and energy benefits accruing from the sales relationships between the projects and the SRDEC and SRMA entities and their members (approximately 60/40 percent respectively).

Response: The Corps has recommended that the 50/50 split of power house operator labor costs be retained at the present time, since it believes that the complexity of Town Bluff power operations coupled with water releases for salt water intrusion may require more than 50 percent of an operator's time. The Corps suggests that, after the initial operation and training time is completed, an actual time/work study could be performed to determine actual operator attention and work performed for the Town Bluff project for use in determining this cost split. This issue could appropriately be reviewed and dicussed as part of the ongoing agenda of the Informal Working Group (IWG) for Town Bluff which SRMA, SWPA and the Corps

have agreed to establish. SWPA believes that, as a practical matter, the entities involved (SRDEC and SRMA) can sort out the costs of the two projects between themselves irrespective of the Corps split, as long as those entities remain the recipients of Sam Rayburn and Town Bluff Dam outputs. Also, as a practical matter, while the assumption of a 50/50 split in operator costs between Sam Rayburn and Town Bluff may remain debatable, the impact of other assumptions regarding the times of the superintendent and clerical support personnel assigned to the operations of Town Bluff (as opposed to maintenance) noted in the discussion of O&M cost estimates in both the Rate Order and the Record of Decision, results in a split of total operations costs of about 60 percent to Sam Rayburn and 40 percent to Town Bluff.

Updating/Replacing Scada and Microwave System

Comment: SRMA is concerned about updating and replacing the SCADA and microwave systems after only 15 years, as per the Corps replacement schedule, and is also concerned about the proposed rotor rewinding rehabilitation at or near the end of the 50-year contract period, submitting that equity argues for continuation of SRMA as the recipient of Town Bluff power after the current 50-year Power Sales Agreement since there will be substantial value in the remaining service lives of other capital investments for which payments will have been initiated.

Response: The estimated service life of the SCADA and microwave systems, as well as other major components of plant, is established by the Corps' Engineering Regulations (ERs). These ERs are based on the best historical information available and the service lives given represent the average experienced lives for that equipment. These service lives do not necessarily mean that the times will be replaced at this time, but items are replaced as needed based on condition and reliability. Incidentally, SWPA is anticipating replacement of its SCADA system in FY 1991 which is about 15 years from the year of installation. This action is necessary due to both physical deterioration and technological obsolescence.

SRMA is correct in recognizing that replacements occurring late in the 50-year replacement period are prorated so that only a portion of the investment cost of such items is charged to SRMA during the initial 50-year term of the Power Sales Agreement. However, while SRMA may believe it has a vested interest in the project, having fully funded its construction and having paid all of its costs including replacement costs, to keep it fully operational past the initial 50-year period, SWPA believes SRMA is no different than any other customer purchasing Federal hydroelectric power, except that it has prepaid a portion of its power bill for 50 years. While this method of paying for its power is different, it results in having paid a certain price for power received and provides no special consideration, or equity interest, for SRMA over another potential applicant for Town Bluff power after the 50-year contract. Current policy provides for continuation of capacity allocations beyond present contract terms, and SRMA's proximity to the project and the ready availability of transmission facilities provided by SRMA would appear to be positive factors in considering any future disposition of the power producing resources of the project.

O&M Cost Increases Since 1983

Comment: SRMA is concerned that the annual costs for O&M and major rehabilitation have increased from some $226,000 estimated in 1983, to over $300,000 today in spite of having directly absorbed several costs included in the original estimate which were intended to reduce those annual O&M costs. While acknowledging recent sizeable salary increase by power operating personnel, SRMA believes further explanation is appropriate.

Response: The earlier estimates of annual costs were based on a generic "cost per megawatt" curve and past plant historical costs. The most recent, approximately $300,000 cost, is based on a detailed operation and scheduled maintenance estimate. Corps maintenance schedules are determined by Engineering Regulations which outline required maintenance for Corps power plants. Operator personnel have received one pay raise in 1983, and two since 1983 totalling over 30%, while inflation has accounted for the remaining increase in the level of estimated O&M costs.

Availability of Information

Information regarding this rate proposal including studies, comments and other supporting material, is available for public review in the offices of the Southwestern Power Administration, 333 West 4th, Tulsa, Oklahoma 74103.

Administrator's Certification

The 1989 Revised Initial Town Bluff Dam Power Repayment Study indicates that an annual Town Bluff Dam Power rate of $373,068 will repay all annual costs of the project including amortization of the expected replacement investment consistent with provisions of Department of Energy Order No. RA 6120.2. In accordance with Section 1 of Delegation Order No. 0204-108, as amended May 30, 1986 (51 FR 19744), the Administrator has determined that the revised proposed Town Bluff Dam power rate is consistent with applicable law and is the lowest possible rate consistent with sound business principles in accordance with Section 5 of the Flood Control Act of 1944.

Environment

The environmental impact of the revised proposed Town Bluff Dam power rate has been analyzed in consideration of the Department of Energy "Environmental Compliance Guide. An Environment Assessment of the revised proposed initial rate resulted in a finding of no significant impact in accordance with these regulations.

Order

In view of the foregoing and pursuant to the authority delegated to me by the Secretary of Energy, I hereby confirm, approve and place in effect on an interim basis, effective on the date of commercial operation (expected about July 1, 1989), the initial annual rate of $373,068 ($31,089 per month) for the sale of power and energy from Town Bluff Dam to Sam Rayburn Municipal Power Agency under Contract No. DE-PM75-85SW00117 as amended. The rate shall remain in effect on an interim basis through September 30, 1993, or until the FERC confirms and approves the rate on a final basis.

Issued at Washington, DC, this 28th day of June 1989.

W. Henson Moore,

Deputy Secretary.

[FR Doc. 89-16122 Filed 7-7-89; 8:45 am]

BILLING CODE 6450-01-M

ENVIRONMENTAL PROTECTION AGENCY

[FRL-3612-8]

Meeting of Policy Review Board of the Gulf of Mexico Program

AGENCY: U.S. Environmental Protection Agency (EPA).

ACTION: Notice of meeting of the Policy Review Board of the Gulf of Mexico Program.

SUMMARY: The Gulf of Mexico Program Policy Review Board will hold a meeting on Wednesday, July 26, 1989, at the EPA Regional Office, 345 Courtland Street NE., Atlanta, Georgia 30365.

DATE: July 11, 1989.

ADDRESSEE: Comments should be mailed to the Gulf of Mexico Program Office, Building 1103, John C. Stennis Space Center, Stennis Space Center, Mississippi 39529-6000.

FOR FURTHER INFORMATION CONTACT: Mr. William Whitson, Assistant Director for Operations, (601) 688-3726 commercial, FTS 494-3726.

SUPPLEMENTARY INFORMATION: A meeting of the Policy Review Board (PRB) of the Gulf of Mexico Program will be held on July 26, 1989, at the EPA Region IV Office in Atlanta, Georgia, starting at 9:30 a.m. and ending at 5:00 p.m.

The PRB consists of senior level representatives from state and federal agencies and representatives of the Gulf Program's Technical Steering Committee and Citizens Advisory Committee. The PRB is chaired by the EPA Region IV Regional Administrator and co-chaired by the EPA Region VI Regional Administrator. The Board guides and reviews activities of the Gulf of Mexico Program, approves program goals and objectives, and establishes priorities and direction for the program. It

provides broad-based support in all policy and political matters.

Agenda meeting items will include the Gulf of Mexico's proposed FY 90 budget, reports from the program's Technical Steering Committee and Citizens Advisory Committee, and the status of several demonstration projects and workshops. Also on the agenda will be discussion of the Charter for the PRB as provided for under the Federal Advisory Committee Act (FACA) administered through the General Services Administration. The meeting will be open to the public with a limited number of seats available.

Joseph R. Franzmathes,

Assistant Regional Administrator for Policy and Management.

Dated: June 29, 1989.

[FR Doc. 89-16030 Filed 7-7-89; 8:45 am]

BILLING CODE 6560-50-M

[OPTS-44532; FRL-3613-2]

TSCA Chemical Testing; Receipt of Test Data

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the receipt of test data on tetrabromobisphenol A (CAS No. 79-94-7), submitted pursuant to a final test rule under the Toxic Substances Control Act (TSCA). Publication of this notice is in compliance with section 4(d) of TSCA.

FOR FURTHER INFORMATION CONTACT: Michael M. Stahl, Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Environmental Protection Agency, Room EB-44, 401 M Street SW Washington, DC 20460, (202) 554-1404, TDD (202) 544-0551.

SUPPLEMENTARY INFORMATION: Section 4(d) of TSCA requires EPA to publish a notice in the **Federal Register** reporting the receipt of test data submitted pursuant to test rules promulgated under section 4(a) within 15 days after it is received.

I. Test Data Submissions

Test data for tetrabromobisphenol A were submitted by the Brominated Flame Retradant Industry Panel and Springborn Life Sciences, Inc. (on behalf of the Brominated Flame Retardant Industry Panel) pursuant to a test rule at 40 CFR 799.4000. They were received by EPA on February 22, 1989. The submissions describe acute toxicity of tetrabromobisphenol A to eastern oysters (*Crassostrea virginica*) under flow-through conditions and bioconcentration and elimination of ^{14}C-residues by eastern oysters (*Crassostrea virginic*) exposed to tetrabromobisphenol A. Acute toxicity and bioconcentration testing are required by this test rule.

EPA has intiated its review and evaluation process for these data submissions. At this time, the Agency is unable to provide any determination as to the completeness of the submissions.

II. Public Record

EPA has established a public record for this TSCA section 4(d) receipt of data notice (docket Number OPTS-44532). This record includes copies of all studies reported in this notice. The record is available for inspection from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays, in the TSCA Public Docket Office, Rm. NE-G004, 401 M Street SW Washngton, DC 20460.

Authority: 15 U.S.C. 2603.

Dated: June 30, 1989.

Richard G. Sigman,

Acting Director, Existing Chemical Assessment Division, Office of Toxic Substances.

[FR Doc. 89-16127 Filed 7-7-89; 8:45 am]

BILLING CODE 6560-50-M

[OPTS-59870; FRL-3613-1]

Toxic and Hazardous Substances; Certain Chemicals Premanufacture Notices

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Section 5(a)(1) of the Toxic Substances Control Act (TSCA) requires any person who intends to manufacture or import a new chemical substance to submit a premanufacture notice (PMN) to EPA at least 90 days before manufacture or import commences. Statutory requirements for section 5(a)(1) premanufacture notices are discussed in the final rule published in the **Federal Register** of May 13, 1983 (48 FR 21722). In the **Federal Register** of November 11, 1984, (49 FR 46066) (40 CFR 723.250), EPA published a rule which granted a limited exemption from certain PMN requirements for certain types of polymers. Notices for such polymers are reviewed by EPA within 21 days of receipt. This notice announces receipt of 8 such PMN(s) and provides a summary of each.

DATES: Close of Review Periods:

Y 89-132, 89-133, June 20, 1989.
Y 89-134, June 22, 1989.
Y 89-135, June 25, 1989.
Y 89-136, June 26, 1989.
Y 89-137 June 29, 1989.
Y 89-138, 89-139, July 3, 1989.

FOR FURTHER INFORMATION CONTACT: Michael M. Stahl, Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Environmental Protection Agency, Room EB-44, 401 M Street SW Washington, DC 20460, (202) 554-1404, TDD (202) 554-0551.

SUPPLEMENTARY INFORMATION: The following notice contains information extracted from the nonconfidential version of the submission provided by the manufacturer on the PMNs received by EPA. The complete nonconfidential document is available in the Public Reading Room NE-G004 at the above address between 8:00 a.m. and 4:00 p.m., Monday through Friday, excluding legal holidays.

Y 89-132

Manufacturer. H.B. Fuller Company.

Chemical. (G) Polyethylene glycol ester.

Use/Production. (S) Adhesive. Prod. range: Confidential.

Toxicity Data. Acute oral toxicity: LD50 28 G/KG species(Rat). Eye irritation: slight species(Rabbit).

Y 89-133

Manufacturer. Reichhold Chemicals, Inc.

Chemical. (G) An aqueous solution of a polyacrylate.

Use/Production. (G) Additive used in the manufacture of concrete. Prod. range: Confidential.

Y 89-134

Manufacturer. Confidential.

Chemical. (G) Polymer of alkaline glycol, alkane polyol, benezene dicarboxylic acid maleic anhydride dibasic acids.

Use/Production. (G) Degree of containment—open, nondispersive use. Prod. range: Confidential.

Y 89-135

Importer. Confidential.

Chemical. (G) Ketone resin.

Use/Import. (G) Dispersive additive. Import range: Confidential.

Toxicity Data. Mutagenicity: negative.

Y 89-136

Manufacturer. Confidential.

Chemical. (G) Polyester resin of alkyl and aryl dibasic acids and alkyl polyols.

Use/Production. (G) Resin for coatings, Prod. range: Confidential.

Y 89-137

Manufacturer. Confidential.

Chemical. (G) Polymer of an alkanedioic acid and alkanediols.

Use/Production. (G) Polyurethane production. Prod. range: Confidential.

Y 89-138

Manufacturer. Confidential.
Chemical. (G) Alkyd resin.
Use/Production. (G) Container coating. Prod. range: Confidential.

Y 89-139

Manufacturer. Confidential.
Chemical. (G) Acrylic resin.
Use/Production. (G) Container coating. Prod. range: Confidential.

Date: June 27 1989.

Steven Newburg-Rinn,

Acting Director, Information Management Division, Office of Toxic Substances.

[FR Doc. 89-16128 Filed 7-7-89; 8:45 am]

BILLING CODE 6560-50-M

[FRL-3612-9]

Approvals and Disapprovals of Lists and Individual Control Strategies Submitted Under Section 304(1) of the Clean Water Act

AGENCY: Environmental Protection Agency.

ACTION: Notice of availability of approvals and disapprovals of lists and individual control strategies (ICSs) submitted under Section 304(1) of the Clean Water Act.

SUMMARY: Notice is hereby given of the availability and opportunity to comment on the United States Environmental Protection Agency's (U.S. EPA) decisions of approval and disapproval of the lists of waters, point sources and pollutants and the individual control strategies for the States of North Carolina, South Carolina, Georgia, Florida, Mississippi, Alabama, Tennessee, and Kentucky under Section 304(1) of the Clean Water Act as amended by the Water Quality Act of 1987

DATES: Comments on all aspects of the Agency's decisions with regard to the lists of waters, point sources, pollutants and individual control strategies must be submitted to U.S. EPA on or before October 4, 1989. Petitions to add waters to the lists must be submitted on or before October 4, 1989.

ADDRESSES: The U.S. EPA's decisions with regard to approving and disapproving the lists of waters, point sources, and pollutants and the individual control strategies are available for public review and comment upon request at the following location. Comments and petitions are also mailed to the following address. Diane Brown, Public Notice Coordinator, Office of Public Affairs, U.S. Environmental Protecton Agency, Region IV 345 Courtland Street NE., Atlanta, GA 30365.

FOR FURTHER INFORMATION CONTACT: Diane Brown of the EPA, Region IV at the address given above; telephone (404) 347-3004, (FTS) 257-3004.

SUPPLEMENTARY INFORMATION: Section 304(1) of the Clean Water Act (CWA) as amended by the Water Quality Act of 1987 requires every State to develop lists of impaired waters, identify certain point sources and amounts of pollutants causing toxic impact, and to develop individual control strategies for each point source.

The deadline for submitting lists of waters, point sources, amounts of pollutants and the individual control strategies by each State to the U.S. EPA was February 4, 1989. The administrative record containing the U.S. EPA's documentation on its decisions of approval and disapproval is on file and may be inspected at the U.S. EPA, Region IV office between the hours of 8:30 a.m and 4:30 p.m., Monday through Friday except holidays. To make arrangements to examine the administrative record, contact the person named as the contact person above.

Section 304(1) allows any person to submit to the U.S. EPA a petition to add waters to one or more of the three lists of waters submitted by a State. Petitions are due October 4, 1989 and should be addressed to Diane Brown, Public Notice Coordinator, Office of Public Affairs, U.S. EPA, Region IV 345 Courtland St., NE., Atlanta, Georgia 30365. The petition should identify and describe the water with sufficient detail so that the U.S. EPA is able to determine the location and boundaries of the water. The petition must also identify the list or lists for which the petitioner believes the water qualifies, and the petiton must explain why the water satisfies the criteria for the list or lists.

Following the close of the comment and petition period and after a public hearing, if such hearing is held, the Regional Administrator will issue a response to comments and petitions. The Regional Administrator will consider all petitions and comments received and will provide a written response to the comments and petitions no later than January 4, 1990.

Joseph R. Franzmathes,

Assistant Regional Administrator for Policy and Management.

Dated: June 29, 1989.

[FR Doc. 89-16031 Filed 7-7-89; 8:45 am]

BILLING CODE 6560-50-M

FEDERAL HOME LOAN BANK BOARD

Alamo Federal Savings Association of Texas; Appointment of Conservator

Notice is hereby given that pursuant to the authority contained in section 5(d)(6)(A) of the Home Owners' Loan Act, as amended, 12 U.S.C. 1464(d)(6)(A) (1982), the Federal Home Loan Bank Board duly appointed the Federal Savings and Loan Insurance Corporation as sole conservator for Alamo Federal Savings Association, San Antonio, Texas on June 28, 1989.

Dated: July 31, 1989.

By the Federal Home Loan Bank Board.

John F Ghizzoni,

Assistant Secretary.

[FR Doc. 89-16080 Filed 7-7-89; 8:45 am]

BILLING CODE 6720-01-M

Benjamin Franklin Federal Savings Association; Appointment of Conservator

Notice is hereby given that, pursuant to the authority contained in section 5(d)(6)(A) of the Home Owners' Loan Act of 1933, as amended, 12 U.S.C. 1464(d)(6)(A) (1982), the Federal Home Loan Bank Board duly appointed the Federal Savings and Loan Insurance Corporation as sole conservator for Benjamin Franklin Federal Savings Association, Houston, Texas, on June 28, 1989.

Dated: July 3, 1989.

By the Federal Home Loan Bank Board.

John F Ghizzoni,

Assistant Secretary.

[FR Doc. 89-16082 Filed 7-7-89; 8:45 am]

BILLING CODE 6720-01-M

Commonwealth Federal Savings Association; Appointment of Conservator

Notice is hereby given that pursuant to the authority contained in section 5(d)(6)(A) of the Home Owners' Loan Act, as amended, 12 U.S.C. 1464(d)(6)(A) (1982), the Federal Home Loan Bank Board duly appointed the Federal Savings and Loan Insurance Corporation as sole conservator for Commonwealth Federal Savings Association, Houston, Texas, on May 23, 1989.

Dated: July 3, 1989.

By the Federal Home Loan Bank Board.

John F Ghizzoni,

Assistant Secretary.

[FR Doc. 89-16086 Filed 7-7-89; 8:45 am]

BILLING CODE 6720-01-M

First Savings of Americus, a Federal Savings and Loan Association; Appointment of Conservator

Notice is hereby given that pursuant to the authority contained in section 5(d)(6)(A) of the Home Owners' Loan Act, as amended, 12 U.S.C. 1464(d)(6)A) (1982), the Federal Home Loan Bank Board duly appointed the Federal Savings and Loan Insurance Corporation as sole conservator for First Savings of Americus, A Federal Savings and Loan Association, Americus, Georgia on June 22, 1989.

Dated: July 3, 1989.

By the Federal Home Loan Bank Board.

John F Ghizzoni,

Assistant Secretary.

[FR Doc. 89-16087 Filed 7-7-89, 8:45 am]

BILLING CODE 6720-01-M

Great Southern Savings and Loan Association; Appointment of Conservator

Notice is hereby given that pursuant to the authority contained in 5(d)(6)(A) of the Home Owners' Loan Act, as amended, 12 U.S.C. 1464(d)(6)(A) (1982), the Federal Home Loan Bank Board duly appointed the Federal Savings and Loan Insurance Corporation as sole conservator for Great Southern Federal Savings and Loan Association, Savannah, Georgia on June 22, 1989.

Dated: July 3, 1989.

By the Federal Home Loan Bank Board.

John F Ghizzoni,

Assistant Secretary.

[FR Doc. 89-16088 Filed 7-7-89, 8:45 am]

BILLING CODE 6720-01-M

Habersham Federal Savings & Loan Association; Appointment of Conservator

Notice is hereby given that pursuant to the authority contained in section 5(d)(6)(A) of the Home Owners' Loan Act, as amended, 12 U.S.C. 1464(d)(6)(A) (1982), the Federal Home Loan Bank Board duly appointed the Federal Savings and Loan Insurance Corporation as sole conservator for Habersham Federal Savings and Loan Association, Cornelia, Georgia, on June 28, 1989.

Dated: July 3, 1989.

By the Federal Home Loan Bank Board.

John F. Ghizzoni,

Assistant Secretary.

[FR Doc. 89-16089 Filed 7-7-89; 8:45 am]

BILLING CODE 6720-01-M

Mid Missouri Savings & Loan Association, F.A., Appointment of Conservator

Notice is hereby given that pursuant to the authority contained in section 5(d)(6)(A) of the Home Owners' Loan Act, as amended, 12 U.S.C. 1464(d)(6)(A) (1982), the Federal Home Loan Bank Board duly appointed the Federal Savings and Loan Insurance Corporation as sole conservator for Mid Missouri Savings and Loan Association, F.A. Boonville, Missouri, on June 28, 1989.

Dated: July 3, 1989.

By the Federal Home Loan Bank Board.

John F Ghizzoni,

Assistant Secretary.

[FR Doc. 89-16108 Filed 7-7-89; 8:45 am]

BILLING CODE 6720-01-M

Missouri Savings Association, F.A., Appointment of Conservator

Notice is hereby given that pursuant to the authority contained in section 5(d)(6)(A) of the Home Owners' Loan Act, as amended, 12 U.S.C. 1464(d)(6)(A) (1982), the Federal Home Loan Bank Board duly appointed the Federal Savings and Loan Insurance Corporation as sole conservator for Missouri Savings Association, F.A. on June 28, 1989.

Dated: July 3, 1989.

By the Federal Home Loan Bank Board.

John F Ghizzoni,

Assistant Secretary.

[FR Doc. 89-16090 Filed 7-7-89; 8:45 am]

BILLING CODE 6720-01-M

Peoples Savings & Loan Association, FA; Appointment of Conservator

Notice is hereby given that pursuant to the authority contained in section 5(d)(6)(A)(i), of the Home Owner's Loan Act of 1933, as amended, 12 U.S.C. 1464(d)(6)(A)(i), and 12 U.S.C. 1701c (c)(2)(1982), as amended, the Federal Home Loan Bank Board has duly appointed the Federal Savings and Loan Insurance Corporation as sole conservator for Peoples Savings & Loan Association, FA, Hampton, Virginia, on June 28, 1989.

Dated: July 3, 1989.

By the Federal Home Loan Bank Board.

John F. Ghizzoni,

Assistant Secretary.

[FR Doc. 89-16083 Filed 7-7-89; 8:45 am]

BILLING CODE 6720-01-M

Sun State Savings and Loan Association, F.S.A., Appointment of Conservator

Notice is hereby given that, pursuant to the authority contained in section 5(d)(6)(A) of the Home Owner's Loan Act of 1933, as amended, 12 U.S.C. 1464(d)(6)(A) (1982), the Federal Home Loan Bank Board duly appointed the Federal Savings and Loan Insurance Corporation as sole conservator for Sun State Savings and Loan Association, F.S.A., Phoenix, Arizona, on June 14, 1989.

Dated: July 3, 1989.

By the Federal Home Loan Bank Board.

John F. Ghizzoni,

Assistant Secretary.

[FR Doc. 89-16084 Filed 7-7-89; 8:45 am]

BILLING CODE 6720-01-M

Sun State Savings and Loan Association; Appointment of Receiver

Notice is hereby given that, pursuant to the authority contained in section 406(c)(1)(B)(i)(I) of the National Housing Act, as amended, 12 U.S.C. 1729(C)(1)(B)(i)(I) (1982), the Federal Home Loan Bank Board duly appointed the Federal Savings and Loan Insurance Corporation as sole receiver for Sun State Savings and Loan Association, Phoenix, Arizona, on June 14, 1989.

Dated: July 3, 1989.

By the Federal Home Loan Bank Board.

John F. Ghizzoni,

Assistant Secretary.

[FR Doc. 89-16085 Filed 7-7-89; 8:45 am]

BILLING CODE 6720-01-M

University Federal Savings Association; Appointment of Conservator

Notice is hereby given that pursuant to the authority contained in section 5(d)(6)(A) of the Home Owners' Loan Act, as amended, 12 U.S.C. 1464(d)(6)(A) (1982), the Federal Home Loan Bank Board duly appointed the Federal Savings and Loan Insurance Corporation as sole conservator for University Federal Savings Association, Houston, Texas on May 23, 1989.

Dated: July 3, 1989.

By the Federal Home Loan Bank Board.

John F Ghizzoni

Assistant Secretary.

[FR Doc. 89-16091 Filed 7-7-89; 8:45 am]

BILLING CODE 6720-01-M

Victoria Savings Association, F.S.A., Appointment of Conservator

Notice is hereby given that pursuant to the authority contained is section 5(d)(6)(A) of the Home Owners' Loan Act, as amended, 12 U.S.C. 1464(d)(6)(A) (1982), the Federal Home Loan Bank Board duly appointed the Federal Savings and Loan Insurance Corporation as sole conservator for Victoria Savings Association, F.S.A., San Antonio, Texas, on June 28, 1989.

Dated: July 3, 1989.

By the Federal Home Loan Bank Board.

John F Ghizzoni,

Assistant Secretary.

[FR Doc. 89-16097 Filed 7-7-89; 8:45 am]

BILLING CODE 6720-01-M

Western Savings and Loan Association, F.A., Appointment of Conservator

Notice is hereby given that pursuant to the authority contained in section 5(d)(5)(A) of the Home Owners' Loan Act, as amended, 12 U.S.C. 1464(d)(6)(A) (1982), the Federal Home Loan Bank Board duly appointed the Federal Savings and Loan Insurance Corporation as sole conservator for Western Savings and Loan Association, F.A., Phoenix, Arizona, on June 14, 1989.

Dated: July 3, 1989.

By the Federal Home Loan Bank Board.

John F Ghizzoni,

Assistant Secretary.

[FR Doc. 89-16092 Filed 7-7-89; 8:45 am]

BILLING CODE 6720-01-M

[No. 89-1745]

Power of Receiver and Conduct of Receiverships; Repurchase Agreements

Date: June 30, 1989.

AGENCY: Federal Home Loan Bank Board.

ACTION: Notice.

SUMMARY: The Federal Home Loan Bank Board ("Board") is supplementing Board Resolution No. 84-572 to clarify its position concerning the protections afforded to those dealing with insured savings and loan associations in "repos of government and mortgage backed securities. With particular reference to MeraBank, A Federal Savings Bank, Phoenix, Arizona ("MeraBank"), which has engaged in a substantial volume of such "repo" transactions, the Board wishes to make it clear that the protections given to securities dealers and others in the "repo" market by amendments to the Bankruptcy Code would also be afforded to securities dealers and others engaged in repo transactions with MeraBank.

EFFECTIVE DATE: June 30, 1989.

FOR FURTHER INFORMATION CONTACT: Lawrence W Hayes, Deputy General Counsel for FSLIC, (202) 906-6428; or Jody E. Kresch, Attorney, Office of General Counsel, (202) 906-7204: Federal Home Loan Bank Board, 1700 G. Street, NW., Washington, DC 20552.

SUPPLEMENTARY INFORMATION: The Board has adopted the following resolution:

Whereas, The Federal Home Loan Bank Board ("Board") has considered the particular importance of Repos (as defined below) in providing liquidity and funding for MeraBank, A Federal Savings Bank, Phoenix, Arizona ("MeraBank"), the accounts of which are insured by Federal Savings and Loan Insurance Corporation ("FSLIC"), and the potential disruption to the markets in such Repos that could arise as a result of a receivership, conservatorship, or similar proceeding with respect to MeraBank, which disruption could have additional negative effects on the cost of the funding and liquidity of Repo Assets (as defined below) for other FSLIC insured institutions and institutions chartered by the Board; and

Whereas, The Board as operating head of the FSLIC has decided, pursuant to its powers under section 5(d)(11) of the Home Owners Loan Act of 1933, as amended, and section 406(c)(3) of the National Housing Act, as amended, to adopt the following resolutions.

Now, therefore, the Board resolves as follows:

1. The Board commits that it shall use its powers under the National Housing Act to ensure that any receivership (and to the fullest extent permitted by law, any conservatorship or similar proceeding) with respect to MeraBank shall be conducted solely by the FSLIC (and not the Superintendent of Banks for the State of Arizona) as receiver, conservator or similar official ("Receiver") under federal law and regulations, Board Resolution No. 84-572, and these resolutions.

2. The Receiver will perform all of MeraBank's obligations under Repos outstanding at the time of its appointment according to their then existing terms and conditions (including payment and margin maintenance terms) and will perform all obligations under any New Repos (as defined below) in accordance with their terms and conditions.

3. The Receiver shall have the power to renew, extend, or modify any Repo, and to enter into new Repos (collectively, "New Repos"), but may only exercise such power with the consent of the Repo counterparty.

4. In any termination of the receivership of MeraBank or disposition of MeraBank's liabilities under any Repo or New Repo, the Board and the Receiver shall provide for the performance of obligations and the exercise of remedies under Repos and New Repos in a manner consistent with Board Resolution No. 84-572 and these resolutions.

5. Notwithstanding any other provision of law, regulation, or these resolutions, if the Receiver does not perform all such obligations in accordance with their terms, the counterparty to such Repos or New Repos shall have the absolute right to exercise all of its rights and remedies with respect to such Repos and New Repos (including liquidation of Repo Assets).

6. In the event of a Cross-Default (as defined below), a counterparty to a Repo or New Repo shall have the absolute right to accelerate the repurchase and other obligations thereunder (without notice to the Receiver) and exercise all of its rights and remedies with respect to such Repos and New Repos (including liquidation of Repo Assets to satisfy such accelerated obligations).

7 The failure or delay of a counterparty to exercise any of its rights or remedies upon a failure to perform or a Cross-Default shall not constitute a waiver of any rights or remedies in connection therewith.

8. In conncection with a Repo or New Repo counterparty's exercise of remedies upon failure to perform or a Cross-Default, neither the Board nor the Receiver shall object to or seek to oppose or stay such exercise or assert or seek to assert any adverse claims (including stop-transfer instructions) against the Repo Assets or any holder or transferee thereof in connection therewith.

9. The Receiver may enforce its claim to any excess received by a counterparty upon the exercise of such remedies over the stated repurchase price (including interest to the date of liquidation of the Repo Assets) and reasonable expenses of liquidation; *provided,* however, that nothing herein shall be construed to limit any set-off rights that such counterparty shall have against any such excess.

10. Notwithstanding any provision of law or regulation, neither the Board nor

the Receiver shall seek to avoid or recover any payment or transfer of Repo Assets or funds made in connection with any Repo or New Repo or the liquidation thereof as a preferential transfer or fraudulent conveyance (other than any fraudulent conveyance made by MeraBank, voluntarily or involuntarily, with actual intent to hinder, delay or defraud its creditors; provided, however, any transferee of such a transfer that takes for value and in good faith has a lien on or may retain any interests transferred, and shall not be subject to a fraudulent conveyance claim in respect of such transfer, in each case to the extent that such transferee gave value to MeraBank in exchange for such transfer and provided further that in no event shall the Board or the Receiver make any such fraudulent conveyance claim against any Repo Assets).

11. Nothing herein shall limit the power of the Board or the Receiver to make a claim against a counterparty (but not Repo Assets) based on such counterparty's fraud or failure to liquidate a Repo or a New Repo in a commercially reasonable manner. In light of the substantial volume of MeraBank's Repos, the Board and the FSLIC hereby confirm that liquidation of Repo Assets over a period, not in excess of 90 days from the date of termination of a Repo or New Repo, would constitute a liquidation of a Repo or New Repo in a commercially resonable time, and that the counterparty shall be entitled (but in the case of a Repo only from the proceeds of liquidation of Repo Assets or by way of set-off) to interest, at the contract rate, accruing during such period; provided, however, that a liquidation of Repo Assets at any point during such period or after a longer period of time shall not in and of itself constitute a commercially unreasonable time.

12. In connection with any Repo or New Repos, the Board and the FSLIC, in its corporate capacity, each irrevocably waives compliance by counterparties to Repos or New Repos with the FSLIC right or notice and purchase (12 CFR 563.B-2) and the contractual language required thereby, if applicable to any Repo Assets.

13. Nothing herein shall limit the exercise by a counterparty to a Repo or New Repo of its rights and remedies thereunder in reliance on the Board's Resolution No. 84-572, which Resolution shall continue in full force and effect; provided, however, that paragraphs 2, 4, 5, 6, 7 8, 10 and 12, the proviso to paragraph 9, and the second sentence of paragraph 11 of these resolutions shall not apply to a termination of a Repo prior to the stated repurchase or maturity date therefor based solely on the appointment of the Receiver for MeraBank.

14. In recognition of the reliance counterparties to Repos and New Repos place and will place on Resolution No. 84-572 and these resolutions in continuing to renew and enter into Repos and MeraBank, the Board intends itself, the FSLIC, in its corporate capacity, and the Receiver to be bound by Resolution No. 84-572 and these resolutions, and will not amend or rescind them without appropriate public notice of a least 45 days and any such amendment or rescission shall opeerate only prospectively.

"Cross Default" means, as to any counterparty to a Repo or New Repos, the failure by MeraBank or the Receiver to make any payment of funds or delivery of additional Repo Asset to any other Repo or New Repo counterparty when due, (b) the failure by MeraBank or the Receiver to make any payment of funds or delivery of securities under any "securities contract" or "commodities contract" (each as defined in the federal Bankruptcy Code), or interest rate exchange agreement, when due, or (c) such counterparty is unable to finance or sell under repo, on reasonable terms and conditions, any Repo Assets (whether due to market insecurity, a breach by the Board of its commitments hereunder, or otherwise).

"Repo Assets" means assets that are "liquid assets" under 12 CFR 523.10 or assets that would be so "liquid" but for their remaining term to maturity, "mortgage-related securities" (as defined in section 3(a)(41) of the Securities Exchange Act of 1934).

"Repo" means an agreement, whether documented as a purchase and sale transaction or a secured loan transaction, by MeraBank (or the Receiver, in the case of New Repos) pursuant to which MeraBank or the Receiver transfers Repo Assets to a counterparty that is a registered broker-dealer (including a registered government securities broker-dealer) or an affiliate thereof, the Federal Home Loan Mortgage Corporation, or (to the extent that Repo Assets are securities that are direct obligations of or that are fully guaranteed as to principal and interest by the United States of any agency thereof, the Federal Home Loan Mortgage Corporation, or the Federal National Mortgage Association) a Federal Home Loan Bank, against the transfer of funds with a simultaneous agreement by the counterparty to retransfer such Repo Assets to MeraBank or the Receiver on a date certain or on demand against the transfer of funds.

Resolved further, that these resolutions shall be effective immediately upon their adoption by the Board.

Resolved further, that the Secretary to the Board shall forward this resolution for publication in the **Federal Register**.

By the Federal Home Loan Bank Board.

John F Ghizzoni,

Assistant Secretary.

[FR Doc. 89-16043 Filed 7-7-89; 8:45 am]

BILLING CODE 6720-01-M

Benjamin Franklin Savings Association; Replacement of Conservator With Receiver

Notice is hereby given that pursuant to the authority contained in section 5(d)(6)(D) of the Home Owners' Loan Act of 1933, as amended, 12 U.S.C. 1464(d)(6)(D) (1982), the Federal Home Loan Bank Board duly replaced the Federal Savings and Loan Insurance Corporation ("FSLIC") as Conservator for Benjamin Franklin Savings Association, Houston, Texas ("Association"), with the FSLIC as sole Receiver for the Association on June 28, 1989.

Dated: July 3, 1989.

By the Federal Home Loan Bank Board.

John F Ghizzoni,

Assistant Secretary.

[FR Doc. 89-16078 Filed 7-7-89; 8:45 am]

BILLING CODE 6720-01-M

Commonwealth Savings Association; Replacement of Conservator with a Receiver

Notice is hereby given that, pursuant to the authority contained in section 5(d)(6)(D) of the Home Owners Loan Act, as amended, 12 U.S.C. 1464(d)(6)(D) (1982), the Federal Home Loan Bank Board duly replaced the Federal Savings and Loan Insurance Corporation ("FSLIC") as Conservator for Commonwealth Savings Association, Houston, Texas ("Association") with the FSLIC as sole receiver for the Association on May 23, 1989.

Dated: July 3, 1989.

By the Federal Home Loan Bank Board.

John F Ghizzoni,

Assistant Secretary.

[FR Doc. 89-16100 Filed 7-7-89; 8:45 am]

BILLING CODE 6720-01-M

Great Southern Federal Savings Bank; Appointment of Receiver

Notice is hereby given that, pursuant to the authority contained in section 5(d)(6)(A) of the Home Owners' Loan Act, as amended, 12 U.S.C. 1464(d)(6)(A) (1982), the Federal Home Loan Bank Board duly appointed the Federal Savings and Loan Insurance Corporation ("FSLIC") as sole receiver ("Receiver") for Great Southern Federal Savings Bank, Savannah, Georgia ("Association") June 22, 1989.

Dated: July 3, 1989.

By the Federal Home Loan Bank Board.

John F Ghizzoni,

Assistant Secretary.

[FR Doc. 89-16093 Filed 7-7-89; 8:45 am]

BILLING CODE 6720-01-M

Mid Missouri Savings and Loan Association; Appointment of Receiver

Notice is hereby given that, pursuant to the authority contained in section 406(c)(1)(B)(i)(1) of the National Housing Act, as amended, 12 U.S.C. 1729(c)(1)(B)(i)(I) (1982), the Federal Home Bank Board duly appointed the Federal Savings and Loan Insurance Corporation as sole receiver for Mid Missouri Savings and Loan Association, Boonville, Missouri, on June 28, 1989.

Dated: July 3, 1989.

By the Federal Home Loan Bank Board.

John F Ghizzoni,

Assistant Secretary.

[FR Doc. 89-16094 Filed 7-7-89; 8:45 am]

BILLING CODE 6720-01-M

Victoria Savings Association; Appointment of Receiver

Notice is hereby given that, pursuant to the authority contained in section 406(c)(1)(B)(i)(1) of the National Housing Act, as amended, 12 U.S.C. 1729(c)(1)(B)(i)(I) (1982), the Federal Home Bank Board duly appointed the Federal Savings and Loan Insurance Corporation as sole receiver for Victoria Savings and Loan Association, Victoria, Texas, on June 28, 1989.

Dated: July 3, 1989.

By the Federal Home Loan Bank Board.

John F Ghizzoni,

Assistant Secretary.

[FR Doc. 89-16095 Filed 7-7-89; 8:45 am]

BILLING CODE 6720-01-M

Western Savings and Loan Association; Appointment of Receiver

Notice is hereby given that, pursuant to the authority contained in section 406(c)(1)(B)(i)(1) of the National Housing Act, as amended, 12 U.S.C. 1729(c)(1)(B)(i)(I) (1982), the Federal Home Bank Board duly appointed the Federal Savings and Loan Insurance Corporation as sole receiver for Western Savings and Loan Association, Phoenix, Arizona, on June 14, 1989.

Dated: July 3, 1989.

By the Federal Home Loan Bank Board.

John F Ghizzoni,

Assistant Secretary.

[FR Doc. 89-16096 Filed 7-7-89; 8:45 am]

BILLING CODE 6720-01-M

[No. AC-773; FHLBB No. 4869]

DeKalb Federal Savings Bank; Final Action on Approval of Conversion Application

Date: June 30, 1989.

Notice is hereby given that on June 14, 1989, the Office of the General Counsel of the Federal Home Loan Bank Board, acting pursuant to the authority delegated to the General Counsel or his designee, approved the application of DeKalb Federal Savings Bank, Decatur, Georgia, for permission to convert to the stock form of organization. Copies of the application are available for inspection at the Office of the Secretariat at the Federal Home Loan Bank Board, 1700 G Street, NW Washington, DC 20552, and at the Office of the Supervisory Agent at the Federal Home Loan Bank of Atlanta, 1475 Peachtree Street, NE., Atlanta, Georgia 30309.

By the Federal Home Loan Bank Board.

John F Ghizzoni,

Assistant Secretary.

[FR Doc. 89-16081 Filed 7-7-89; 8:45 am]

BILLING CODE 6720-01-M

[No. AC-771]

First Federal Savings and Loan Association; Final Action on Approval of Conversion Application

Date: June 30, 1989.

Notice is hereby given that on April 27 1989, the Federal Home Loan Bank Board ("Board") approved the application of First Federal Savings and Loan Association, Charlotte, North Carolina ("First Federal"), for permission to convert to the stock form of organization pursuant to a voluntary supervisory conversion and the acquisition of First Federal by Fairfield Community, Inc.

By the Federal Home Loan Bank Board.

John F Ghizzoni,

Assistant Secretary.

[FR Doc. 89-16079 Filed 7-7-89; 8:45 am]

BILLING CODE 6720-01-M

[No. AC-772]

Heritage Federal Savings Bank; Final Action on Approval of Conversion Application

Date: June 30, 1989.

Notice is hereby given that on June 22, 1989, the Office of the General Counsel of the Federal Home Loan Bank Board, acting pursuant to the authority delegated to the General Counsel or his designee, approved the application of Heritage Federal Savings Bank, Taylor, Michigan, for permission to convert to the stock form of organization. Copies of the application are available for inspection at the Office of the Secretariat at the Federal Home Loan Bank Board, 1700 G Street, NW., Washington, DC 20552, and at the Office of the Supervisory Agent at the Federal Home Loan Bank of Indianapolis, 1350 Merchants Plaza, South Tower, 115 West Washington Street, Indianapolis, Indiana 46204.

By the Federal Home Loan Bank Board.

John F Ghizzoni,

Assistant Secretary.

[FR Doc. 89-16098 Filed 7-7-89; 8:45 am]

BILLING CODE 6720-01-M

[No. AC-774]

Royal Oak Federal Savings and Loan Association; Final Action on Denial of Conversion Application

Date: June 29, 1989.

Notice is hereby given that on June 29, 1989, the Federal Home Loan Bank Board denied the application of Royal Oak Federal Savings and Loan Association, Randallstown, Maryland ("Association"), for permission to convert to the stock form of organization pursuant to a voluntary supervisory conversion and merger of the Association with and into Liberty Federal Savings Bank, Randallstown, Maryland.

By the Federal Home Loan Bank Board.

John F Ghizzoni,

Assistant Secretary.

[FR Doc. 89-16099 Filed 7-7-89; 8:45 am]

BILLING CODE 6720-01-M

FEDERAL MARITIME COMMISSION

Agreement(s) Filed

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, 1100 L Street, NW Room 10325. 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.. 224-200233-004
Title: Philadelphia Port Corporation Terminal Agreement
Parties: Philadelphia Port Corporation, Holt Cargo Systems, Inc.
Synopsis: The Agreement amends Article 2(b)(4) of Exhibit B of Agreement No. 224-200233 by adding at the end thereof the following: with respect to containers having an immediately prior or subsequent movement to or from the terminal by vessel or barge.

Agreement No.. 224-200263
Title: Port of Seattle Terminal Agreement
Parties: Port of Seattle (Port), Jacob Stern & Sons, Inc.
Synopsis: The Agreement provides for a two and one-half year lease of terminal premises and fixtures for receiving, delivery, processing and storage of non-petroleum bulk liquids, oils and fats and provides for the use of berthing facilities pursuant to the Port's tariff. The Agreement may be renewed for an additional one-year period.

Agreement No.. 224-200264
Title: Port of Seattle Terminal Agreement
Parties: Port of Seattle (Port), Jore Corporation (Jore)
Synopsis: Agreement No. 224-200264 provides for Jore's use of 15.85 acres of the Port's Terminal 115 (Premises) as a barge terminal. Of the 15.85 acres, 11.33 acreas, including a warehouse and other facilities, are assigned to Jore for its exclusive use and 4.52 acres, including a barge loading facility and pier, are assigned to Jore for its preferential use. The lease is for a term of 5 years.

Agreement No.. 224-004161-003
Title: San Francisco Terminal Agreement
Parties: San Francisco Port Commission, Marine Terminals Corporation
Synopsis: The Agreement amends the basic agreement (Agreement No. 224-004161). It provides that the basic agreement originally scheduled to expire on June 30, 1989, shall be extended through July 30, 1989. All other provisions of the agreement remain in effect.

By Order of the Federal Maritime Commission.

Dated: July 3, 1989.

Ronald D. Murphy,

Assistant Secretary.

[FR Doc. 89-16055 Filed 7-7-89; 8:45 am]

BILLING CODE 6730-01-M

Notice of Issuance of Certificate (Performance); China Navigation Co. Ltd.

Notice is hereby given that the following have been issued a Certificate of Financial Responsibility for Indemnification of Passengers for Nonperformance of Transportation pursuant to the provisions of Section 3, Pub. L. 89-777 (80 Stat. 1357 1358) and Federal Maritime Commission General Order 20, as amended (46 CFR Part 540):

The China Navigation Co. Ltd.,
c/o Lamorte Burns & Co., Inc.,
505 Thornall Street, #205,
Edison, New Jersey 08837
Vessel: Coral Princess

Date: July 5, 1989.

Joseph C. Polking,

Secretary.

[FR Doc. 89-16107 Filed 7-7-89; 8:45 am]

BILLING CODE 6730-01-M

[Docket No. 89-13]

Ceres Terminal Incorporated v. Indiana Port Commission et al., Notice of Filing of Complaint and Assignment

Notice is given that a complaint filed by Ceres terminals Incorporated ("Complainant") against the Indiana Port Commission ("IPC"), Lakes and Rivers—a Division of Jack Gray Transport, Inc., Pacific Great Lakes Transport Burns Harbor, Inc., and Brown Inc. (hereinafter "Respondents") was served June 30, 1989. Complainants allege that Respondents violated sections 10(a)(2) and 10(a)(3) of the Shipping Act of 1984 (the Act"), 46 U.S.C. app. 1709 (a)(2) and (a)(3), by operatng under an unfiled agreement to refuse to deal or negotiate with Complainant and to eliminate Complainant as a marine terminal operator and/or stevedore at Burns International Harbor (Indiana). Complainant also alleges that Respondents' practices violate sections 10 (d)(1), (d)(3), and (b)(12) of the Act, 46 U.S.C. app. 1709 (d)(1), (d)(3), and (b)(12), and that practices of Respondent IPC also violate section 10(b)(11) of the Act, 46 U.S.C. app. 1709(b)(11).

This proceeding has been assigned to Administrative Law Judge Charles E. Morgan ("Presiding Officer"). Hearing in this matter, if any is held, shall commence within the time limitations prescribed in 46 CFR 502.61. The hearing shall include oral testimony and cross-examination in the discretion of the Presiding Officer only upon proper showing that there are genuine issues of material fact that cannot be resolved on the basis of sworn statements, affidavits, depositions, or other documents or that the nature of the matter in issue is such that an oral hearing and cross-examination are necessary for the development of an adequate record. Pursuant to the further terms of 46 CFR 502.61, the initial decision of the Presiding Officer in this proceeding shall be issued by June 30, 1990, and the final decision of the Commission shall be issued by October 30, 1990.

Joseph C. Polking,

Secretary.

[FR Doc. 89-16073 Filed 7-7-89; 8:45 am]

BILLING CODE 6730-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control

Injury Research Grant Review Committee: Meeting—Notice of Change

This notice announces a change in the telephone number for the contact person for a previously announced meeting.

Federal Register Citation of Previous Announcement: 54 FR 26254.

Name: Injury Research Grant Review Committee.

Previously Announced Time and Date: 8:00 a.m.-5:00 p.m.—July 24-25, 1989, 8:00 a.m.-12:00 Noon—July 26, 1989.

Previously announced telephone number: Commercial: 404/639-4690.

Change in the Telephone Number: Commercial: 404/488-4690.

Dated: July 4, 1989.

Elvin Hilyer,

Associate Director for Policy Coordination, Centers for Disease Control.

[FR Doc. 89-16060 Filed 7-7-89; 8:45 am]

BILLING CODE 4160-18-M

Food and Drug Administration

[Docket No. 89D-0204]

Country of Origin Labeling; Compliance Policy Guide; Availability

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of revised Compliance Policy Guide (CPG) 7119.02, "Country of Origin Labeling. FDA has revised CPG 7119.02 to make explicit that it is FDA's policy to defer to the U.S. Customs Service (Customs) on matters related to false or misleading country of origin labeling.

ADDRESSES: Submit written requests for single copies of CPG 7119.02 to the Division of Compliance Policy (HFC-230), Office of Enforcement, Food and Drug Administration, Rm. 12A-55, 5600 Fishers Lane, Rockville, MD 20857 Requests should be identified with the docket number found in brackets in the heading of this document. Send two self-addressed adhesive labels to assist that office in processing your requests. CPG 7119.02 is available for public examination in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857 between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Alvin L. Gottlieb, Division of Compliance Policy (HFC-230). Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857 301-443-1500.

SUPPLEMENTARY INFORMATION: A statement of the country of origin on the labeling of imported foods is not required by the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.). Such a statement is required by Customs, as authorized by the Tariff Act and Customs' regulations (19 U.S.C. 1304 and 19 CFR Part 134). Thus, FDA s policy regarding false or misleading country of origin labeling is to defer to Customs. FDA has revised CPG 7119.02, "Country of Origin Labeling, to explain FDA s and Customs' respective jurisdiction over false and misleading country of origin labeling, to set forth FDA's policy to defer to Customs for actions against false or misleading country labeling, and to provide guidance to FDA personnel regarding referrals to Customs.

This notice is issued under 21 CFR 10.85.

Dated: June 30, 1989.

Alan L. Hoeting,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 89-16071 Filed 7-7-89; 8:45 am]

BILLING CODE 4160-01-M

Advisory Committees; Meetings; Amendment of Notice of Meeting

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is amending a notice that announces a public meeting of the Vaccines and Related Biological Products Advisory Committee. The amendment reflects a change in the location of the meeting. Notice of the July 20 and 21, 1989, meeting was published in the **Federal Register** of June 23, 1989 (54 FR 26418 at 26419).

SUPPLEMENTARY INFORMATION: In FR Doc. 89-14872, appearing at page 26418 in the **Federal Register** of Friday, June 23, 1989, the following correction is made: On page 26419, in the 2nd column, under the heading "Vaccines and Related Biological Products Advisory Committees" the *"Date, time, and place"* paragraph is corrected to read *"Date, time, and place.* July 20 and 21, 1989, 8:30 a.m., Hyatt Regency, 1 Bethesda Metro Center, Bethesda, MD.

Dated: July 3, 1989.

Alan L. Hoeting,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 89-16070 Filed 7-7-89; 8:45 am]

BILLING CODE 4160-01-M

Health Care Financing Administration

Medicare and Medicaid Programs; Meeting of the Advisory Panel on the Development of Uniform Needs Assessment Instrument(s)

[HSQ-174-N]

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice.

SUMMARY: This notice announces the sixth and final meeting of the Advisory Panel on the Development of Uniform Needs Assessment Instrument(s). The Panel is responsible for the development of a standard method to be used to evaluate the post-hospitalization needs of patients. The meeting is open to the public.

DATES: July 24-25, 1989.

Time:

July 24: 8:30 a.m.-5:00 p.m.
July 25: 9:00 a.m.-5:00 p.m.
Eastern Daylight Saving Time

ADDRESSES: Washington Marriott, 1221 22nd Street, NW Washington, D.C. 20037

FOR FURTHER INFORMATION CONTACT: Sue Nonemaker, (301) 966-6825.

SUPPLEMENTARY INFORMATION: Section 9305(c) of the Omnibus Budget Reconciliation Act of 1986 (OBRA '86), Pub. L. 99-509, in amending section 1861(e) of the Social Security Act, requires that hospitals, as a condition to participate in the Medicare program, provide discharge planning. Discharge planning activities vary and we currently lack a standardized method for evaluating a patient's need for health care after hospitalization. The development of a standardized method would allow more uniformity among those responsible for discharge planning and improve detemination of a patient's need for post-hospital services.

Section 9305(h) of OBRA'86 requires the secretary to develop a uniform needs assessment instrument in consultation with an advisory panel made up of experts in the delivery of post-hospital extended care services, home health services, and long term care services. The panel is made up of experts in the delivery of post-hospital extended care services, home health services, long term care services and representatives of physicians, Medicare beneficiaries, hospitals, skilled nursing facilities, home health agencies, long term care providers, and fiscal intermediaries.

Mr. Jay Rudman, Director of the Clinical Social Work Department at the University of California at Los Angeles Medical Center is chairman of the panel.

At the previous panel meetings, the activities have focused on the following:

Developing a standard method to evaluate an individual's ability to function or engage in activities of daily living, the nursing and other care requirements necessary to meet health care needs, and the social and familial resources available to the individual;

Constructing the standard method so that it could be used by discharge planners, hospitals, nursing facilities, ther health care providers and fiscal intermediaries in evaluating an individual's needs for post-hospital extended care; and

Evaluating the advantages and disadvantages of using the tool as a

basis for determining whether payment should be made for posthospital extended care services and home health services which are provided to Medicare beneficiaries.

At this final meeting the Advisory Panel will hear a report summarizing the results of a period of review and comment on the draft needs assessment instrument by experts in the health services delivery field. There will be discussion regarding the need to modify the draft instrument and the Panel's recommendations for its use. The Advisory Panel will also ratify its report to the Secretary of Health and Human Services.

Items of discussion are subject to change as priorities dictate. With the exception of Executive Sessions to be held at 7:30 a.m. on July 24 and 25, the meeting is open to the public and there is no registration fee. There will be an opportunity for public comment. The chairman reserves the right to adjourn the public portion of the meeting and reconvene in Executive Session should it prove necessary to facilitiate the business of the Advisory Panel.

(Catalog of Federal Domestic Assistance Program No. 13.714, Medical Assistance Program; No. 13.773, Medicare—Hospital Insurance; No. 13.774, Medicare—Supplementary Medical Insurance)

Dated: July 6, 1989.

Louis B. Hays,

Acting Administrator, Health Care Financing Administration.

[FR Doc. 89-16234 Filed 7-6-89; 1:31 am]

BILLING CODE 4120-01-M

Public Health Service

Indian Health Service; Medical Reimbursement Rates for Fiscal Year 1989; Inpatient and Outpatient Medical Care

Notice is given that the Assistant Secretary for Health, under the authority of sections 321(a) and 322(b) of the Public Health Service Act (42 U.S.C. 248(a) and 249(b)), has approved the following reimbursement rates for inpatient and outpatient medical care in facilities operated by the Indian Health Service for Fiscal Year 1989: Emergency Non-Beneficiaries, Beneficiaries of Other Federal Agencies, Medicare and Medicaid Beneficiaries.

Inpatient Services Per Day
Hospital—$380
Physician—$20
(In Alaska—Hospital $458
Physician $22)
Outpatient—$72 Per Visit
(In Alaska—$122 Per Visit)

Ambulatory Surgery shall be charged at the current Medicare rates as published in the **Federal Register** by the Health Care Financing Administration.

Dated: June 26, 1989.

James O. Mason,

Assistant Secretary for Health.

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. N-89-2017]

Submission of Proposed Information Collections to OMB

AGENCY: Office of Administration, HUD.

ACTION: Notices.

SUMMARY: The proposed information collection requirements described below have been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposals.

ADDRESS: Interested persons are invited to submit comment regarding these proposals. Comments should refer to the proposal by name and should be sent to: John Allison, OMB Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: David S. Cristy, Reports Management Officer, Department of Housing and Urban Development, 451 7th Street, Southwest, Washington, DC 20410, telephone (202) 755-6050. This is not a toll-free number. Copies of the proposed forms and other available documents submitted to OMB may be obtained from Mr.Cristy.

SUPPLEMENTARY INFORMATION: The Department has submitted the proposals for the collections of information, as described below, to OMB for review, as required by the Paperwork Reduction Act (44 U.S.C. Chapter 35).

The Notices list the following information: (1) The title of the information collection proposal; (2) the office of the agency to collect the information; (3) the description of the need for the information and its proposed use; (4) the agency form number, if applicable; (5) what members of the public will be affected by the proposal; (6) how frequently information submissions will be required; (7) an estimate of the total number of hours needed to prepare the information submission including number of respondents, frequency of response, and hours of response; (8) whether the proposal is new or an extension, reinstatement, or revision of an information collection requirement; and (9) the names and telephone numbers of an agency official familiar with the proposal and of the OMB Desk Officer for the Department.

Authority: Section 3507 of the Paperwork Reduction Act, 44 U.S.C. 3507· Section 7(d) of the Department of Housing and Urban Development Act, 42 U.S.C. 3535(d).

Date: June 30, 1989.

John T. Murphy,

Director, Information Policy and Management Division.

Proposal: Application for Approval as a Mortgage Backed Securities Issuer

Office: Government National Mortgage Association (GNMA)

Description of the Need for the Information and Its Proposed Use: This form will be used by applicants proposing to become Mortgage-Backed Securities Issuers. It will summarize the applicants' business background and experience and is necessary for GNMA to determine whether the applicant meets all GNMA eligibility requirements contained in CFR, Part 390.

Form Number: HUD-11701

Respondents: Businesses or Other For-Profit and Small Businesses or Organizations

Frequency of Submission: On Occasion

Reporting Burden:

	Number of respondents	×	Frequency response	×	Hours per response	=	Burden hours
HUD-11701	50		1		.75		38

Total Estimated Burden Hours: 38
Status: Extension
Contact: Charles Clark, HUD, (202) 755-5535; John Allison, OMB, (202) 395-6880

Date: June 30, 1989.

Proposal: Insurance Information
Office: Public and Indian Housing
Description of the Need for the Information and Its Proposed Use: The Annual Contributions Contract requires public housing agencies and Indian housing authorities to obtain adequate fire insurance, extended coverage insurance, and boiler insurance to protect the Federal interest. Form HUD-5460 provides the format for determining the initial amount of insurance required for each project.
Form Number: HUD-5460
Respondents: Non-Profit Institutions
Frequency of Submission: Other
Reporting Burden:

	Number of respondents	×	Frequency of response	×	Hours per response	=	Burden hours
HUD-54601	125		1		1.00		125
Recordkeeping	125		1		0.25		31

Total Estimated Burden Hours: 156
Status: Extension
Contact: Ralph Lecky, HUD, (202) 755-8145; John Allison, OMB, (202) 395-6880

Date: June 30, 1989.

Proposal: Statement of Profit and Loss
Office: Housing
Description of the Need for the Information and Its proposed Use: Multifamily project owners are required to submit HUD-92410 each year to the Department as part of their annual financial statement. The data will be used by HUD to review requests for rent increases and to prevent defaults by monitoring the reasonableness of the projects s operating expenses and the adequacy of the projects's cash flow.
Form Number: HUD-92410
Respondents: Businesses or Other For-Profit
Frequency of Submission: Annually
Reporting Burden:

	Number of respondents	×	Frequency response	×	Hours per response	=	Burden hours
HUD-92410	16,000		1		1		16,000

Total Estimated Burden Hours: 16,000
Status: Extension
Contact: Tom Coleman, HUD, (202) 426-3944; John Allison, OMB, (202) 395-6880

Date: June 30, 1989.

Proposal: Annual Contributions for Operating Subsidies—Performance Funding System; Determination of Operating Subsidy
Office: Public and Indian Housing
Description of the Need for the Information and Its Propsed Use: Public Housing Authorities (PHAs) and Indian Housing Authorities (IHAs) must determine an appropriate and justifiable occupancy percentage to be used in calculating operating subsidy eligibility under the Performance Funding System. PHAs/IHAs classified as "Low Occupany" must submit a Comprehensieve Occupancy Plan to use an occupany percentage less that 97 percent.
Form Number: HUD-52728A, HUD-52728B, and HUD 52728C
Respondents: State of Local Governments and Non-Profit Institutions
Frequency of Submission: Annually and Other
Reporting Burden:

	Number of respondents	×	Frequency response	×	Hours per response	=	Burden hours
HUD-52728A	2,400		1		1		2,400
HUD-52728B	45		1		40		1,800
HUD-52728C	45		1		80		3,600

Total Estimated Burden Hours: 7,800
Status: Extension
Contract: John T. Comerford, HUD (202) 426-1872; John Allison, OMB, (202) 395-6880

Date: June 30, 1989.

[FR Doc. 89-16056 Filed 7-7-89; 8:45 am]
BILLING CODE 4210-01-M

[Docket No. N-89-2018]

Submission of Proposed Information Collection to OMB

AGENCY: Office of Administration, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

ADDRESS: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and should be sent to: John Allison, OMB Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: David S. Cristy, Reports Management Officer, Department of Housing and Urban Development, 451 7th Street, Southwest, Washington, DC 20410, telephone (202) 755-6050. This is not a toll-free number. Copies of the proposed forms and other available documents submitted to OMB may be obtained from Mr. Cristy.

SUPPLEMENTARY INFORMATION: This Notice informs the public that the

Department of Housing and Urban Development has submitted to OMB, for emergency processing, an information collection package with respect to the section 8 Moderate Rehabilitation Program.

This information collection will allow the Department to respond to a request for information from the Employment and Housing Subcommittee of the Committee on the Government Operations, House of Representatives, which is holding fact-finding hearings on the section 8 Moderate Rehabilitation Program. The Subcommittee's request includes a listing of the Moderate Rehabilitation project names and owners for projects funded FY 1984 through FY 1989. In order for the Department to respond to this request, we must obtain the information from Public Housing Authorities by July 7 1989. Any control number issued by OMB to cover this emergency situation would be valid for no more than 90 days.

The Department has submitted the proposal for the collection of information, as described below, to OMB for review, as required by the Paperwork Reduction Act (44 U.S.C. Chapter 35).

The Notice lists the following information: (1) The title of the information collection proposal; (2) the office of the agency to collect the information; (3) the description of the need for the information and its proposed use; (4) the agency form number, if applicable; (5) what members of the public will be affected by the proposal; (6) how frequently information submissions will be required; (7) an estimate of the total number of hours needed to prepare the information submission including number of respondents, frequency of response, and hours of response; (8) whether the proposal is new or an extension, reinstatement, or revision of an information collection requirement; and (9) the names and telephone numbers of an agency official familiar with the proposal and of the OMB Desk Officer for the Department.

Authority: Section 3507 of the Paperwork Reduction Act, 44 U.S.C. 3507· section 7(d) of the Department of Housing and Urban Development Act, 42 U.S.C. 3535(d).

Date: July 3, 1989.

David S. Cristy,

Deputy Director, Information Policy and Management Division.

Proposal: Section 8 Moderate Rehabilitation—A listing of the Moderate Rehabilitation Project Names and Owners for Projects Funded from Fiscal Year (FY) 1984 through FY 1989.

Office: Housing

Description of the Need for the Information and Its Proposed Use: Selected public housing authorities will compile a list of moderate rehabilitation project names and owner for section 8 Moderate Rehabilitation projects funded from FY 1984 through FY 1989 for the Employment and Housing Subcommittee of the Committee on Government Operations, House of Representatives.

Form Number: None

Respondents: State or Local Governments

Frequency of Submission: One Time Only

Reporting Burden:

	Number of respondents	x	Frequnecy of response	x	Hours per response	=	Burden hours
Information Collection	250		1		1		250

Total Estimated Burden Hours: 250

Status: New

Contact: Maddie Hastings, HUD, (202) 755-6887· John Allison, OMB, (202) 395-6880

Date: July 3, 1989.

[FR Doc. 89-16057 Filed 7-7-89; 8:45 am]

BILLING CODE 4210-01-M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[WY-920-08-4120-11; WYW116383]

Coal Exploration License; Cheyenne, WY

AGENCY: Bureau of Land Management, Interior.

ACTION: Invitation for coal exploration license.

SUMMARY: Cordero Mining Company hereby invites all interested parties to participate on a pro rata cost sharing basis in its coal exploration program concerning federally owned coal underlying the following described land in Campbell County, Wyoming:

T. 46 N., R. 71 W., 6th P.M., WY
Sec. 11: Lots 1-10, 15, 16.
Containing 486.95 acres

All of the coal in the above land consists of unleased Federal coal, within the Powder River Basin known coal leasing area. The purpose of the exploration is to investigate the potential of acquiring this area of unleased Federal coal for incorporation into an existing mining operation.

ADDRESSES: A detailed description of the proposed drilling program is available for review during normal business hours in the following offices (under serial number WYW116383): Bureau of Land Management, 2515 Warren Avenue, Cheyenne, Wyoming 82003; and Bureau of Land Management, 1701 East 'E' Street, Casper, Wyoming 82601.

SUPPLEMENTARY INFORMATION: This notice of invitation will be published in a newspaper once each week for two consecutive weeks beginning the week of July 10, 1989, and in the **Federal Register**. Any party electing to participate in this exploration program must send written notice to both the Bureau of Land Management and to Cordero Mining Company no later than 30 days after publication of this invitation in the **Federal Register**. The written notice should be sent to the following addresses: Mr. Stephen M. Schoen, Regulatory Affairs and Permitting Coordinator, Cordero Mining Company, P.O. Box 1499, Gillette, Wyoming 82717-1449 and the Bureau of Land Management, Wyoming State Office, Branch of Mining Law and Solid Minerals, P.O. Box 1828, Cheyenne, Wyoming 82003-1828.

The foregoing is published in the **Federal Register** pursuant to Title 43 Code of Federal Regulations, § 3410.2-1(c)(1).

David J. Walters,

Acting State Director.

[FR Doc. 89-16046 Filed 7-7-89; 8:45 am]

BILLING CODE 4310-22-M

[NV-060-4321-02]

Battle Mountain District Advisory Council; Rescheduled Meeting

AGENCY: Bureau of Land Management, Interior.

ACTION: Correction; Date of Battle Mountain District Advisory Council meeting in Battle Mountain, Nevada.

SUMMARY: Federal Register Document 89-14292, appearing in 54 Federal Register 25502 on June 15, 1989, incorrectly identified the date of the Battle Mountain District Advisory Council meeting. The meeting will be held on Wednesday, July 12, 1989, and will convene at 9:00 a.m.

With the exception of the date of the meeting, all other items published in Federal Register Document 89-14292 remain unchanged.

Date: June 27, 1989.

James D. Currivan,

District Manager.

[FR Doc. 89-16047 Filed 7-7-89; 8:45 am]

BILLING CODE 4310-HC-M

[NV-060-09-4320-02]

Battle Mountain District Grazing Advisory Board Meeting

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Grazing Advisory Board Meeting

SUMMARY: In accordance with Pub. L. 94-579 and section 3, Executive Order 12548 of February 14, 1986, a meeting of the Battle Mountain District Grazing Advisory Board will be held.

DATE: August 16, 1989, beginning at 1:00 p.m. in the Tonopah Convention Center, 301 Brougher, Tonopah, Nevada.

SUPPLEMENTAL INFORMATION: The meeting agenda will include: (1) Election of Chairperson and Vice Chairperson, (2) Status of FY 89 range improvements, and (3) FY 90 range improvement proposals.

The meeting is open to the public. Interested persons may make oral statements to the board between 4:00 and 4:30 p.m. on August 16, 1989, or file written statements for the Board's consideration. If you wish to make oral comments, please contact James D. Currivan by August 9, 1989.

FOR FURTHER INFORMATION CONTACT: James D. Currivan, District Manager, P.O. Box 1420, Battle Mountain, Nevada 89820 or phone (702) 635-5181.

Date Signed: June 30, 1989.

James D. Currivan,

District Manager, Battle Mountain, Nevada.

[FR Doc. 89-16074 Filed 7-7-89; 8:45 am]

BILLING CODE 4310-HC-M

[CO-920-89-4111-15; COC44871]

Colorado; Proposed Reinstatement

Notice is hereby given that a petition for reinstatement of oil and gas lease COC44871 for lands in Mesa County, Colorado, was timely filed and was accompanied by all the required rentals and royalties accruing from February 1, 1989, the date of termination.

The lessee has agreed to new lease terms for rentals and royalties at rates of $5.00 and 16⅔ percent, respectively.

The lessee has paid the required $500 administrative fee for the lease and has reimbursed the Bureau of Land Management for the estimated cost of this **Federal Register** notice.

Having met all the requirements for reinstatement of the lease as set out in section 31 (d) and (e) of the Mineral Lands Leasing Act of 1920, as amended, (30 U.S.C. 188), the Bureau of Land Management is proposing to reinstate the lease effective February 1, 1989, subject to the original terms and conditions of the lease and the increased rental and royalty rates cited above.

Questions concerning this notice may be directed to Joan Gilbert of the Colorado State Office at (303) 236-1772.

Janet M. Budzilek,

Chief, Fluid Minerals Adjudication Section.

[FR DOC. 89-16048 Filed 7-7-89; 8:45 am]

BILLING CODE 4310-JB-M

[AZ-942-09-4730-12]

Arizona; Filing of Plats of Survey

June 28, 1989.

1. The plats of survey of the following described lands were officially filed in the Arizona State Office, Phoenix, Arizona, on the dates indicated:

A plat (in two sheets) representing a dependent resurvey of a portion of the south boundary and a portion of the subdivisional lines, and a survey of the subdivision of section 33 and a metes-and-bounds survey in sections 28 and 33, Township 14 North, Range 20 West, Gila and Salt River Meridian, Arizona, was accepted June 2, 1989, and was officially filed June 5, 1989.

This plat was prepared at the request of the Bureau of Land Management, Lands and Minerals Operations.

2. These plats will immediately become the basic records for describing the land for all authorized purposes. These plats have been placed in the open files and are available to the public for information only.

3. All inquiries relating to these lands should be sent to the Arizona State Office, Bureau of Land Management, P.O. Box 16563, Phoenix, Arizona 85011.

James P. Kelley,

Chief, Branch of Cadastral Survey.

[FR Doc. 89-16049 Field 7-7-89; 8:45 am]

BILLING CODE 4310-32-M

Fish and Wildlife Service

Availability of Draft Recovery Plan for White Cat's Paw Pearly Mussel for Review and Comment

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability and public comment period.

SUMMARY: The U.S. Fish and Wildlife Service announces the availability for public review of a draft recovery plan for the white cat's paw pearly mussel. This species occurs in streams in northwestern Ohio and possibly in northeastern Indiana. The Service solicits review and comment from the public on this draft plan.

DATES: Comments on the draft recovery plan must be received on or before August 24, 1989 to receive consideration by the Service.

ADDRESSES: Persons wishing to review the draft recovery plan may examine a copy during normal business hours at the Twin Cities Regional Office, the Reynoldsburg Field Office, or the Bloomington Field Office. Persons wishing to obtain a copy of the recovery plan should contact the Twin Cities Office. Written comments and materials regarding the plan should be addressed to the Twin Cities Office. All comments and materials received will be available for public inspection, by appointment, during normal business hours at that office for the duration of the comment period.

Twin Cities Regional Office: Division of Endangered Species, U.S. Fish and Wildlife Service, Federal Building, Fort Snelling, Twin Cities, Minnesota 55111, (612) 725-3276.

Reynoldsburg Field Office: U.S. Fish and Wildlife Service, 6950-H Americana Parkway, Reynoldsburg, Ohio 43068, (614) 469-6923.

Bloomington Field Office: U.S. Fish and Wildlife Service, 718 North Walnut Street, Bloomington, Indiana 47401, (812) 334-4261.

FOR FURTHER INFORMATION CONTACT: Ronald L. Refsnider, at the above Twin Cities Regional Office address.

SUPPLEMENTARY INFORMATION:

Background

Restoring endangered or threatened animals and plants to the point where they are again secure, self-sustaining members of their ecosystems is a primary goal of the U.S. Fish and Wildlife Service's endangered species program. To help guide the recovery effort, the Service is working to prepare recovery plans for most of the listed species native to the United States. Recovery plans describe actions considered necessary for conservation of the species, criteria for recognizing the recovery levels for downlisting or delisting them, and initial estimates of times and costs to implement the recovery measures needed.

The Endangered Species Act of 1973 (Act), as amended (16 U.S.C. 1531 et seq.) requires the development of recovery plans for listed species unless such a plan would not promote the conservation of a particular species. Section 4(f) of the Act as amended in 1988 requires that public notice and an opportunity for public review and comment be provided during recovery plan development. The Service will consider all information presented during a public comment period prior to approval of each new or revised recovery plan. The Service and other Federal agencies will also take these comments into account in the course of implementing approved recovery plans.

The white cat's paw pearly mussel is currently known to occur only in Fish Creek (a tributary of the St. Joseph River) in Williams County, Ohio. Due to its low population level and limited distribution, the species is unlikely to recovery to the point that it can be removed from the list of threatened and endangered species. Therefore, the recovery plan is focused upon protecting and preserving the only known population of white cat's paw pearly mussels. Other recovery plan tasks deal with surveys for additional populations, life history research, and public education programs. If the Fish Creek population can be adequately protected the recovery plan describes subsequent steps to be taken to reestablish additional populations of the species within its historic range.

Public Comments Solicited

The Service solicits written comments on this recovery plan. All comments received by the date specified above will be considered prior to approval of the plan.

Authority

The authority for this action is Section 4(f) of the Endangered Species Act, 16 U.S.C. 1533(f).

Dated: June 29, 1989.

Marvin E. Moriarty,

Acting Regional Director.

[FR Doc. 89-16045 Filed 7-7-89; 8:45 am]

BILLING CODE 4310-55-M

Minerals Management Service

Outer Continental Shelf Advisory Board Gulf of Mexico Regional Technical Working Group Meeting

AGENCY: Minerals Management Service, Interior.

ACTION: Notice of Gulf of Mexico Regional Technical Working Group (RTWG) Meeting.

SUMMARY: Notice of this meeting is issued in accordance with the Federal Advisory Committee Act (Pub. L. No. 92-463). The Gulf of Mexico RTWG meeting will be held August 1-2, 1989, at the Ramada Inn-North, 2900 North Monroe Street, Tallahassee, Florida. Dates and times are as follows:

August 1, 1989—9:00 a.m. to 4:15 p.m.
August 2, 1989—9:00 a.m. to 11:30 a.m.

Tentative agenda items for the business meeting include:

Gulf of Mexico Current Activities
Gulf of Mexico Trends in Leasing, Exploration, and Development
Status of Task Forces: Presidential and State/Federal
Call for Comments on New 5-Year Program (1992-1997)
Scoping Report—Call for Information, Proposed Sales 131/135/137
Exxon Valdez Oil Spill—Government's and Industry's Response

FOR FURTHER INFORMATION: This meeting is open to the public. Individuals wishing to make oral presentations to the Committee concerning agenda items should contact Eileen P Angelico of the Gulf of Mexico OCS Regional Office at (504) 736-2959 by July 28, 1989. Written statements should be submitted by the same date to the Gulf of Mexico OCS Region, Minerals Management Service, 1201 Elmwood Park Boulevard, New Orleans, Louisiana 70123. A taped cassette transcript and complete summary minutes of the Business Meeting will be available for public inspection in the Office of the Regional Director at the above address not later than 60 days after the meeting.

SUPPLEMENTARY INFORMATION: The Gulf of Mexico RTWG is one of six such Committees that advises the Director of the Minerals Management Service on technical matters of regional concern regarding offshore prerelease and postlease sale activities. The RTWG membership consists of representatives from Federal Agencies, the coastal States of Alabama, Florida, Louisiana, Mississippi, and Texas, the petroleum industry, the environmental community, and other private interests.

Date: June 29, 1989.

J. Rogers Pearcy,

Regional Director, Gulf of Mexico OCS Region.

[FR Doc. 89-16068 Filed 7-7-89; 8:45 am]

BILLING CODE 4310-MR-M

RAILROAD RETIREMENT BOARD

Agency Forms Submitted for OMB Review

AGENCY: Railroad Retirement Board.

ACTION: In accordance with the Paperwork Reduction Act of 1980 (44 U.S.C. Chapter 35), the Board has submitted the following proposal(s) for the collection of information to the Office of Management and Budget for review and approval.

Summary of Proposal(s)

(1) *Collection title:* Railroad Separation Allowance or Severance Pay Report.

(2) *Form(s) submitted:* BA-9.

(3) *OMB Number:* New collection.

(4) *Expiration date of current OMB clearance:* Three years from date of OMB approval.

(5) *Type of request:* New collection.

(6) *Frequency of response:* Quarterly.

(7) *Respondents:* Businesses or other for-profit.

(8) *Estimated annual number of respondents:* 500.

(9) *Total annual responses:* 1,500.

(10) *Average time per response:* 1.25 hours.

(11) *Total annual reporting hours:* 1,875.

(12) *Collection description:* Section 7301 of the Railroad Unemployment and Retirement Improvement Act of 1988 (Pub. L. 100-647) provides for a lump-sum payment to an employee or the employee's survivor equal to the Tier 2 taxes paid by the employee on a separation allowance or severance payment for which the employee did not receive credits towards retirement. The collection obtains the information needed from railroad employers concerning the separation allowances and severance payments paid after December 31, 1988.

Additional Information or Co
Copies of the proposed forms a: supporting documents can be obtained from Ronald Ritter, the agency clearance officer, (312–751–4692). Comments regarding the information collection should be addressed to Ronald Ritter, Railroad Retirement Board, 844 Rush Street, Chicago, Illinois 60611 and the OMB reviewer, Justin Kopca, (202–395–7316), Office of Management and Budget, Room 3002, New Executive Office Building, Washington, DC 20503.

Ronald Ritter,

Acting Director of Information Resources Management.

[FR Doc. 89–16050 Filed 7–7–89; 8:45 am]

BILLING CODE 7905–01–M

Agency Forms Submitted for OMB Review

AGENCY: Railroad Retirement Board.

ACTION: In accordance with the Paperwork Reduction Act of 1980 (44 U.S.C. Chapter 35), the Board has submitted the following proposal(s) for the collection of information to the Office of Management and Budget for review and approval.

Summary of Proposal(s)

(1) *Collection title:* Medical Reports.

(2) *Form(s) submitted:* G–3EMP G–250, G–260, RL–11b and RL–11d.

(3) *OMB Number:* 3220–0038.

(4) *Expiration date of current OMB clearance:* Three years from date of OMB approval.

(5) *Type of request:* Extension of the expiration date of a currently approved collection without any change in the substance or in the method of collection.

(6) *Frequency of response:* On occasion.

(7) *Respondents:* State or local governments, Businesses, or other for-profit, Non-profit institutions, Small businesses or organizations.

(8) *Estimated annual number of respondents:* 27,400

(9) *Total annual responses:* 27,400

(10) *Average time per response:* .38883 hours.

(11) *Total annual reporting hours:* 10,654.

(12) *Collection description:* The Railroad Retirement Act provides disability annuities for qualified railroad employees whose physical or mental condition renders them incapable of working in their regular occupation (occupational disability) or any occupation (total disability). The medical reports obtain information needed for determining the nature and severity of the impairment.

Additional Information or Comments: Copies of the proposed forms and supporting documents can be obtained from Ronald Ritter, the agency clearance officer (312–751–4692). Comments regarding the information collection should be addressed to Ronald Ritter, Railroad Retirement Board, 844 Rush Street, Chicago, Illinois 60611 and the OMB reviewer, Justin Kopca (202–395–7316), Office of Management and Budget, Room 3002, New Executive Office Building, Washington, DC 20503.

Ronald Ritter,

Acting Director of Information Resources Management.

[FR Doc. 89–16051 Filed 7–7–89; 8:45 am]

BILLING CODE 7905–01–M

SECURITIES AND EXCHANGE COMMISSION

[Rel. No. 34–26974; File No. SR–CBOE–89–10]

Self-Regulatory Organizations; Proposed Rule Change by Chicago Board Options Exchange, Inc., Relating to Delta Position Limits

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934, 15 U.S.C. 78s(b)(1), notice is hereby given that on June 12, 1989 the Chicago Board Options Exchange, Incorporated ("CBOE" or "Exchange") filed with the Securities and Exchange Commission the proposed rule change as described in Items I, II and III below, which Items have been prepared by the self-regulatory organization. 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

(Brackets indicate deletions and italic indicates additions.)

Rule 24.4 (a)*(i)* In determining compliance with Rule 4.11, option contracts on a market index shall be subject to a contract limitation fixed by the board, which shall not be larger than 25,000 contracts on the same side of the market, with no more than 15,000 of such contracts in the series of such market index with the nearest expiration date, *except as described in subparagraph (ii) below.*

(ii) In determining compliance with Rule 4.11, market-makers in options contracts on a market index may elect, subject to prior Exchange approval, position limits not to exceed the following standard:

15,000 DEC (total delta equivalent contracts); and 35,000 adjusted DEC (adjusted for potential liquidation risk), where DEC is defined as the absolute value of the sum of the number of series contracts (i.e., the number of contracts held of a given series) multiplied by the series delta for all series of a market index class. The adjusted DEC is the number of delta equivalent contracts calculated separately for the long call/short put series and for the short call/long put series, where the option series deltas are constrained to be at least .25. The maximum DEC and maximum adjusted DEC positions are the greatest positions, respectively, determined by calculating the DEC and the adjusted DEC at 2% intervals over a range of market movement of from −20% through +20%.

Where the positions of related accounts are currently aggregated to determine compliance with subparagraph (a)(i), such positions shall similarly be aggregated to determine compliance with this subparagraph (a)(ii). Where the use of this alternate standard for any of such aggregated accounts is disapproved, none of the aggregated accounts may elect the position limits of this subparagraph (a)(ii). Positions in the same series in aggregated accounts shall not be netted when calculating either the DEC or the adjusted DEC.

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 self-regulatory organization 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 and is set forth in sections (A), (B), and (C) below.

(A) Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

The Exchange herein proposes a one year pilot of a market maker position limit based upon delta equivalent contracts in market index option classes. The purpose of the proposal is to provide market makers the ability to more effectively respond to retail and institutional orders without increasing unduly the risk in maintaining the resulting positions.

This position limit proposal is divided

into two components: the total delta equivalent contracts in a market index class (DEC) and the DEC adjusted for potential liquidation risk (adjusted DEC). Both the DEC and the adjusted DEC are to be calculated at 2% intervals over a range of market movement of from −20% to +20%, with a minimum delta set at .25 when determining the adjusted DEC. The maximum number of contracts calculated under these two tests may not exceed 15,000 and 35,000, respectively. The calculation of a maximum DEC over a broad range of market movement has been proposed to account for the tendency of delta to change rapidly in volatile markets. The establishment of a minimum delta of .25 for the liquidation test ensures that the potential impact of deep out-of-the-money contracts is not minimized. The pilot shall be limited to those market makers in market index contracts who have received Exchange approval to elect this delta standard, based upon their submissions to the Exchange of acceptable written applications, which shall include, but not be limited to, a copy of the member's computer program for calculating the DEC and adjusted DEC positions.

This proposal is consistent with the provisions of the Securities Exchange Act of 1934, and in particular, section 6(b)(5), in that the proposal is designed to perfect the mechanism for a free and open market, to enhance the ability of investors to use options for investment purposes, and to protect investors and the public interest.

(B) Self-Regulatory Organization's Statement on Burden on Competition

This 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

Comments were neither solicited nor 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 published its reasons forso 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 submission 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 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 above-mentioned self-regulatory organization. All submissions should refer to the file number in the caption above and should be submitted by July 31, 1989.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.

Jonathan G. Katz,

Secretary.

Dated: June 26, 1989.

Exhibit 1

The DEC is defined as the absolute value of: Sum [series contracts series delta] for all series.

The maximum DEC is defined in the relation:

Max DEC=Max [DEC(−20%), DEC(−18%), DEC(−2%), DEC, DEC(2%) DEC(18%), DEC(20%)] which must be less than 15,000.

Similarly, the maximum adjusted DEC is defined in the relation:

Max adjusted DEC=Max [Sum LongMarket, Sum ShortMarket] which must be less than 35,000,

where, at a given index level:

Sum LongMarket=Sum (abs (series contracts × option delta) for all series that are long the market i.e., long calls and short puts, and

Sum ShortMarket=Sum (abs (series contacts × option delta) for all series that are short the market i.e., long calls and short puts, and

subject to the condition that the option delata is set at 0.25 if it is less than 0.25 initially, and the Max is over the index moves −20% to +20% by 2% increments. The term "abs" means the absolute value.

EXAMPLE.—AS AN EXAMPLE, CONSIDER THE FOLLOWING CALENDAR SPREAD: DATE; 9-1-88. INDEX AT 250. INTEREST RATE: 7%. VOLATILITY: 20%.

[long 20,000 255 NOV calls—79 days to exp.]

[short 20,000 255 OCT calls—51 days to exp.]

Index at	NOV delta	OCT delta	DEC	Adj DEC
−20% 200	.0082	.0010	143	5,000
−18% 205	.0163	.0030	267	5,000
−16% 210	.0302	.0076	453	5,000
−14% 215	.0521	.0173	698	5,000
−12% 220	.0842	.0354	976	5,000
−12% 225	.1280	.0660	1,240	5,000
−8% 230	.1842	.1128	1,428	5,000
−6% 235	.2519	.1777	1,485	5,038
−4% 240	.3292	.2602	1,379	6,583
−2% 245	.4127	.3568	1,117	8,254
250	4986	4615	742	9,972
+2% 255	.5829	.5668	322	11,658
+4% 260	.6620	.6657	(72)	13,313
+6% 265	.7333	.7526	(387)	15,052

EXAMPLE.—AS AN EXAMPLE, CONSIDER THE FOLLOWING CALENDAR SPREAD: DATE; 9-1-88. INDEX AT 250. INTEREST RATE: 7%. VOLATILITY: 20%.—Continued

[long 20,000 255 NOV calls—79 days to exp.]

[short 20,000 255 OCT calls—51 days to exp.]

Index at	NOV delta	OCT delta	DEC	Adj DEC
+8% 270	.7949	.8245	(592)	16,491
+10% 275	.8463	.8806	(686)	17,613
+12% 280	.8877	.9221	(687)	18,442
+14% 285	.9200	.9511	(624)	19,023
+16% 290	.9443	.9705	(525)	19,411
+18% 295	.9621	.9829	(416)	19,658
+20% 300	.9748	.9904	(313)	19,908
Max [adj DEC]				1,485
Max [adj DEC]				19,808

DEC=20,000×NOV Delta−20,000×OCT delta.
adj DEC=Max [20,000×NOV Delta, 20,000×OCT delta] where the option delta is taken to be at least 0.25.

[FR Doc. 89-16109 Filed 7-7-89; 8:45 am]
BILLING CODE 8010-01-M

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

Reports, Forms, and Recordkeeping Requirements; Submittals to OMB on July 3, 1989

AGENCY: Department of Transportation (DOT), Office of the Secretary.

ACTION: Notice.

SUMMARY: This notice lists those forms, reports, and recordkeeping requirements imposed upon the public which were transmitted by the Department of Transportation on July 3, 1989, to the Office of Management and Budget (OMB) for its approval in accordance with the requirements of the Paperwork Reduction Act of 1980 (44 U.S.C. Chapter 35).

FOR FURTHER INFORMATION CONTACT: John Chandler, Annette Wilson, or Cordelia Shepherd, Information Requirements Division, M-34, Office of the Secretary of Transportation, 400 Seventh Street, SW Washington, DC 20590, telephone, (202) 366-4735, or Gary Waxman or Edward Clarke, Office of Management and Budget, New Executive Office Building, Room 3228, Washington, DC 20503, (202) 395-7340.

SUPPLEMENTARY INFORMATION:

Background

Section 3507 of Title 44 of the United States Code, as adopted by the Paperwork Reduction Act of 1980, requires that agencies prepare a notice for publication in the **Federal Register**, listing those information collection requests submitted to the Office of Management and Budget (OMB) for initial approval, or for renewal, under that Act. OMB reviews and approves agency submittals in accordance with criteria set forth in that Act. In carrying out its responsibilities, OMB also considers public comments on the proposed forms, reporting and recordkeeping requirements. OMB approval of an information collection requirement must be renewed at least once every three years.

Information Availability and Comments

Copies of the DOT information collection requests submitted to OMB may be obtained from the DOT officials listed in the "For Further Information Contact" paragraph set forth above. Comments on the requests should be forwarded, as quickly as possible, directly to the OMB officials listed in the "For Further Information Contact" paragraph set forth above. If you anticipate submitting substantive comments, but find that more than 10 days from the date of publication are needed to prepare them, please notify the OMB officials of your intent immediately.

Items Submitted for Review by OMB

The following information collection requests were submitted to OMB on July 2, 1989.

DOT No.. 3237
OMB No.. 2130-0504
Administration: Federal Railroad Administration
Title: Special Notice for Repairs

Need for Information: To determine if proper repairs have been made to freight cars, locomotives, or track which was found unsafe and was removed from service.

Proposed Use of Information: To notify the railroad in writing of an unsafe condition involving a car, a locomotive, or track.

Frequency: On occasion
Burden Estimate: 47 hours
Respondents: 400 Railroads
Form(s): None
Average Burden Hours Per Respondent: 5 minutes
DOT No.. 3238
OMB No.. 2137-0575
Administration: Research and Special Programs Administration
Title: Bulk Packaging Marking Requirements

Need for Information: To aid emergency response personnel in determining what hazards and actions are needed in the event of an accident or other incident involving hazardous materials in transportation.

Proposed Use of Information: To allow emergency response personnel to determine if necessary to evacuate persons not involved in combatting the incident and type of equipment needed to control the fire, leakage, etc.

Frequency: Each package of bulk hazardous materials.
Burden Estimate: 247,000 hours annually
Respondents: Shippers and carriers of bulk packages of hazardous materials.
Form(s): None
Average Burden Hours Per Respondent: 5 minutes
DOT No: 3239
OMB No: 2133-0008
Administration: Maritime Administration

Title: Statement of Shipbuilder or ship operator in Compliance with Section 807 of the Merchant Marine Act 1936.

Need for Information: To document requests to present matters before the agency.

Proposed Use of Information: To evaluate requests to present matters before the agency.

Frequency: Monthly
Burden Estimate: 290 hours
Respondents: Attorneys, Lobbyists
Form(s): MA-807-2

Average Burden Hours Per Respondent: 20 minutes
DOT No: 3240
OMB No: 2115-0504
Administration: U.S. Coast Guard
Title: Tank Vessel Examination Letter, Certificate of Compliance, Boiler/Pressure Vessel Repairs, Cargo Gear Records and Shipping Papers
Need for Information: This information collection requirement is needed to enable the Coast Guard to fulfill its responsibilities of ensuring maritime safety.
Proposed Use of Information: Coast Guard uses this information as a means to indicate compliance with safety standards and regulation.
Frequency: On occasion
Total Estimated Burden: 22202
Respondents: Some owners/operators of large merchant vessels and all foreign flag tankers calling at U.S. ports
Form(s): CG-840S-1 and CG-840S-2
Average Burden Per Response: Reporting burden is 10 minutes; recordkeeping burden is 3 hours and 24 minutes.
DOT No: 3241
OMB No: 2115-0553
Administration: U.S. Coast Guard
Title: Equivalent and Approved Equipment
Need for Information: This information is needed to implement the best available and safest technological concept to comply with the Outer Continental Shelf (OCS) Lands Act.
Proposed Use of Information: Coast Guard uses this information for comparison with existing standards or procedures to insure that at least an equivalent level of safety is maintained as provided for in the regulations.
Frequency: On occasion
Burden Estimate: 10
Respondents: Owners, operators, equipment manufacturers and subcontractors
Form(s): N/A
Average Burden Hours Per Respondent: 10 hours
DOT No: 3242
OMB No: 2115-0559
Administration: U.S. Coast Guard
Title: Stability Regulation
Need for Information: Coast Guard needs this requirement to enforce the laws and regulations promoting the safety of life and property in marine transportation.
Proposed Use of Information: Coast Guard uses this information to determine if the vessel meets the appropriate stability requirements.
Frequency: On occasion
Burden Estimate: 12,360
Respondents: Naval Architects, Shipbuilders and Ship Operators
Form(s): N/A
Average Burden Hours Per Respondent: 3 hours reporting; 4 hours and 30 minutes recordkeeping
DOT No: 3243
OMB No: 2137-0550
Administration: Research and Special Programs Administration
Title: Rail Carrier and Tank Car Tank Requirements
Need for Information: To verify that rail tank cars are properly maintained for transport of hazardous materials.
Proposed Use of Information: To verify that rail tank cars are in a safe condition for transporting hazardous materials and that they are properly routed, stored, loaded and unloaded.
Frequency: Annually
Burden Estimate: 10,159 hours annually
Respondents: Rail carriers and owners of rail tank car tanks.
Form(s): None
Average Burden Hours Per Respondent: 43 minutes
DOT No: 3244
OMB No: 2125-0541
Administration: Federal Highway Administration
Title: Certification of Enforcement of Heavy Vehicle Use Tax
Need for Information: For FHWA to obtain certification from each State as proof of payment of the heavy vehicle use tax.
Proposed Use of Information: For each State to certify proof of payment of heavy vehicle use tax and to provide supporting records for each vehicle subject to the tax.
Frequency: Annually
Burden Estimate: 612
Respondents: State highway agencies
Form(s):
Average Burden Hours Per Response: 2 hours reporting and 10 hours recordkeeper.
DOT No: 3245
OMB No: 2120-0098
Administration: Federal Aviation Administration
Title: Airplane Operator Security—FAR 108
Need for Information: The information is needed to ensure compliance with FAR 108 by the air carriers in providing protection of persons and property of the traveling public against criminal violence and aircraft piracy.
Proposed Use of Information: The security programs required by FAR 108 indentify the procedures to be used by air carriers in carrying out their responsibilities under the law with regard to the protection of persons and property against acts of criminal violence and aircraft piracy. The information is reviewed by FAA Civil Aviation Security Inspectors to ensure that the contents of the program are current, complete, and correct. The X-ray System Radiation Leakage Report is used to ascertain that the X-ray system meets all applicable requirements.
Frequency: On occasion
Burden Estimate: 6,479 total hours annually
Respondents: Air carriers
Form(s): FAA Form 1650-17
Average Burden Hours Per Response: 1 hour and 20 minutes

Issued in Washington, DC on July 3, 1989.

Richard B. Chapman,
Acting Director of Information Resource Management.

[FR Doc. 89-16052 Filed 7-7-89; 8:45 am]
BILLING CODE 4910-62-M

Coast Guard

[CGD 89-051]

Houston/Galveston Navigation Safety Advisory Committee Meeting

Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463; 5 U.S.C. App. I) notice is hereby given of the twenty-first meeting of the Houston/Galveston Navigation Safety Advisory Committee. The meeting will be held on Thursday, September 21, 1989 in the conference room of the Houston Pilots Office, 8150 South Loop East, Houston, Texas. The meeting is scheduled to begin at approximately 9:30 a.m. and end at approximately 1:00 p.m. The agenda for the meeting consists of the following items:

1. Call to Order
2. Presentation of the minutes of the Inshore and Offshore Waterways Subcommittees and discussion of recommendations.
3. Discussion of previous recommendations made by the Committee.
4. Presentation of any additional new items for consideration of the Committee.
5. Adjournment.

The purpose of this Advisory Committee is to provide recommendations and guidance to the Commander, Eighth Coast Guard District on navigation safety matters affecting the Houston/Galveston area.

Attendance is open to the public. Members of the public may present written or oral statements at the meeting.

Additional information may be obtained from Commander C. T. Bohner, USCG, Executive Secretary, Houston/Galveston Navigation Safety Advisory Committee, c/o Commander, Eighth Coast Guard District (oan), Room 1141, Hale Boggs Federal Building, 500 Camp Street, New Orleans, LA 70130-3396, telephone number (504) 589-4686.

Dated: June 20, 1989.

W.F Merlin,

Rear Admiral, U.S. Coast Guard Commander, Eighth Coast Guard District.

[FR Doc. 89-16065 Filed 7-7-89; 8:45 am]

BILLING CODE 4910-14-M

[CGD 89-052]

Houston/Galveston Navigation Safety Advisory Committee; Inshore Waterway Management Subcommittee Meeting

Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463; 5 U.S.C. App. I) notice is hereby given of a meeting of the Inshore Waterway Management Subcommittee of the Houston/Galveston Navigation Safety Advisory Committee. The meeting will be held on Thursday, August 24, 1989 at the West Gulf Maritime Association, 1717 East Loop, Suite 200, Houston, Texas.The meeting is scheduled to begin at 9:00 a.m. and end at 10:30 a.m. The agenda for the meeting consists of the following items:

1. Call to Order
2. Discussion of previous recommendations made by the full Advisory Committee and the Inshore Waterway Management Subcommittee.
3. Presentation of any additional new items for consideration of the Subcommittee.
4. Adjournment.

Attendance is open to the public. Members of the public may present written or oral statements at the meeting.

Additional information may be obtained from Commander C.T. Bohner, USCG, Executive Secretary, Houston/Galveston Navigation Safety Advisory Committee, c/o Commander, Eighth Coast Guard District (oan), Room 1141, Hale Boggs Federal Building, 500 Camp Street, New Orleans, LA 70130-3396, telephone number (504) 589-4686.

Dated: June 20, 1989.

W.F Merlin,

Rear Admiral, U.S. Coast Guard Commander, Eighth Coast Guard District.

[FR Doc. 89-16066 Filed 7-7-89; 8:45 am]

BILLING CODE 4910-14-M

[CGD 89-053]

Houston/Galveston Navigation Safety Advisory Committee; Offshore Waterway Management Subcommittee Meeting

Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463; 5 U.S.C. App. I) notice is hereby given of a meeting of the Offshore Waterway Management Subcommittee of the Houston/Galveston Navigation Safety Advisory Committee. The meeting will be held on Thursday, August 24, 1989 at the West Gulf Maritime Association, 1717 East Loop, Suite 200, Houston, Texas. The meeting is scheduled to begin at 10:30 a.m. and end at 12:00 p.m. The agenda for the meeting consists of the following items:

1. Call to Order
2. Discussion of previous recommendations made by the full Advisory Committee and the Onshore Waterway Management Subcommittee.
3. Presentation of any additional new items for consideration by the Subcommittee.
4. Adjournment.

Attendance is open to the public. Members of the public may present written or oral statements at the meeting.

Additional information may be obtained from Commander C.T. Bohner, USCG, Executive Secretary, Houston/Galveston Navigation Safety Advisory Committee, c/o Commander, Eighth Coast Guard District (oan), Room 1141, Hale Boggs Federal Building, 500 Camp Street, New Orleans, LA 70130-3396, telephone number (504) 589-4686.

Dated: June 20, 1989.

W.F Merlin,

Rear Admiral, U.S. Coast Guard Commander, Eighth Coast Guard District.

[FR Doc. 89-16067 Filed 7-7-89; 8:45 am]

BILLING CODE 4910-14-M

Federal Highway Administration

Environmental Impact Statement; Lucas, Ottawa, and Wood Counties, OH

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of intent.

SUMMARY: The FHWA is issuing this notice to advice the public that an environmental impact statement (EIS) will be prepared for a proposed highway project in Lucas, Ottawa, and Wood Counties, Ohio.

FOR FURTHER INFORMATION CONTACT: Mr. Fred J. Hempel, Division Administrator, or Mr. Roberto Fonseca-Martinez, District Engineer, Federal Highway Administration, 200 North High Street, Columbus, Ohio 43215. Telephone: (614) 469-6896 or 469-7443.

SUPPLEMENTARY INFORMATION: The Federal Highway Administration, in cooperation with the Ohio Department of Transportation, will prepare an environmental impact statement on the proposed construction of approximately 27.4 miles of new highway in Lucas, Ottawa, and possibly Wood Counties, from the interchange of Interstate Route 280 and State Route 2 in the City of Oregon easterly to a point on an improved section of State Route 2 approximately 1.25 miles west of State Route 358 near Camp Perry, just west of the City of Port Clinton on Lake Erie.

The proposed highway, an improvement of the State Route 2, would have new roadway on or adjacent to the alignment of the existing route. Approximately 13.2 miles would be five-lane roadway and approximately 14.2 miles would be four-land divided roadway, with full access.

Other alternatives under consideration include the following: (1) Adding additional lanes to existing Interstate Route 280 from its interchange with State Route 2 south to the Curtice Road interchange, constructing a four-lane divided highway on new location easterly to the existing alignment of State Route 2 near its junction with State Route 579, and then following the existing alignment to the easterly terminus near Camp Perry; (2) modifying the last scheme to shift the alignment south of State Route 579 for approximately four miles east of Williston; and (3) providing Interstate 280 with additional lanes south to the Walbridge Road interchange, constructing a fully controlled, limited access facility easterly to existing State Route 2 south of the Toussaint River, approximately six miles west of State Route 358, and then paralleling existing State Route 2 to the easterly terminus on the improved portion of the route. The no-build alternative is also under consideration.

The proposed project would complete the improvement of State Route 2 from the Toledo metropolitan area to the Cleveland metropolitan area, thereby providing an uninterrupted multiple-lane facility. It would also give better access to the numerous recreational facilities and area, along Lake Erie and in the surrounding area, helping to allieviate seasonal and weekend traffic. It would serve commuters in the Toledo area. The

proposed project would also fulfill the goals of long-term planning for the region.

A program of public involvement and coordination with Federal, State, and local agencies has been conducted. It is envisioned that involvement with the public and other agencies will continue throughout the development of the project and, therefore, it is not anticipated that a formal scoping meeting will held.

To insure that the full range of issues related to this proposed action are addressed and that all significant issues are identified, comments or questions concerning this action and the EIS should be addressed to the FHWA at the address provided above.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program)

Issued on:

Roberto Fonseca-Martinez,

District Engineer.

[FR Doc. 89-16114 Filed 7-7-89; 8:45 am]

BILLING CODE 4910-22-M

Environmental Impact Statement; Wayne and Wilson Counties, NC

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of intent.

SUMMARY: The FHWA is issuing this notice to advise the public that an environmental impact statement will be prepared for a proposed highway project between the cities of Goldsboro and Wilson, North Carolina.

FOR FURTHER INFORMATION CONTACT: Robert L. Lee, District Engineer, Federal Highway Administration, 4505 Falls of Neuse Road, Raleigh, North Carolina 27611, Telephone (919) 790-2856.

SUPPLEMENTARY INFORMATION: The FHWA in cooperation with the North Carolina Department of Transportation (NCDOT) will prepare an environmental impact statement (EIS) for the improvement of the US 117 Corridor between Wilson and Goldsboro. The proposed action would be the construction of a multilane divided highway, potentially on a new location with controlled access from US 301, southwest of Wilson, to US 70, north of Goldsboro, a distance of about 21 miles. The thoroughfare plans for both Wilson and Wayne Counties include US 117 Improvements to the corridor are considered necessary to increase safety and traffic service between Wilson and Goldsboro.

Alternatives under consideration include: (1) The "no-build" (2) improving existing facilities, (3) partial relocation, and (4) a controlled access highway on new location.

Solicitation of comments on the proposed action are being sent to appropriate Federal, State and local agencies. A complete public involvement program has been developed for the project to include: the distribution of newsletters to interested parties, along with public meetings and a public hearing to be held in the study area. Information on the time and place of the public hearing will be provided in the local news media. The draft EIS will be available for public and agency review and comment prior to the public hearing. No formal scoping meeting is planned at this time.

To assure that the full range of issues related to this proposed action are addressed and all significant issues identified, comments and suggestions are invited from all interested parties. Comments or questions concerning this proposed action and the EIS should be directed to the FHWA at the address provided above.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Research, Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program)

Issued on: June 29, 1989.

Robert L. Lee,

District Engineer, Raleigh, NC.

[FR Doc. 89-16076 Filed 7-7-89; 8:45 am]

BILLING CODE 4910-22-M

Federal Railroad Administration

Petitions for Waivers of Compliance; Southern Pacific Transportation Co. et al.

In accordance with 49 CFR 211.9 and 211.41, notice is hereby given that the Federal Railroad Administration (FRA) has received requests for waivers of compliance with certain requirements of its safety standards. The individual petitions are described below, including the parties seeking relief, the regulatory provisions involved, and the nature of the relief being requested.

Southern Pacific Transportation Company

[Waiver Petition Docket Number LI-89-4]

The Southern Pacific Transportation Company (SP) requests a conditional waiver of compliance with § 229.91 of the Railroad Locomotive Safety Standards (49 CFR Part 229) which stiulates that, A motor or generator may not have any of the following conditions:

(a) Be shorted or grounded.

(b) Throw solder excessively.

(c) Show evidence of coming apart.

(d) Have an overheated support bearing.

(e) Have an excessive accumulation of oil.

Section 229.9(b) states that, A locomotive that develops a non-complying condition enroute may continue to utilize its propelling motors, if the requirements of paragraph (a) are otherwise fully met, until the earlier of—

(1) The next calendar day inspection, or

(2) The nearest forward repair point where the repairs necessary to bring it into compliance can be made.

If condition (1) occurs first and the calendar day inspection performed on a locomotive with a traction motor cut out enroute reveals that said traction motor is defective as described in § 229.91, the carrier is permitted to move the locomotive only under the provisions of § 229.9(a), that is, tagged as a non-complying locomotive and moved to a repair point as a lite locomotive or a dead locomotive. The SP states, "Even though [traction] motors may be cutout for a variety of reasons (i.e. transition problems, loading problems, etc.), Rule 229.9(b) requires that traction motors cutuout enroute be considered a 'major defect' and requires that the locomotive be tagged 'non-complying locomotive' and the defect repaired at the *nearest* forward point where repairs can be made or within the 'next calendar day inspection' or moved lite or dead in train.

The SP goes on to say, "[D]ue to extreme distances [between a calendar day inspection point and a repair facility where traction motors can be repaired], strict compliance is oftentimes difficult within the next calendar day inspection and it is punitive to cut a serviceable unit out of revenue service and suffer the cost incurred from out of service time, delay and dead in train movement. When motors are cut out, SP practice is to inspect it for unsafe conditions (i.e. locked axle, noise, etc.), and operate the locomotive to destination.

The SP requests that it be granted a waiver providing that if a traction motor is cut out enroute and no safety-related condition exists with the motor (and it is not in compliance with § 229.91), that the locomotive be allowed to operate in

revenue service beyond the next calendar day inspection, if necessary, to reach a destination at which repairs can be made by direct route. The SP says, "In considering this matter, please understand the significant detrimental impact a negative finding would have on train schedules and locomotive utilization, with no off-setting safety benefits.

Napa Valley Railroad Company

[Waiver Petition Docket Number LI-89-5]

The Napa Valley Railroad Company (NVR) requests a waiver of compliance with certain provisions of the Railroad Locomotive Safety Standards (49 CFR Part 229). The NVR request is that it be permitted to operate a dead locomotive as a controlling locomotive contrary to the requirements of § 229.9(d), which states, A dead locomotive may not continue in use following a calendar day inspection as a controlling locomotive or at the head end of a train of locomotive consist. Also, the dead locomotive would have its slip/slide alarm nullified and not be in compliance with § 229.115(b), which states in part that "* an equipped locomotive may not be dispatched in road service, or continue in road service following a daily inspection, unless the wheel slip/slide protective device of whatever type—

(1) Is functioning for each powered axle under power; and

(2) Would function on each powered axle if it were under power.

The NVR recently purchased four Alco FA-4 passenger diesel electric locomotives to be used in hauling passenger trains at low speeds (25 mph) through the Napa Valley between Napa and St. Helena, California, a distance of 21 miles. Two of the four locomotives, Nos. 70 and 71, were purchased in excellent operating condition, according to the railroad. The locomotives Nos. 72 and 73 were not operable when purchased, but the NVR thought that it would not require much work or cost to return them to service. However, the carrier found this not to be the case and states that budget constraints and manpower shortages could affect its ability to complete repairs for a year.

The NVR plan is to operate the four locomotives, which are carbody type A locomotives with an engineer's control compartment at one end, in back-to-back paired consists. One paired consist would be used per train. Each consist would have two operating control compartments, but only one locomotive would be capable of producing power and the other would be dead and not capable of producing power. The carrier selected this operational procedure because it has no turning facility at either end of its railroad, but does have passing sidings where the locomotive consist can run around the train.

The NVR is requesting a temporary one-year waiver from § 229.9(d) and § 229.115(b) in order for it to operate dead locomotives Nos. 72 and 73 as controlling locomotives when hauling a passenger train. The carrier needs the one-year period of time to complete repairs to the two dead locomotives.

Oregon, California & Eastern Railway Company

[Waiver Petition Docket Number LI-89-6]

The Oregon, California & Eastern Railway Company (OC&E) requests a waiver of compliance with certain provisions of the Railroad Locomotive Safety Standards (49 CFR Part 229) in Subpart B, "Inspection and Tests. The OC&E specifically seeks waivers of § 229.23, "Periodic Inspection, General" and § 229.33, "Out-of-Use Credit.

The OC&E states that it "is a 64-mile long common carrier primarily engaged in hauling logs for conversion to finished products and asphaltic compounds for road oiling and paving The OC&E owns five locomotives that are maintained by Weyerhaeuser Company, the parent of the OC&E. As a result of severe economic conditions, the OC&E now only operates about six months a year. However, during the six-month period of no log hauling, periodic cars of asphalt are switched for our other customers. This could be one job per month for approximately two hours

The OC&E states that "very seldom is a locomotive out of service for the '30 or more consecutive days' described in § 229.33, which is a necessary prerequisite for automatically extending the time intervals for the inspections required in Subpart B. During the "92-day inspection period, the locomotive could conceivably run no more than four times (eight hours total) but still require a 'periodic inspection' as described in § 229.23.

The OC&E is requesting a waiver that will allow it to use actual hours run (eight hours equals one day) to reach the 92-day inspection frequency. All of [their] locomotives are operated on a per-hour basis, they are not interchanged, and there would be no additional costs in tracking operating time to schedule inspections. The OC&E estimates a savings of $11,000 per year if the waiver petition is approved; further, it feels that this current expenditure "has not resulted in an increase in safety or productivity.

Southern Pacific Transportation Company; Norfolk Southern Corporation

[Waiver Petition Docket Numbers PB-89-3 and SA-89-6]

The Southern Pacific Transportation Company (SP) and the Norfolk Southern Corporation (NS) (on behalf of its operating subsidiaries) jointly request waivers of compliance with certain provisions of the Railroad Safety Appliance Standards (49 CFR Part 231), under Docket No. SA-89-6, and the Railroad Power Brakes and Drawbars Regulations (49 CFR Part 232), under Docket No. PB-89-3.

The SP and NS seek these waivers of compliance to permit the operation of railroad/highway vehicles which are designated as "RoadRailer" units. The SP and NS are entering into an agreement for the SP to use NS RoadRailer equipment between East St. Louis, Illinois and Dallas, Houston and San Antoinio, Texas. The SP proposes to interchange RoadRailer equipment with the NS at Valley Junction in East St. Louis.

The NS is presently operating 1,600 RoadRailer vehicles under a conditional waiver (Docket Numbers SA-87-2 and PB-87-4) issued by FRA on July 28, 1987 (See notice of waiver petitions, 52 FR 16326, May 4, 1987 for more detailed discussion.) These vehicles are almost identical to the standard semi-trailer presently used to haul cargo over the highway, the only difference being that they are equipped with a special drawbar, railroad running wheels and a special railroad air brake system. The railroad wheels are mounted on a single axle between the tandem highway wheels of the semi-trailer on the Mark IV RoadRailer. The Mark V RoadRailer is carried on a standard 70-ton freight car truck equipped with a suitable adaptor to accommodate and support the vehicle. The Mark IVs and Mark Vs are indiscriminately operated together in NS trains. The RoadRailer vehicles, by design, cannot be subjected to traditional switching procedures conducted in railroad classification yards. The coupler assembly will only couple to another RoadRailer vehicle or to a specially designed adapter car between the locomotive and a RoadRailer train, and the drawbar height is nonstandard.

The conditional waiver granted to the NS permits noncompliance with all the provisions of the Railroad Safety Appliance Standards (49 CFR Part 231). These standards nclude provisions that provide the number, location and

dimensional specifications for the handholds, ladders and sill steps that are required for each railroad freight and passenger car. In addition, the NS waiver permits noncompliance with a provision of the Railroad Power Brakes and Drawbars Regulations (49 CFR 232.2) which regulates height of drawbars. It was for these reasons that the NS applied for relief from Parts 231 and 232. It is for the same reasons that the SP is seeking conditional waivers similar to those that were granted to the NS. One of the conditions of the NS waiver is that the NS is not permitted to interchange the RoadRailer units with any other railroads, except the operating subsidiaries of the NS Corporation (Norfold Western Railway and Southern Railway). The SP and NS are petitioning the FRA to have this conditgion modified so as to allow interchange of the RoadRailer units between the SP and NS to provide the service described in the SP's petition. The SP and NS would agree to all other terms and conditions that presently exist for the operation of the RoadRailer equipment by the NS.

Interested parties are invited to participate in this proceeding by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with this proceeding since the facts do not appear to warrant a hearing. If any interested parties desire an opportunity for oral comment they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning this proceeding shold identify the appropriate docket number (e.g., Waiver Petition Docket Numbert LI 89–4) ands must be submitted in triplicate to the Docket Clerk, Office of Chief Counsel, Federal Railroad Administration, Nassif Building, 400 Seventh Street SW Washington. DC 20590. Communications received before August 24, 1989 will be considered by FRA before final action is taken. Comments received after that date will be considered as far as practicable. All written communications concerning this proceeding are available for examination during regular business hours (9 a.m. to 5 p.m.) in Room 8201 Nassif Building, 400 Seventh Street SW Washington, DC 20590.

Issued in Washington, DC on June 30, 1989.

J.W. Walsh,

Associate Administrator for Safety.

[FR Doc. 89–16059 Filed 7–7–89; 8:45 am]

BILLING CODE 4910–06–M

Maritime Administration

[Docket No. S–853]

Waterman Steamship Corp., Application for Privilege Call Service on Trade Routes 10 and 13

By letter of June 29, 1989, Waterman Steamship Corporation (Waterman), applied pursuant to the Merchant Marine Act, 1936, as amended (Act), for authority to provide privilege call service on Trade Routes (TR) 10 and 13, excluding ports in Portugal, Spain, France, and Italy. Alternatively stated, the proposed privilege call service would encompass trade between U.S. Atlantic and Gulf ports and ports in Atlantic Morocco and the Mediterranean Sea, including the Adriatic Sea, Ionian Sea, Aegean Sea, and Black Sea, but excluding ports in Spain, France, and Italy. Waterman proposes to make its privilege calls on a maximum of 25 sailings annually.

Waterman presently operates four LASH vessels on TRs 18 and 17 between U.S. Atlantic and Gulf ports and ports in the Middle East and South and Southeast Asia, with authorization to perform up to 40 subsidized sailings annually. On 18 of those sailings, Waterman already is authorized to provide privilege call service between the U.S. Gulf/South Atlantic and Egypt. However, Waterman believes that since all of its TRs 18/17 sailings transit the Mediterranean, and since there is an obvious need for added service to and from other Mediterranean countries, Waterman seeks to expand its privilege call service. Nevertheless, Waterman claims that there would be no increase in the operating-differential subsidy paid to it, since all the proposed privilege calls would be performed in conjunction with Waterman s already authorized sailings on TRs 18/17

Waterman states that the requested privilege service will be provided with the U.S.-flag LASH vessels now owned or operated by Waterman and its affiliates, or with vessels that may be acquired hereafter, excluding full containerships. Waterman will continue to operate its service, including the requested privilege calls, in a manner that will not preclude it from receiving at least 50 percent of its inbound gross revenues and at least 50 percent of its out gross revenues from the carriage of commercial cargoes, conference-rated civilian preference cargoes, or open-rated civilian preference cargoes carried at world rates.

According to Waterman, under the provisions of section 605(c) of the Act, Waterman's application should be granted if U.S.-flag service on TRs 10 and 13 (excluding Portugal, Spain, France, and Italy) is found to be inadequate and in the accomplishment of the purposes and policy of the Act additional US.-flag service should be provided. Waterman submits that the most recently available U.S. Bureau of Census data for these routes shows the following cargo movements in long tons:

	Outbound total	U.S. (percent)	Inbound total	U.S. (percent)
TRs 10 and 13	10,035,647	29	837,926	31
TR 10	287,136	26	425,202	33
TR 13	748,511	30	412,724	28

1988 preliminary annual totals, excluding Portugal, Spain, France, and Italy.

Thus, for the predominant leg of the combined TR 10/13 service proposed by Waterman, U.S.-flag service is only 29 percent, which Waterman indicates is drastically below the 50 percent U.S. flag participation consistently required in order to achieve adequate U.S.-flag service. Waterman avers that the relevant percentages for TRs 10 and 13, taken separately, are virtually the same, demonstrating obvious U.S.-flag inadequacy.

Given the clear inadequacy of U.S. flag service in the trades encompassed by Waterman's application, Waterman contends that the need for added U.S. flag service is readily apparent. That need especially exists in regard to *non*-container service by U.S.-flag vessels, according to Waterman, which has been sorely lacking since the termination of the TRs 10 and 13 LASH service previously offered by Prudential Lines, Inc. Waterman proposes to fill that gap and to offer an attractive U.S.-flag alternative to the foreign-flag vessels that overwhelmingly dominate non-container service to these routes.

Waterman believes that all the foregoing facts establish a prima facie

case warranting approval of this particular privilege call application without the need for a full evidentiary hearing. Rather, a "show-cause" type proceeding would suffice to afford full participation and a hearing to all interested parties.

This application may be inspected in the Office of the Secretary, Maritime Administration. Any person, firm, or corporation having any interest in such request and desiring to submit comments concerning the application must file written comments in triplicate with the Secretary, Maritime Administration, Room 7300, Nassif Building, 400 Seventh Street SW Washington, DC 20590. Comments must be received no later than 5:00 P.M. on July 20, 1989. The Maritime Subsidy Board will consider any comments submitted and take such action with respect thereto as may be deemed appropriate.

(Catalog of Federal Domestic Assistance Program No. 20.804 (Operating-Differential Subsidies))

By Order of the Maritime Subsidy Board.

Date: July 6, 1989.

James E. Saari,

Secretary.

[FR Doc. 89-16169 Filed 7-7-89; 8:45 am]

BILLING CODE 4910-81-M

National Highway Traffic Safety Administration

Announcement of Fifth Meeting of the Rollover Subcommittee of the Motor Vehicle Safety Research Advisory Committee

AGENCY: National Highway Traffic Safety Administration (NHTSA), DOT.

ACTION: Meeting announcement.

SUMMARY: This notice announces the fifth meeting of the Rollover Subcommittee of the Motor Vehicle Safety Research Advisory Committee (MVSRAC). The MVSRAC established this subcommittee at the February 1988 meeting to examine research questions regarding crashworthiness and crash avoidance for vehicles under 10,000 pounds GVW

DATE AND TIME: The meeting is scheduled for Thursday, July 27 1989, from 10:00 a.m. to 5:00 p.m.

ADDRESS: The meeting will be held in Room 6200 of the U.S. Department of Transportation Building, which is located at 400 Seventh Street, SW Washington, DC.

SUPPLEMENTARY INFORMATION: In May 1987 the Motor Vehicle Safety Research Advisory Committee was established. The purpose of the Committee is to provide an independent source of ideas for safety research. The MVSRAC will provide information, advice, and recommendations to NHTSA on matters relating to motor vehicle safety research, and provide a forum for the development, consideration, and communication of motor vehicle safety research, as set forth in the MVSRAC Charter.

This meeting of the Rollover Subcommittee will focus on crash avoidance and crashworthiness subjects. Discussions will cover: effects of high lift suspensions on braking, steering and rollover; effects of stability and control on rollover propensity; reconstruction of rollover accidents; test maneuvers to induce rollover; and other crash avoidance research.

The meeting is open to the public, and participation by the public will be determined by the Subcommittee Chairman.

Records shall be kept of all Subcommittee proceedings and shall be available for public inspection in public reference file Number 88-01—Rollover Subcommittee during the hours of 8:00 a.m. to 4:00 a.m. in the National Highway Traffic Safety Administration s Technical Reference Division, Room 5108, 400 Seventh Street, SW Washington, DC 20590, telephone: (202) 366-2768.

FOR FURTHER INFORMATION CONTACT: Louis V Lombardo, Office of Research and Development, 400 Seventh Street, SW Room 6208, Washington, DC 20590, telephone: (202) 366-4862.

Issued on: July 3, 1989.

Howard M. Smolkin,

Chairman, Motor Vehicle Safety Research Advisory Committee.

[FR Doc. 89-16036 Filed 7-7-89; 8:45 am]

BILLING CODE 4910-59-M

DEPARTMENT OF THE TREASURY

Public Information Collection Requirements Submitted to OMB for Review

Date: July 3, 1989.

The Department of Treasury has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1980, Pub. L. 96-511. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, Room 2224, 1500 Pennsylvania Avenue, NW Washington, DC 20220.

Internal Revenue Service

OMB Number: 1545-0091
Form Number: 1040X
Type of Review: Revision
Title: Amended U.S. Individual Income Tax Return
Description: Form 1040X is used by individuals to claim a refund of income taxes, pay additional income taxes, or designate a dollar to a presidential election campaign fund. The information is needed to help verify that the individual has correctly figured his or her income tax.
Respondents: Individuals or households, Farms, Businesses or other for-profit
Estimated Number of Respondents/ Recordkeepers: 2,300,000
Estimated Burden Hours Per Response:
Recordkeeping, 1 hour, 12 minutes
Learning about the law or the form, 19 minutes
Preparing the form, 1 hour, 13 minutes
Copying, assembling, and sending the form to IRS, 35 minutes
Frequency of Response: On occasion
Estimated Total Recordkeeping/ Reporting Burden: 7,636,000 hours

OMB Number: 1545-0121
Form Number: 1116
Type of Review: Revision
Title: Computation of Foreign Tax Credit—Individual, Fiduciary, or Nonresident Alien Individual
Description: Form 1116 is used by individuals (including nonresident aliens) and fiduciaries who paid foreign income taxes on U.S. taxable income, to compute the foreign tax credit. This information is used by IRS to verify the foreign tax credit.
Respondents: Individuals or households
Estimated Number of Respondents/ Recordkeepers: 589,900
Estimated Burden Hours Per Response:
Recordkeeping, 2 hours, 44 minutes
Learning about the law or the form, 39 minutes
Preparing the form, 1 hour, 23 minutes
Copying, assembling, and sending the form to IRS, 35 minutes
Frequency of Response: Annually
Estimated Total Recordkeeping/ Reporting Burden: 3,150,066 hours

OMB Number: 1545-0139
Form Number: 2106
Type of Review: Revision
Title: Employee Business Expenses
Description: Internal Revenue Code section 62 allows employees to deduct their businesses expenses to the extent of reimbursement in computing Adjusted Gross Income. Expenses in

excess of reimbursements are allowed as an itemized deduction. Unreimbursed meals and entertainment are allowed to the extent of 80% of the expense. Form 2106 is used to figure these expenses.
Respondents: Individuals or households
Estimated Number of Respondents/ Recordkeepers: 5,797,756
Estimated Burden Hours Per Response:
Recordkeeping, 2 hours, 17 minutes
Learning about the law or the form, 19 minutes
Preparing the form, 1 hour, 19 minutes
Copying, assembling, and sending the form to IRS, 35 minutes
Frequency of Response: Annually
Estimated Total Reporting Burden: 26,089,902 hours
OMB Number: 1545–0257
Form Number: 8109, 8109A, and 8109B
Type of Review: Extension
Title: Federal Tax Deposit Coupon, FTD Reorder Form
Description: Federal Tax Deposit Coupons are used to deposit various taxes at authorized depositaries. Coupons are sent to IRS centers for crediting to taxpayers' accounts. Data is used by IRS to make the credit and to verify tax deposits claimed on returns. FTD Reorder Form is used to request more coupons. Affected public is all taxpayers required to use the deposit system.
Respondents: State or local governments, Farms, Businesses or other for-profit, Federal agencies or employees, Non-profit institutions, Small businesses or organizations
Estimated Number of Respondents/ Recordkeeping: 9,800,700
Estimated Burden Hours Per Response:

	8109	8109a	8109B
Recordkeeping	1 hr., 39 min	58 minutes	1 hr., 55 min.
Preparing the form	1 minute	2 minutes	2 minutes.

Frequency of Response: Eight-monthly and semi-monthly
Estimated Total Recordkeeping/ Reporting Burden: 175,709,825 hours
OMB Number: 1545–0998
Form Number: 8615
Type of Review: Revision
Title: Computation of Tax for Children Under Age 14 Who Have Investment Income of More Than $1,000
Description: Under section 1 (i), children under age 14 who have unearned income may be taxed on part of that income at their parent's tax rate. Form 8615 is used to see if any of the child's unearned income is taxed at the parent's rate and, if so, to figure the child's tax on his or her unearned income and earned income, if any
Respondents: Individuals or households
Estimated Number of Respondents/ Recordkeepers: 500,000
Estimated Burden Hours Per Response:
Recordkeeping, 7 minutes
Learning about the law or the form, 5 minutes
Preparing the form, 28 minutes
Copying, assembling, and sending the form to IRS, 17 minutes
Frequency of Response: Annually
Estimated Total Reporting Burden: 480,000 hours
Clearance Officer: Garrick Shear, (202) 535–4297 Internal Revenue Service, Room 5571, 1111 Constitution Avenue NW Washington, DC 20224
OMB Reviewer: Milo Sunderhauf, (202) 395–6880, Office of Management and Budget, Room 3001, New Executive Office Building, Washington, DC 20503.

Lois K. Holland,
Departmental Reports Management Officer.

[FR Doc. 89–16075 Filed 7–7–89; 8:45 am]
BILLING CODE 4810–25–M

UNITED STATES INFORMATION AGENCY

Grants Program for Private Not-For-Profit Organizations in Support of International Educational and Cultural Activities

The United States Information Agency (USIA) announces a program of selective assistance and limited grant support to non-profit activities of United States institutions and organizations in the private sector. The program is designed to increase mutual understanding between the people of the U.S. and other countries and to strengthen the ties which unite our societies. The information collection involved in this solicitation is covered by OMB Clearance Number 3116–0175 entitled A Grants Program for Private, Non-Profit Organization in Support of International Educational and Cultural Activities, announced in the **Federal Register** February 9, 1989.

Private Sector organizations interested in working cooperatively with USIA on the following concept are encouraged to so indicate:

Government Regulation of Private Enterprise

This project would bring to the United States two separate twelve-member mixed delegations of government officials and private business executives from Africa, the Near East, and South Asia. This four-week program is designed to explain how private sector business activities in the United States are regulated, both by government agencies at the national, state and local levels and by businesses themselves, often through professional associations. Each delegation will be from four to six key countries. The project would provide the participants with alternative models of regulating business practices through various kinds of government regulation, self regulation and free market competition.

The Government Regulation of Private Enterprise program will take place in the Fall of 1989. USIA prefers that the project include stops in the midwest, south, New York City and Washington, DC If necessary to insure logistical coordination, the program may include co-sponsorship on a consultative basis with one or more other non-profit organizations.

USIA is most interested in working with organizations that show promise for innovative and cost-effective programming; and with organizations that have potential for obtaining private sector funding in addition to USIA

support. Organizations must have the substantive expertise and logistical capability needed to successfully develop and conduct the above project and should also demonstrate a potential for designing programs which will have lasting impact on their participants.

Interested organizations should submit a request for complete application materials—postmarked no later than twenty-one days from the date of this notice—to the address listed below. The Office of Private Sector Progams will then forward a set of materials, including proposal guidelines. Please refer to this specific program by name in your letter of interest: Office of Private Sector Programs, Bureau of Educational and Cultural Affairs (Attn: Dr. Raymond H. Harvey), United States Information Agency, 301 4th Street SW Room 216, Washington, DC 20547

Roger C. Rasco,

Deputy Director, Office of Private Sector Programs.

Date: June 30, 1989.

[FR Doc. 89-16054 Filed 7-7-89; 8:45 am]

BILLING CODE 8230-01-M

Sunshine Act Meetings

Federal Register
Vol. 54, No. 130
Monday, July 10, 1989

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).

July 5, 1989.

FEDERAL ENERGY REGULATORY COMMISSION.

DATE AND TIME: July 12, 1989, 10:00 a.m.

PLACE: 825 North Capitol Street, N.E., Room 9306, Washington, D.C. 20426.

STATUS: Open.

MATTERS TO BE CONSIDERED: Agenda.

*Note.—Items listed on the agenda may be deleted without further notice.

CONTACT PERSON FOR MORE INFORMATION: Lois D. Cashell, Secretary, Telephone (202) 357-8400.

This is a list of matters to be considered by the Commission. It does not include a listing of all papers relevant to the items on the agenda; however, all public documents may be examined in the Public Reference Room.

Consent Power Agenda, 900th Meeting—July 12, 1989 Regular Meeting (10:00 a.m.)

CAP-1.
Project No. 7633-004, Kenai Hydro, Inc.
CAP-2.
Project No. 190-002, Moon Lake Electrical Association, Inc.
CAP-3.
Project No. 5251-016, City of Fort Smith, Arkansas
CAP-4.
Project No. 10726-001, City and County of San Francisco
Project No. 10658-001, Pacific Water and Power, Inc.
CAP-5.
Project No. 10739-001, Casitas Municipal Water District
Project No. 10656-001, Pacific Water and Power, Inc.
CAP-6.
Project No. 3195-027 Sayles Hydro Associates
CAP-7
Project No. 2216-007, Power Authority of the State of New York
CAP-8.
Project No. 6221-003, Weyerhaeuser Company
CAP-9.
Project No. 2959-019, The City of Seattle, Washington
CAP-10.
Docket No. ER89-265-000, Arizona Public Service Company
CAP-11.
Docket No. ER89-110-001, Duke Power Company
CAP-12.
Docket No. EC88-2-006, Utah Power & Light Company, PacifiCorp and PC/UP&L Merging Corporation
CAP-13.
Docket No. ER89-47-000, Montaup Electric Company
CAP-14.
Omitted
CAP-15.
Docket No. EL89-26-000, Southern California Edison Company v. Arizona Public Service Company
CAP-16.
Docket No. QF89-98-000, United States Army Training Center and Fort Dix

Consent Miscellaneous Agenda

CAM-1.
Docket No. RM87-33-001, Hydroelectric Relicensing Regulations Under the Federal Power Act
CAM-2.
Docket No. RM89-15-000, Generic Determination of Rate of Return on Common Equity for Public Utilities
CAM-3.
(A) Docket No. FA86-23-002, Montaup Electric Company
(B) Docket No. RA85-8-001, Public Service Company of New Hampshire
CAM-4.
Docket No. GP89-35-000, Jennings Exploration Company
CAM-5.
Docket No. GP88-31-000, BASF Corporation, Complaint v. Samson Resources Company, Respondent

Consent Gas Agenda

CAG-1.
Docket No. RP89-136-003, Northern Natural Gas Company
CAG-2.
Docket No. RP89-196-000, Northwest Pipeline Corporation
CAG-3.
Docket Nos. RP85-209-023, RP86-93-000, RP86-156-000, RP88-8-000, CP86-246-000, RP87-34-000, TC88-6-000, RP88-92-017, RP88-27-000, RP88-263-000, RP88-264-000, RP88-265-000, CP88-440-000, CP87-524-000, CP88-329-000, CP88-478-000, RP82-42-000, IN86-5-001 and CP88-6-001, United Gas Pipe Line Company
CAG-4.
Docket Nos. RP89-140-003 and RP89-195-000, Williams Natural Gas Company
CAG-5.
Docket No. RP89-194-000, Texas Gas Transmission Corporation
CAG-6.
Docket Nos. TQ89-2-45-002 and RP89-14-006, Inter-City Minnesota Pipeline Ltd., Inc.
CAG-7
Docket Nos. RP89-130-003 and RP89-130-004, Transwestern Pipeline Company
CAG-8.
Docket No. TA89-1-59-000, Northern Natural Gas Company
CAG-9.
Omitted
CAG-10.
Docket No. RP88-94-024, Natural Gas Pipeline Company of America
CAG-11.
Docket No. RP88-221-007 Texas Eastern Transmission Corporation
CAG-12.
Docket Nos. RP89-154-001 and TM89-6-17-001, Texas Eastern Transmission Corporation
CAG-13.
Docket No. RP89-153-001, Texas Eastern Transmission Corporation
CAG-14.
Docket No. RP89-150-002, Texas Eastern Transmission Corporation
CAG-15.
Docket Nos. CP89-470-001 and CP88-552-006, Tennessee Gas Pipeline Company
CAG-16.
Docket No. TM89-3-21-001, Columbia Gas Transmission Corporation
CAG-17
Docket No. TQ89-7-51-002, Great Lakes Gas Transmission Company
CAG-18.
Docket No. RP89-44-002, Florida Gas Transmission Company
CAG-19.
Docket No. RP89-158-001, Mississippi River Transmission Corporation
CAG-20.
Docket No. RP89-51-002, United Gas Pipe Line Company
CAG-21.
Omitted
CAG-22.
Docket No. RP89-147-001, United Gas Pipe Line Company
CAG-23.
Docket No. RP88-259-009, Northern Natural Gas Company, Division of Enron Corporation
CAG-24.
Docket No. RP88-211-005, CNG Transmission Corporation
CAG-25.
Docket Nos. RP89-140-002, TA89-1-43-001 and RP88-39-002, Williams Natural Gas Company
CAG-26.
Docket Nos. RP88-190-002, TM89-2-27-003, TA88-1-27-004, RP88-57-002 and RP88-110-002, North Penn Gas Company
Docket Nos. RP85-178-000 and RP88-191-000, Tennessee Gas Pipeline Company
Docket Nos. RP88-68-000, RP88-68-001 and RP87-7-012, Transcontinental Gas Pipe Line Corporation
Docket No. RP88-217-000, CNG Transmission Corporation
CAG-27
Docket Nos. TQ89-1-46-017 RP86-165-011 and RP89-166-011, Kentucky West Virginia Gas Company
CAG-28.

Docket Nos. RP89-84-002 and RP88-228-015, Tennessee Gas Pipeline Company
CAG-29.
Omitted
CAG-30.
Docket Nos. RP88-45-000 and RP88-46-000, Arkla Energy Resources, A Division of Arkla, Inc.
CAG-31.
Docket Nos. IS88-24-000, Texas Eastern Products Pipeline Company
CAG-32.
Docket No. ST89-2352-000, Cranberry Pipeline Corporation
CAG-33.
Docket No. G-16679-001, Jupiter Corporation and Tennessee Gas Pipeline Company
CAG-34.
Docket No. GP89-37-000, Lester Pollack
CAG-35.
Omitted
CAG-36.
(A) Docket No. CP89-3-002, Panhandle Eastern Pipe Line Company
(B) Docket Nos. CP88-490-001 and CP88-548-001, Panhandle Eastern Pipe Line
(C) Docket Nos. CP89-23-000, CP89-64-000 and CP89-67-000, Williams Natural Gas Company
CAG-37
Docket No. CP84-34-001, Trunkline Gas Company
CAG-38.
Docket No. CP87-358-002, Tennessee Gas Pipeline Company
Docket No. CP87-428-002, CNG Transmission Corporation
CAG-39.
Docket No. CP87-75-002, Tennessee Gas Pipeline Company
CAG-40.
Docket No. CP89-465-001, Arkansas Oklahoma Gas Corporation
CAG-41.
Docket No. CP89-819-001, Panhandle Eastern Pipe Line Company
CAG-42.
Docket No. CP89-138-001, Panhandle Eastern Pipe Line Company
CAG-43.
Docket No. CP88-540-001, Northern Natural Gas Company, Division of Enron Corporation
CAG-44.
Docket No. CP88-286-003, Cascade Natural Gas Corporation v. Northwest Pipeline Corporation, Chevron Chemical Company, Intermountain Gas Company, Hadson Gas Systems, Inc., Llano, Inc., Corpus Christi Industrial Pipeline Company, and Transco Energy Marketing Company
CAG-45.
Docket No. CP86-232-028, Panhandle Eastern Pipe Line Company
CAG-46.
Docket No. CP89-782-001, Columbia Gas Transmission Corporation
CAG-47
Omitted
CAG-48.
Docket Nos. CP89-7-000 and 001, Transcontinental Gas Pipe Line Corporation
Docket Nos. CP88-194-000 and 001, National Fuel Gas Supply Corporation
Docket Nos. CP88-195-000, 001 and 002, PennEast Gas Service Company
CAG-49.
Docket Nos. CP89-129-000, 001, 002, 003, CP88-163-000 and 001, Columbia Gas Transmission Corporation
Docket Nos. CP89-656-000 and 001, Algonquin Gas Transmission Corporation
CAG-50.
Docket No. CP88-825-000, Northwest Pipeline Corporation
CAG-51.
Docket No. CP89-274-000, United Gas Pipe Line Company
CAG-52.
Docket No. CP88-869-000, Natural Gas Pipeline Company of America
CAG-53.
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Reserved

Lois D. Cashell,
Secretary.
[FR Doc. 89-16266 Filed 7-6-89; 3:57 pm]
BILLING CODE 6730-01-M

FEDERAL MARITIME COMMISSION

"FEDERAL REGISTER" CITATIONS OF PREVIOUS ANNOUNCEMENT: July 6, 1989—54 FR 28552.

PREVIOUSLY ANNOUNCED DATE AND TIME OF THE MEETING: July 10, 1989—3:00 p.m.

CHANGE IN THE MEETING: This meeting has been canceled.

CONTACT PERSON FOR MORE INFORMATION: Joseph C. Polking, Secretary, (202) 523-5725.

Joseph C. Polking,
Secretary.
[FR Doc. 89-16253 Filed 7-6-89; 2:45 pm]
BILLING CODE 6730-01-M

FEDERAL RETIREMENT THRIFT INVESTMENT BOARD

TIME AND DATE: 9:00 A.M. July 17 1989.

PLACE: 5th Floor, Conference Room, 805 Fifteenth Street, N.W Washington, D.C.

STATUS: Open.

MATTERS TO BE CONSIDERED:

1. Approval of the minutes of last meeting.
2. Thrift Savings Plan activities report by the Executive Director.
3. Review of proposed legislation.

CONTACT PERSON FOR MORE INFORMATION: Tom Trabucco, Director, Office of External Affairs, (202) 523-5660.

Francis X. Cavanaugh,
Executive Director, Federal Retirement Thrift Investment Board.
[FR Doc. 89-16320 Filed 7-7-89; 11:48 am]
BILLING CODE 6760-01-M

federal register

Monday
July 10, 1989

Part II

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 10, 310, 314, and 320
Abbreviated New Drug Application Regulations; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 10, 310, 314, and 320

[Docket No. 85N-0214]

RIN 0905-AB63

Abbreviated New Drug Application Regulations

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing regulations to implement Title I of the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417), which amends section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355). The proposal provides for the submission of abbreviated new drug applications for generic versions of drug products first approved after 1962. Before enactment of Pub. L. 98-417 abbreviated applications were permitted under FDA regulations for generic versions of drug products first approved between 1938 and 1962. These new provisions will benefit consumers by making generic drug products available more quickly.

DATES: Comments by October 10, 1989. FDA proposes that any final rule based on this proposal would become effective 60 days after its publication in the **Federal Register**.

ADDRESSES: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857

FOR FURTHER INFORMATION CONTACT: Marilyn L. Watson, Center for Drug Evaluation and Research (HFD-360), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857 301-295-8038.

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I. Introduction

On September 24, 1984, the President signed into law the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417). Title I of the law amended the Federal Food, Drug, and Cosmetic Act (the act) to expand the universe of drugs for which FDA would accept abbreviated new drug applications (ANDA s). Before enactment of Pub. L. 98-417 ANDA's were permitted under FDA regulations for duplicates, i.e., generic (different manufacturers') versions, only of drug products first approved between 1938 and 1962. The term "duplicate" applied to a drug product that was the same as an already approved drug product in dosage form, route of administration, kind and amount of active ingredient, indication(s), and any other conditions of use. The regulations permitted ANDA's for "similar" and "related" products only if FDA had made a separate finding, following a manufacturer's petition, that an ANDA was appropriate for that product. Title I provides for the submission of ANDA's for duplicates and certain related versions of drug products previously approved by FDA for safety and effectiveness and listed in the approved drug product list published by the agency. Title I further makes the existence of a patent on an approved drug a factor in the approval of generic copies of that drug, and establishes a system (the so-called "exclusivity provisions") for rewarding research associated with significant innovation by providing for a delay in the submission or effective approval date of certain generic applications.

Title II of Pub. L. 98-417 amended the patent law to provide for the extension, under certain circumstances, of the normal 17-year term of a product, use, or process patent of a patented product which is subject to premarketing clearance.

The proposed rule set forth below, if adopted as a final rule, will implement Title I of Pub. L. 98-417 Final regulations implementing the provisions of Title II of the law were published in the **Federal Register** of March 7 1988 (53 FR 7298). It should be noted that although antibiotics are expressly covered by Title II, they are not covered by Title I. Title I applies only to drugs approved under section 505 of the act (21 U.S.C. 355). Antibiotics are approved under section 507 of the act (21 U.S.C. 357). This proposed rule would, however, reorganize the current regulations governing the abbreviated antibiotic application procedures by placing them in a new subpart.

II. Background

The act as passed by Congress in 1938 established a system of premarket clearance for drugs under which applicants seeking drug approval were required to submit to FDA a new drug application containing, among other things, data showing the drug's safety. (Sections 201(p)(1) and 505(a) as enacted (21 U.S.C. 321(p) and 355(a)).) The law at that time provided that a new drug application would automatically become effective (i.e., the product could be lawfully marketed) within a fixed period unless the agency affirmatively refused to approve the application.

In addition to products for which a new drug application had become effective, many products were marketed without effective applications that were

identical, similar, or related to products with effective applications. Manufacturers of such products either had concluded that their products were generally recognized as safe, or had received advisory opinions from the agency that a new drug application was not required because their products were generally recognized as safe (i.e., were not "new drugs").

In 1962, Congress amended the drug approval provisions of the act to require affirmative approval of new drug applications before marketing. That approval was to be granted on the basis of a showing that a drug product was not only safe but also effective. (Pub. L. 87-781 (October 10, 1962).) Thus, on or after October 10, 1962, a new drug could not be marketed without an approved new drug application that contained, in addition to safety data, substantial evidence establishing that the drug was effective for its intended uses (21 U.S.C. 355(d)).

Under the 1962 amendments, new drug applications that had become effective before the effective date of those amendments were "deemed" approved. The requirement that drugs be shown to be effective for their intended uses was also made applicable to drugs that had been deemed approved. To implement this Congressional mandate, FDA undertook a program to evaluate the drugs that had been deemed approved to determine whether there was substantial evidence of their effectiveness, as the law required. The systematic evaluation of these drugs and the implementation of the findings of this evaluation became known as the Drug Efficacy Study Implementation (DESI). Under this program, FDA contracted with the National Academy of Sciences/National Research Council (NAS/NRC), which established panels of experts to review available evidence of effectiveness and to provide recommendations to the agency. FDA considered the NAS/NRC panels' recommendations about the effectiveness of these DESI drugs, and announced the agency's conclusions in **Federal Register** notices. These notices, referred to as DESI notices, set forth the acceptable marketing conditions for the class of products covered by the notice. The DESI review covered over 4,000 specific products which had had new drug applications evaluated for safety only and had been allowed to become effective between 1938 and 1962.

A. The Abbreviated New Drug Application (ANDA) Procedure for Pre-1962 Drugs

If a manufacturer had a pre-1962 new drug application in effect for a drug product, FDA continued its approval if the manufacturer submitted a supplemental new drug application to conform the product's indications for use to those determined to be effective in the DESI review. As noted above, however, there were many drug products on the market that were identical in active ingredients and indications or very similar to the drug products found effective in the DESI review but for which no new drug application had ever been submitted. In implementing the DESI program with respect to these duplicate products, FDA concluded that each such drug product was a "new drug" that required its own approved new drug application before it could be legally marketed. *United States* v. *Generix Drug Corp.*, 460 U.S. 453 (1983) (act's definition of "new drug" applies to the drug product rather than to the generic active ingredient). In addition, FDA issued a statement of policy that revoked the earlier advisory opinions that drugs could be marketed without preclearance by the agency. The statement of policy was published in the **Federal Register** of May 28, 1968 (33 FR 7758), and later codified at 21 CFR 310.100.

To provide an appropriate procedure for approval of duplicate products in reliance on the DESI evaluation, a procedure for submission of ANDA's was established (34 FR 2673 (February 27 1969); 35 FR 6574 (April 24, 1970)). After FDA had found through the DESI review that a particular drug product was effective and suitable for ANDA's, FDA published in the **Federal Register** a DESI notice announcing these conclusions; any manufacturer of a duplicate of the drug not already holding an approved new drug application was then required to submit an ANDA to obtain approval to market the duplicate version of the approved drug (35 FR 11273; July 14, 1970).

The approval of an ANDA before passage of Pub. L. 98-417 was based on the theory that the evidence of effectiveness necessary for approval of a new drug application had been provided, reviewed, and accepted during the DESI process. The evidence of safety of the drug had been determined on the basis of information included in the pioneer new drug application and by the subsequent marketing experience with the drug. The information currently required to be in an ANDA is specified in FDA's regulations in 21 CFR 314.55(e) and consists of information showing the applicant's ability to manufacture a product of acceptable quality that will be equivalent in its effectiveness and safety to the drug product whose safety and effectiveness is established. The ANDA thus contains information on the drug product's formulation, manufacture, quality control procedures, and labeling. In addition, the DESI notice may identify other information that FDA requires in an ANDA for a specific drug product, usually data on the bioavailability of the product showing that it is similar to that of a standard product. The ANDA, therefore, provides for agency review of the same kind of product quality information required in a full new drug application but omits the reports of investigations establishing the safety and effectiveness of the drug which are already established.

B. Procedure for Duplicates of Post-1962 Drugs ("Paper NDA Policy)

FDA's ANDA policy established for pre-1962 drugs was never extended to duplicates of drugs first approved for marketing on or after October 10, 1962. The agency long recognized the value of an ANDA system for the post-1962 drugs and at various times considered and announced the possibility of establishing such a system either by regulation or through legislation (see, e.g., Drug Regulation Reform Act of 1978 (95th Cong., 2d Sess. (1978), Drug Regulation Reform Act of 1979 (96th Cong., 1st Sess. (1979), and proposed rule of September 1, 1978 (43 FR 39126)). During the 1970's and early 1980's, patents expired for many post-1962 drugs, including some high volume, therapeutically important drugs. As a result, many drug manufacturers became increasingly interested in changing FDA's new drug approval system to permit the submission of ANDA s for duplicate versions of post-1962 drugs.

FDA did allow some duplicate drug products of drugs first marketed after 1962 to be marketed under FDA's "paper NDA policy. (See 46 FR 27396; May 19, 1981, publication of "Paper NDA memorandum.) Under that policy, FDA could approve new drug applications for post-1962 duplicate drug products on the basis of evidence of safety and effectiveness derived primarily from published reports, if those reports were of well-controlled studies, thus eliminating the need for manufacturers to perform most of their own tests. Although the courts upheld the legality of paper NDA's (see, e.g., *Burroughs Wellcome Co.* v. *Schweiker*, 649 F.2d 221 (4th Cir. 1981)), adequate literature, including detailed reports of adequate and well-controlled studies, was available for only a fraction of post-1962 drugs. Moreover, the staff effort involved in reviewing paper NDA s for

drugs that were already available and whose evidence of safety and effectiveness was already well documented in a prior application was a substantial and wasteful use of agency resources.

C. The Drug Price Competition and Patent Term Restoration Act of 1984

Beginning in 1978, Congress considered various forms of legislation that would have expressly authorized an ANDA procedure for duplicate versions of post-1962 drugs, and, concurrently, legislation to restore patent life lost during the new drug approval process. In 1984, Congress passed the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) which became law on September 24, 1984. The new law consists of two titles. Title I authorizes approval of generic new drugs and Title II authorizes extension of patent terms for approved new drugs. The two parts of the bill were intended to provide a careful balance between promoting competition among pioneer or brand-name and generic drugs, and encouraging research and innovation. The ANDA provisions of Title I provide for approval of duplicate or related versions of approved drugs whose patents have expired, and that have been shown through the ANDA approval requirements to be as safe and effective as their brand name counterparts, but without the submission of duplicative safety and effectiveness data. Thus, these provisions are intended to encourage competition by decreasing the time and expense of bringing generic drugs to market, and thereby to provide the public with low cost drugs.

The patent term extension provisions of Title II provide for the extension of drug patent terms beyond the normal 17 years to reflect the period of patent life lost during FDA's review of safety and effectiveness data for the drug. These extensions of patent life are intended to encourage the innovation necessary for the development of important new drug products, by increasing the period during which innovative products are protected from competition.

Title I specifically amends only the new drug provisions of the act at section 505 and applies only to nonantibiotic human drugs submitted and approved under section 505 of the act. The statutory authority for approving antibiotics, including generic antibiotics and antibiotics in combination with other antibiotics or nonantibiotic active ingredients, is section 507 of the act. Therefore, Title I does not apply to antibiotics. Title I does, however, apply to new drugs containing insulin. Although certified under section 506 of the act (21 U.S.C. 356), insulin-containing products are approved under section 505 of the act.

Section 505(j) of the act, as amended by the 1984 Amendments, establishes a statutory ANDA procedure for duplicate and related versions of previously approved pioneer drug products, in which Congress intended to adopt with few modifications the policies developed by FDA in the agency's approval of ANDA's for pre-1962 drugs. Section 505(b)(1) of the act, as amended, requires that certain patent information be submitted to FDA for all previously approved new drug applications, all newly submitted applications, and all applications previously submitted but not yet approved. Section 505(b)(2) of the act, as amended, provides for the submission and approval of applications for which the investigations relied on by the applicant to satisfy the "full reports" of safety and effectiveness requirement were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person who conducted the investigations.

Section 505(l) of the act establishes rules for the public disclosure of safety and effectiveness data submitted as part of a new drug application.

The new law also provides patent protection for the developer of pioneer new drugs by delaying the effective date of approval of an ANDA or 505(b)(2) application until all relevant product and use patents for the pioneer drug have expired, or until the patent owner is notified of, and given an opportunity to litigate, a challenge to such patents. In addition, for new chemical entities (active moieties never before approved in the U.S.) and significant innovations in already approved chemical entities, the law prohibits the submission or delays the effective date of approval of an ANDA or 505(b)(2) application during specified periods that are independent of the patent status of the pioneer drug.

The 1984 Amendments require FDA to promulgate new implementing regulations. The new law further provides that, until such time as FDA has new implementing regulations in effect, the currently existing regulations or ANDA's under § 314.55 (formerly § 314.2) will be effective, absent a conflict with the new law.

In the **Federal Register** of May 24, 1985 (50 FR 21460), FDA published a notice requesting public comment on Title I of Pub. L. 98–417 The notice also announced the establishment of a public file (Docket No. 85N–0214) for all comments, views, and other information submitted to FDA concerning Title I. The purpose of the notice was to obtain public comment on interpretation of the new law to assist the agency in its regulation writing process. In the **Federal Register** of August 7 1985 (50 FR 31887), FDA published a notice reopening for an unspecified period of time the period for public comment on Title I. Interested persons may now focus their comments on this proposed rule during the 90 day comment period on the proposal. Therefore, the period of time for comment on Title I under the August 7 notice ends on July 10, 1989.

Since passage of the 1984 Amendments, FDA has issued a series of letters to NDA and ANDA holders and applicants offering interim guidance on the more controversial provisions of the new law. Copies of these letters are in a public file under Docket No. 85N–0214. To the extent that the provisions of this proposed rule differ from the guidance in these letters, this proposed rule supersedes the previous guidance.

D. Relationship to New Drug Regulations

In the **Federal Register** of February 22, 1985 (50 FR 7452), FDA published revised regulations in 21 CFR Part 314 governing the approval for marketing of new drugs and antibiotic drugs for human use. Those regulations set forth procedures and requirements for the submission to, and the review by, FDA of full applications (NDA's) and abbreviated applications, as well as amendments, supplements, and postmarketing reports to such applications, by persons seeking or holding approval from FDA of an application under section 505 of the act to market a new drug or an application under section 507 of the act to market an antibiotic drug. Those regulations were not intended to implement the 1984 Amendments to the act. (See 50 FR 7466.) The provisions of this proposed rule further revise 21 CFR Part 314 to implement the 1984 Amendments.

III. Highlights of This Proposal

This proposed rule would (1) reorganize and revise 21 CFR Part 314 to incorporate the new requirements and procedures imposed upon applicants by the 1984 Amendments, and (2) revise 21 CFR Part 320 consistent with the bioequivalence requirements of the 1984 Amendments and current agency policy. The major provisions implementing the 1984 Amendments are summarized as follows:

A. Abbreviated Applications

New section 505(j) of the act governs the requirements and procedures for ANDA s. Under the statute, an ANDA is permitted for (1) a drug product that is the "same" as a drug product listed in the approved drug product list published by the agency (listed drug), with respect to active ingredient(s), route of administration, dosage form, strength, and conditions of use recommended in the labeling and (2) a drug product with certain changes from a listed drug if FDA has approved a petition from a prospective applicant permitting the submission of an ANDA for the changed drug product. The agency proposes in a new Subpart C to describe the content of and procedures for submission of an ANDA. The proposal would retain the current ANDA format which requires the submission of an archival and review copy of the ANDA. For an ANDA for a drug product that is the "same" as a listed drug, the focus of the proposed requirements is to provide FDA with sufficient information to assure that the drug product for which the applicant is seeking approval (1) is the same as the listed drug referred to by the applicant with respect to active ingredient(s), route of administration, dosage form, strength, and conditions of use, except for those conditions of use that are protected by patent or that have been accorded periods of exclusivity, (2) is bioequivalent to the listed drug, and (3) has the same labeling as that of the listed drug except for changes because the proposed drug has a different manufacturer or distributor. In addition, the regulations would require that the ANDA contain a certification with respect to product and use patents covering the listed drug and information about the applicant's ability to manufacture a drug product of acceptable quality.

B. ANDA Suitability Petitions

The statute provides that an ANDA applicant may petition FDA for permission to file an ANDA under section 505(j)(2)(C) of the act for a drug product that has one different active ingredient (permitted only in a combination product), or whose route of administration, dosage form, or strength differs from that of a listed drug. These are the only types of changes permitted in an ANDA. The proposed rule describes the kinds of information a petitioner must include in its petition to demonstrate to FDA that the change from the listed drug requested for the proposed drug product may be adequately evaluated for approval without data from investigations to show the safety and effectiveness of the proposed drug product or that a drug product with a different active ingredient may be adequately evaluated for approval as safe and effective on the basis of the information required to be submitted in an ANDA.

An ANDA submitted pursuant to an approved petition generally would be required to contain the same information as an ANDA for a drug product that is the same as a listed drug except that additional information may be required regarding the difference in the proposed drug product from the listed drug. In addition, FDA proposes to require that the listed drug referred to in the ANDA be the one upon which the petition was based and that the applicant refer in its ANDA to the petition and include in the ANDA a copy of FDA's response approving submission of the ANDA.

C. 505(b)(2) Applications

In addition to ANDA's, the 1984 Amendments recognize another type of application for an applicant seeking approval of a generic drug: a 505(b)(2) application. Although similar to FDA s "paper NDA policy, section 505(b)(2) of the act has broader applicability. Section 505(b)(2) of the act applies to any application for which the investigations relied on by the applicant to provide the "full reports" of safety and effectiveness required by section 505(b)(1)(A) of the act were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person who conducted the investigations. Thus, section 505(b)(2) of the act covers not only literature-supported NDA's for duplicates of approved drugs, but any NDA's for drug products that rely for approval on studies not conducted by or for the applicant or for which the applicant does not have a right of reference.

Applications described in section 505(b)(2) of the act are submitted under section 505(b)(1) of the act. They are therefore subject to the same statutory provisions that govern full new drug applications. However, the new statutory provisions impose on a 505(b)(2) applicant additional requirements with respect to patent certification, notification of such certification to the patent owner, and exclusivity that are generally the same as those that apply to ANDA's. The agency proposes to include in the regulations requirements applicable to 505(b)(2) applications.

D. Patent Information, Certification, and Notice of Certification to Patent Owner and Certain Application Holders

The statute prohibits the agency from making effective the approval of an ANDA or an application described by section 505(b)(2) of the act before all relevant product and use patents for the listed drug have expired, except where the generic applicant asserts either that its product will not infringe the patent or that the patent is invalid. In the latter case, approval of the ANDA or 505(b)(2) application may not be made effective until the patent owner and NDA holder have been notified and have had an opportunity to litigate the issue of patent infringement or validity. To facilitate the patent protection provisions, the statute requires that applications submitted under section 505(b) of the act include the patent number and expiration date of all relevant product patents that claim the drug in the application or use patents that claim a method of using the drug. The agency publishes this patent information in its approved drug product list for each listed drug for which patent information has been submitted. A generic drug applicant submitting an ANDA that refers to a listed drug must include a certification as to the status of all patents applicable to the listed drug. Similarly, an applicant submitting a 505(b)(2) application must make certifications with respect to patents claiming any listed drug on which investigations that are relied upon by the applicant for approval of its application were conducted or claiming a use for such listed drug. If a generic applicant certifies that a relevant patent expires on a specified date, the effective date of approval of the ANDA or 505(b)(2) application will be delayed until the expiration of the patent. When a generic applicant certifies that any product or use patent is invalid or will not be infringed, the applicant must give notice of such certification to the patent owner and appropriate approved application holder for the listed drug. The generic applicant must include in the notice the factual and legal basis for the applicant's opinion that the patent is invalid or will not be infringed. Finally, a patent owner or NDA holder has 45 days from receipt of the notice of certification to file suit against the generic applicant to defend the patent. If the patent owner or NDA holder files suit within 45 days, the effective date of approval of the ANDA or 505(b)(2) application may be delayed up to 30 months pending resolution of the lawsuit.

The proposed rule describes (1) the requirements for the submission of patent information by a pioneer NDA holder, (2) the patent certification requirements applicable to generic applicants and (3) the content of a patent certification notice. The proposal also specifies (1) when and to whom the notice is to be sent and (2) the effect of each type of patent certification on the effective date of approval of an application for a generic drug product.

E. Exclusivity

Sections 505(j)(4)(D) and 505(c)(3)(D) of the act protect certain listed drugs, or certain changes in listed drugs, from generic copying for specified periods by placing a moratorium on the submission, or by delaying the effective date of approval, of ANDA's and 505(b)(2) applications for those listed drugs. These so-called "exclusivity provisions" provide the following periods of protection from generic competition: (1) a 10-year period of exclusivity for new chemical entities approved during the period January 1, 1982, to September 24, 1984, the date of enactment of the 1984 Amendments; (2) a 5-year period of exclusivity for new chemical entities approved after September 24, 1984; (3) a 3-year period of exclusivity for non-new chemical entities approved after September 24, 1984, if the applicant submitted an application containing reports of "new clinical investigations (other than bioavailability studies) essential to the approval and conducted or sponsored by the applicant"· (4) a 3-year period of exclusivity for certain changes made after September 24, 1984, if the applicant submitted a supplement containing reports of "new clinical investigations (other than bioavailability studies) essential to the approval and conducted or sponsored by the person submitting the application"· and (5) a 2-year period of exclusivity for non-new chemical entities, or for certain changes made to already approved drug products, approved during the period January 1, 1982, to September 24, 1984.

The agency proposes to codify the first four of these five exclusivity provisions; the fifth provision will not be codified because it expired on September 24, 1986. The agency also proposes to define certain terms used in the regulations, and clarify the agency's interpretation of each of the provisions.

F Withdrawal or Suspension of Approval of an ANDA

The statute authorizes the Secretary to remove from the market, by withdrawal or suspension of approval, any generic drugs already approved if the approval of the listed drug referred to by the generic applicant is withdrawn or suspended or if the listed drug is voluntarily withdrawn from sale by its manufacturer for what the agency determines are safety or effectiveness reasons. The agency proposes to establish in the regulations a procedure for the withdrawal or suspension of approval of an ANDA under these circumstances.

IV The List

Section 505(j)(6) of the act requires FDA to publish and make publicly available a list of all drug products approved for safety and effectiveness under section 505(c) or approved under section 505(j) of the act. The agency's publication, Approved Drug Products with Therapeutic Equivalence Evaluations" (the list), and its monthly supplements, are being used to satisfy this statutory requirement. In accordance with section 505(j)(6) of the act, FDA updates the list monthly through publication of cumulative supplements. Under the act, a drug product approved for safety and effectiveness under section 505(c) or approved under section 505(j) is deemed to be a listed drug on the date of its approval even though the drug product is not actually included in the list until the next monthly update of the agency's published list. (See section 505(j)(6)(B) of the act.) A drug will not be listed as eligible for approval under an ANDA for the following reasons: (1) the approval of the drug product has been withdrawn or suspended for grounds described under section 505(e) (1) through (5) or 505(j)(5) of the act, or (2) FDA determines that the drug product has been voluntarily withdrawn from sale by the manufacturer due to safety or effectiveness concerns. (See discussion about removing drugs from listed status at part V section P below.)

Further, the agency will withdraw approval of and remove from the list any drug product that is the subject of a new drug application and that may now be marketed over-the-counter (OTC) pursuant to an effective final OTC monograph. Drug products that conform to an OTC final monograph are considered by the agency to be generally recognized as safe and effective and, as such, are no longer considered to be "new drugs" as defined in section 201(p) of the act. Thus, such products do not require an approved new drug application. In addition, FDA's enforcement policy for prescription drugs undergoing review in the agency's OTC drug review (21 CFR 330.13) permits a prescription drug to be marketed OTC without approval before a final monograph issues in each of the following circumstances: (1) where the drug is classified by an OTC advisory review panel in Category I (generally recognized as safe and effective and not misbranded) and FDA does not dissent in the preamble to the panel report or thereafter, (2) where FDA concludes that a drug that was not classified by a panel in Category I later tentatively qualifies for classification in Category I and so states in a **Federal Register** announcement, and (3) where the agency, on its own initiative, proposes by **Federal Register** announcement OTC marketing of a prescription drug not reviewed by an OTC advisory review panel, and public notice that OTC marketing may commence is issued after a formal comment period on the agency's proposed change.

Section 505(j)(6) of the act also requires FDA to include in the list the date of approval and application number of each drug product approved after 1981, whether in vitro or in vivo bioequivalence studies or both such studies are required for ANDA's for a listed drug, and the patent information required by section 505 (b) or (c) of the act. Although not required by the act, the list, as published, also identifies all drug products that qualify under the act for periods of exclusive marketing, regardless of patent status, and states therapeutic equivalence evaluations for approved multisource prescription drug products. (Information on therapeutic equivalence evaluations is provided under the policy announced in the **Federal Register** of October 31, 1980 (45 FR 72582). These proposed regulations do not modify or affect in any way the policy announced in that notice, nor do they affect any therapeutic equivalence evaluation published in the list.) As a general rule, FDA intends to use the list and its supplemental updates as the primary means of announcing information regarding patent status, exclusivity, type of bioequivalence study needed, and eligibility for consideration in an ANDA.

The list and its supplements are available on an annual subscription basis from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402. In addition, a copy of the list and its supplemental updates will be placed on public display in the Dockets Management Branch (address above) when FDA sends them forward for printing.

V Provisions of This Proposal

FDA proposes to reorganize 21 CFR Part 314 by revoking existing §§ 314.55 and 314.56, which describe the

requirements for abbreviated applications and the drug products for which abbreviated applications are suitable, by adding a new Subpart C, and by redesignating the existing subparts. The agency further proposes to revise existing sections of 21 CFR Part 314, where necessary, to implement the 1984 Amendments. New proposed Subpart C contains regulations on abbreviated applications for new drugs and antibiotics and the responsibilities and rights of applicants concerning their abbreviated applications. As revised, Subpart B would contain regulations on new drug applications submitted under section 505(b) of the act and antibiotic applications other than abbreviated antibiotic applications. FDA proposes to revise existing sections under Subpart B to remove any reference to abbreviated applications. Existing Subparts C through F are redesignated as Subparts D through G, respectively. Because the 1984 Amendments impose new procedural requirements upon applicants submitting ANDA s, FDA believes that placement of these requirements in a separate subpart will make them easier to find, read, and understand.

As noted above, Title I of the 1984 Amendments does not apply to antibiotics. Section 507 of the act, however, already provides for abbreviated applications for duplicates of approved antibiotic drugs. Therefore, except for a proposed revision to the adverse drug experience reporting requirements for new drugs and antibiotics, the agency proposes to retain the current requirements contained in Subpart B for abbreviated antibiotic applications, but restate them in the new Subpart C. (See discussion under part V section G. below.)

A. Definitions

FDA proposes to revise § 314.3(b) to incorporate definitions and interpretations necessary to implement the 1984 Amendments. The regulations would define "abbreviated application to mean the application described under § 314.94, including all amendments and supplements to the application. The term "abbreviated application" applies to both an abbreviated new drug application and an abbreviated antibiotic application. When particular regulations apply to only one of these groups, or to specific drugs, however, the agency will be more specific by referring to an "abbreviated new drug application" or an "abbreviated antibiotic application. The proposed regulations would revise the definition of "application" to mean the application described under § 314.50, including all amendments and supplements to the application.

Proposed revised § 314.3(b) incorporates the statutory description in section 505(b)(2) as the definition of a "505(b)(2) application.

The agency proposes to retain the current definition of "drug product" under § 314.3(b). The agency notes that the term "drug" is used throughout section 505 of the act. For purposes of this proposed rule, FDA interprets the term "drug" to mean "drug product" unless otherwise specified.

The agency proposes to define "listed drug" to mean a new drug product that has been approved for safety and effectiveness under section 505(c) of the act or approved under section 505(j) of the act, the approval of which has not been withdrawn or suspended under section 505(e) (1) through (5) or (j)(5) of the act, and which has not been withdrawn from sale for what FDA has determined are reasons of safety or effectiveness. A list of such drugs is published in the current edition of FDA's publication, Approved Drug Products with Therapeutic Equivalence Evaluations" (the list) and any current supplement to the list. A drug product is deemed to be a "listed drug" if it has been approved for safety and effectiveness under section 505(c) of the act or approved under section 505(j) of the act but has not yet been included in the list. For a drug product that is subject to FDA's DESI review, the agency will consider the applicable DESI notice published in the **Federal Register** a listed drug until a drug product subject to the notice meets the conditions for approval of effectiveness set forth in the notice and becomes a listed drug.

FDA recognizes that approved drug products with delayed effective dates, see part V sections K. and L. below, will be considered "listed" drugs to which subsequent ANDA's can refer. The agency believes that permitting such references will, in some cases, conserve agency resources and reduce burdens on ANDA applicants. For example, there will be drug products with delayed effective dates for which changes in dosage form, strength, route of administration or active ingredients were approved pursuant to ANDA suitability petitions. Some of these products will represent beneficial alternatives to, or improvements over, existing drug products. Permitting subsequent ANDA applicants to refer to these drug products with delayed effective dates will eliminate the burden on the subsequent applicants to submit, and FDA to review, duplicative ANDA suitability petitions. However, consistent with the patent protection and exclusivity provisions of the 1984 Amendments, the subsequent applicant's ANDA will generally share the same delayed effective date as the listed drug.

The agency proposes to define "reference listed drug" to mean the listed drug identified in an abbreviated new drug application or identified by FDA as the drug product upon which an applicant relies in seeking approval of its abbreviated application.

The agency proposes to define "the list" to mean the current edition of FDA s publication Approved Drug Products with Therapeutic Equivalence Evaluations" and any current supplement to the publication.

B. Drug Products for Which Abbreviated Applications May Be Submitted

The agency proposes to revoke existing § 314.56 and propose a new § 314.92 that describes the drug products for which abbreviated applications may be submitted to the agency. As described in proposed § 314.92(a), FDA proposes to accept an abbreviated application for the following drug products:

1. *Duplicates of a listed drug.* Section 505(j) of the act provides for the submission of ANDA's for generic versions (duplicates) of any drug product listed under section 505(j)(6) of the act (hereinafter referred to as a "listed drug"). Thus, an applicant may submit an ANDA for a drug product that has the same active ingredient(s), dosage form, strength, route of administration, and conditions of use as a listed drug, so long as its submission is not precluded by exclusivity. (See discussion at part V section L.1.)

Drug products approved after enactment of the 1984 Amendments, but not marketed, or those approved and for which marketing has been discontinued but for which FDA has made no determination that the marketing ceased for reasons of safety or effectiveness will be included in the list, but identified with a special symbol or placed in a special appendix. In addition, some drug products reviewed under DESI and approved for safety and effectiveness and some post 1962 approved drug products are not published in the list because marketing was discontinued before September 24, 1984. Although technically such drug products are listed drugs under section 505(j)(6)(B) of the act, FDA does not intend to update the list retrospectively to include drug products that no longer generate interest with respect to marketing either by the

pioneer applicant or by another applicant. A firm wishing to submit an ANDA for such a listed drug should petition the agency under § 314.122 to relist the drug product and submit information to show that its withdrawal from sale was not for safety or effectiveness reasons. (Also see discussion under part V section 0.1. below.)

2. *Drug Products that differ from a listed drug.* Section 505(j) of the act permits the submission of an ANDA for a drug product that differs from the listed drug if FDA has approved a petition from a prospective applicant requesting the change. The differences from the listed drug for which petitions may be submitted are differences in route of administration, dosage form, and strength, or, when the listed drug contains more than one active ingredient, a change in one of its active ingredients. To alert interested persons to petitions that have been approved permitting the submission of an abbreviated application for a drug product that differs from a listed drug, the agency will publish in the list all approved petitions submitted under section 505(j)(2)(C) of the act and a description of the permitted changes. Subsequent applicants who wish permission to make a change permitted in an already approved petition may refer in their ANDA's to the approved petition rather than filing a duplicative petition. To aid potential petitioners in preparing their petitions, the list also includes all petitions that have been denied. All such petitions are also on public display in FDA's Dockets Management Branch (address above).

3. *Antibiotics.* Section 507(a) of the act permits the submission of abbreviated applications for duplicates of all antibiotics the agency has already approved for marketing. The agency includes approved antibiotic drug products in the list, even though antibiotics are not covered in the 1984 Amendments, and, therefore, are not subject to, for example, the patent certification and exclusivity provisions of the act.

4. *DESI drug products.* Under its DESI program, the agency has accepted ANDA s for drug products that were the same as certain pre-1962 drug products reviewed under the DESI program. Under this program, each **Federal Register** notice announcing that a particular drug has been found effective has included, when appropriate, an FDA finding that an ANDA is the suitable mechanism by which manufacturers or suppliers of the drug product may obtain FDA approval. In addition, an ANDA may be submitted for a drug product that is similar or related to a DESI drug and for which FDA has made a separate finding, in response to a petition, that an ANDA is suitable.

A pre-1962 approved drug product in the DESI review does not qualify for marketing exclusivity under the 1984 Amendments if the applicant seeks only approval of the indications in the DESI notice. However, DESI products for which additional new uses beyond those reviewed in the DESI program are approved may qualify for periods of marketing exclusivity for the new use under certain circumstances.

C. ANDA Suitability Petitions

Proposed § 314.93 would implement section 505(j)(2)(C) of the act. That section of the act permits an applicant to petition the agency for permission to submit an ANDA for a drug product that differs from a listed drug when the change is one authorized by the statute and the agency has granted a petition for the change. Under the proposal, an applicant may petition FDA for permission to submit an ANDA for a drug product that differs from a listed drug in route of administration, dosage form, or strength. If a proposed drug product were more bioavailable than the innovator's product and the applicant proposed to reduce the dose to a level that delivered plasma levels equivalent to the innovator's product, a petition for a change in strength would be permitted.

In addition, an applicant may seek to change one of the active ingredients of the listed drug when the listed drug is a combination product. For example, the agency may find acceptable the substitution of one analgesic for another, e.g., acetaminophen for aspirin, in a combination product. The active ingredient the applicant wishes to substitute in its product must be approved for safety and effectiveness in a listed drug or must be an ingredient of a drug product that does not meet the definition of "new drug" under section 201(p) of the act. The remaining active ingredients of the combination product, however, must be identical to the other active ingredients of the reference listed drug. (See discussion at part V section D.1.c. below.)

An applicant is not permitted to petition for any other kinds of changes from listed drugs. H. Rept. 98–857 Part 1, 98th Cong., 2d Sess. at 23 (1984). Thus, for example, an applicant may not petition to submit an ANDA for a different active ingredient in a single active ingredient drug product, for an extra active ingredient in a combination product, or for a new use for an already approved drug product. The legislative history of the 1984 Amendments supports the agency's position that a different active ingredient may be substituted only in a combination drug product. Part 1 of the House Report describes FDA's authority to grant petitions requesting changes from listed drugs:

> If an applicant wishes to vary the route of administration, dosage form or strength of the generic drug from the listed drug, it must first petition the FDA for permission to file an ANDA for the differing generic drug. In addition, the applicant may request to vary one of the active ingredients in the generic drug from the listed drug *when the listed drug is a combination product.* The remaining active ingredients of the generic drug must be the same as the other active ingredients of the listed drug.
>
> *These are the only changes from the listed drug for which an applicant may petition.*

H. Rept. 98–857 Part 1, 98th Cong., 2d Sess. 23 (1984) (emphasis added). Section 314.93(e)(1)(ii) requires denial of a petition seeking to change an active ingredient, if the drug that is the subject of the petition is not a combination drug.

FDA considers a salt or ester of an active ingredient to be a different active ingredient, and will not approve petitions that seek permission to submit an ANDA for a drug product which substitutes a different salt or ester of an active ingredient from that of a listed drug, unless the petition seeks a change in a combination product and the new salt or ester has been approved or is not a new drug. No petition is necessary for a change in the inactive ingredients from those of the listed drug.

Proposed § 314.93(d) would require a petitioner to identify a listed drug and include in its petition a copy of the proposed labeling for the drug product that is the subject of the petition and a copy of the approved labeling for the reference listed drug. A petitioner may, under limited circumstances, identify more than one listed drug, e.g., when the petitioner seeks permission to submit an ANDA for a drug product that substitutes one of the active ingredients in a combination listed drug and the substituted ingredient itself is a listed drug. (Also see discussion under submitting an application for, or a suitability petition that relies on, a listed drug that is no longer marketed at part V section 0.1.)

Sections 505(j)(2)(A)(v) and 505(j)(3)(G) of the act require that the labeling of generic drugs be the "same" as the labeling approved for the listed drug, except where a change in labeling is "required because of differences approved under a petition filed under section 505(j)(2)(C) of the act or because

the drug and the listed drug are produced or distributed by different manufacturers. FDA emphasizes that the exceptions to the requirement of "same labeling" are limited. The agency will not approve a petition under section 505(j)(2)(C) of the act that seeks permission to submit an ANDA for a product with significant changes in labeling (such as new warnings or precautions) intended to address newly introduced safety or effectiveness problems not presented by the listed drug. Such labeling changes are not the kind that were intended to fall within the limited exceptions in sections 505(j)(2)(A)(v) and 505(j)(3)(G) of the act. FDA does not believe that it would be consistent with the purpose of section 505(j) of the act, which is to assure the marketing of generic drugs that are as safe and effective as their brand-name counterparts, to interpret section 505(j)(2)(C) of the act as permitting the marketing of generic drugs with diminished safety or effectiveness and concomitantly heightened labeled warnings. Rather than waste agency resources by approving a petition for a drug that cannot satisfy the ANDA approval requirements, FDA is proposing to deny a suitability petition for a change that would necessitate significant new labeled warnings or precautions.

Under the act, the agency must approve an appropriately submitted petition for a change authorized by the statute, unless it finds (1) that investigations are necessary to show the safety and effectiveness of the drug product or of any of its active ingredients, the route of administration, dosage form, or strength which differ from the listed drug (see section 505(j)(2)(C)(i) of the act), or (2) in reviewing a petition to substitute one of the active ingredients in a combination product, that the safety or effectiveness of the drug product may not be adequately evaluated by the information in an ANDA (see section 505(j)(2)(C)(ii) of the act).

The legislative history of the 1984 Amendments makes clear that section 505(j)(2)(C)(ii) of the act was added to clarify FDA's authority to reject petitions for new combination products that raise safety or effectiveness issues. See H. Rept. 98-857 Part 1, 98th Cong., 2d Sess. 23 (1984); 130 Cong. Rec. H9114 (daily edition September 6, 1984) (statement of Representative Waxman). The agency anticipates that it will only rarely approve petitions to submit ANDA's for new combinations, because data on the safety and effectiveness of the new combinations will almost always be needed. See hearing on S. 2748 before the Committee on Labor and Human Resources, 98th Cong., 2d. Sess. 31-2 (June 28, 1984) (statement of Mark Novitch, Acting Commissioner of Food and Drugs).

Section 314.93(e)(1)(iii) specifies the grounds for denying a petition to change an active ingredient in a combination product. Under the proposal at § 314.93(e)(1)(iii)(B), the agency would not approve a petition to substitute one of the active ingredients in a combination product if the petition failed to contain information to show that the different active ingredient of the drug product is of the same pharmacological or therapeutic class as the ingredient of the reference listed drug that is to be changed and that the drug product could be expected to have the same therapeutic effect as the reference listed drug when administered to patients for a condition of use identical to that of the reference listed drug. Under section 505(j)(2)(A)(iv) of the act, this information is required to be contained in an ANDA for a product with a different active ingredient than the listed drug. (See § 314.94(a)(7) and discussion at Part V section D.1.f.) FDA believes that this information must also be included in a petition to substitute an active ingredient because the ANDA could not be approved without this information and because substitution of an active ingredient of a pharmacological or therapeutic class different from that of the ingredient in the reference listed drug that is to be changed may be presumed to result in a product with a different degree of safety or effectiveness. Such a product would require investigations to show its safety and effectiveness; thus an ANDA would not be appropriate.

The information needed to provide scientific support for the safety and effectiveness of the new combination drug product should consist of well-documented evidence of the general acceptance that the ingredients to be substituted for each other are interchangeable and have known equipotent doses. Such information could be in the form of agency findings or conclusions in previous **Federal Register** notices. For example, FDA has allowed, in appropriate cases, substitution between aspirin and acetaminophen based on extensive scientific data establishing their safety and effectiveness and their equipotent doses and on long-term experience with these ingredients when used in combination with other drugs (see 47 FR 34636 at page 34641; August 10, 1982). If interchangeability is not generally accepted, investigations would be required to establish the safety and effectiveness of the new proposed combination product, and the product would properly be the subject of a new drug application submitted under section 505(b) of the act. New clinical data would not be an appropriate means of establishing that a new combination would have the same therapeutic effect as the listed combination drug because the need to review such data would require denial of the petition.

Sections 314.93(e)(1)(iii) (C) and (D) similarly require denial of a petition if the petition fails to demonstrate that the substituted active ingredient is already approved in a listed drug or is in a drug satisfying the requirements of section 201(p) of the act, or that the remaining active ingredients in the combination are identical to those of the listed combination drug. (See section 505(j)(3)(C) and H. Rept. 98-857 Part 1, *supra*, at 23.) In the absence of information that the safety and effectiveness of the changed ingredient has already been established and that the remaining active ingredients have not also been changed, the safety and effectiveness of the new combination cannot be evaluated without new investigations and thus cannot be the subject of an ANDA.

Under the proposal at § 314.93(e)(1)(v), the agency would not approve a petition that relies on a listed drug that has been voluntarily withdrawn from sale and that has not been referred to in an approved ANDA, unless the agency determines that the withdrawal of the listed drug was not for safety or effectiveness reasons. A generic applicant may obtain approval of a suitability petition to submit an ANDA for a change from a listed drug only when the safety and effectiveness of the listed drug can be relied on to support approval of the change. To assure that ANDA's will not be submitted for drug products that rely on a listed drug whose safety or effectiveness is questionable, the agency will refuse to approve a suitability petition that relies on a listed drug that has been voluntarily withdrawn from sale until the agency can determine that there are no safety or effectiveness concerns about the listed drug.

If the agency approves a petition for a change from a listed drug, FDA may require that certain information supporting the change be included in the ANDA. (See section 505(j)(2)(A) of the act.) The agency may also require additional data concerning the change during its review of an application.

If preclinical or clinical data are needed to support safety, or if clinical data are needed to support the effectiveness of the requested change, then an ANDA is not appropriate for the proposed drug product, and FDA will not approve a petition. However, under certain circumstances, data from limited confirmatory testing to show that the characteristics that make the proposed drug product different from the listed drug do not alter its safety and effectiveness may be accepted in a petition or as additional data to be included in an ANDA resulting from an approved petition. By limited confirmatory testing, the agency means simple studies intended to rule out unlikely problems. For example, data from acute animal studies to show the absence of liver enzyme induction properties of the substituted analgesic active ingredient might be required and be acceptable in a petition. (See 48 FR 2751 at 2753; January 21, 1983, at paragraph 4.) A study intended to answer basic safety or effectiveness questions or one that would require substantial scientific review would not be considered limited confirmatory testing.

A petitioner must use the procedures set forth in § 10.20 (21 CFR 10.20) and the format of a petition established in § 10.30 (21 CFR 10.30). However, unlike a citizen petition under § 10.30, section 505(j)(2)(C) requires FDA to approve or disapprove a petition requesting permission to submit an ANDA for a drug product differing from a listed drug within 90 days of its submission to the agency. Both proposed § 314.93 and proposed revised § 10.30 incorporate this statutory requirement. As is the case under the DESI review in which the hearing opportunity provided by section 505(c) of the act does not apply to ANDA applicants who disagree with an adverse agency decision on whether their products may rely on DESI conclusions, there is no legal right to an opportunity for a hearing on a petition denial under section 505(j)(2)(C) of the act. See H. Rept. 98-857 Part 1, 98th Cong., 2d Sess. 23 (1984). In addition, for the purposes of 21 CFR 10.45, the agency is proposing, at 21 CFR 10.45(d), that a petition for reconsideration of a response to an ANDA suitability petition be submitted and acted upon before the agency's response will be considered final agency action.

The proposal retains the current regulations on the public availability of data and information in a petition. The availability of a petition for public examination and copying is governed by 21 CFR Part 20. Under those provisions, all data submitted in a petition, except data incorporated by reference, are available for public disclosure. The agency has on several occasions been asked to maintain confidentiality of petitions in which a petitioner seeks a determination of the suitability of an ANDA for a proposed drug product. Some petitioners oppose the public availability of such petitions on the ground that information contained in the petition may provide commercial advantage to competitors by, for example, disclosing a petitioner's marketing plans or new dosage form technology. The agency considered revising the regulations to provide for the confidentiality of any petition submitted under section 505(j)(2)(C) of the act until FDA has either approved or disapproved the petition, and if the agency disapproved a petition, to provide confidentiality for an additional 30 days to permit the petitioners to file a petition for reconsideration. The agency has initially rejected that position because it believes that the benefits in keeping the process a public one outweigh potential commercial problems to petitioners. In addition, data requiring confidentiality would ordinarily not need to be submitted in a petition under section 505(j)(2)(C) of the act. The public is specifically invited to comment on the alternative policy of nondisclosure of a petition submitted under section 505(j)(2)(C) of the act until final agency action on the petition. FDA does not anticipate that it will need to repropose this regulation if it ultimately adopts such a policy. Interested persons should prepare their comments accordingly.

D. Content and Format of an ANDA

The agency proposes to retain the current requirement that an applicant submit two copies of an ANDA, an archival copy, and a review copy. The agency will maintain guidelines under § 10.90(b) (21 CFR 10.90(b)) to help applicants comply with the content and format requirements of an ANDA.

1. *Archival copy.* Section 314.94 of the proposed rule describes the content and format requirements for ANDA's. In addition to the proposed requirements described below, the archival copy of an ANDA would contain, as now, the application form that contains the information described in § 314.50 (a) (1), (3), (4), and (5), a statement whether the submission is an abbreviated application under § 314.94 or a supplement under § 314.97 and a table of contents.

The proposed content requirements for an ANDA under § 314.94 (a) implement section 505(j)(2)(A) of the act. For a drug product that is the same as the reference listed drug, the ANDA procedures focus on the kinds of information necessary to assure that the duplicate product is the same as the reference listed drug and on the ability of the applicant to produce a drug product of acceptable quality. In these regulations, the term "same as" is used to describe drug products that are identical in specific key aspects (i.e., indications, dosage form, strength, route of administration, and active ingredient(s)), but allows certain appropriate differences due to different manufacturers (e.g., differences in inactive ingredients and certain labeling statements). (See discussion under Samples and labeling at part V section D.1.i.) A description of the proposed requirements for information to be included in an ANDA follows.

a. *Basis for ANDA submission.* The agency proposes in § 314.94(a)(3)(i) to require applicants to submit the name of the reference listed drug, including its dosage form and strength, that is the basis for the ANDA. In addition, for ANDA's submitted pursuant to an approved petition, proposed § 314.94(a)(3)(iii) would require reference to the petition by FDA assigned docket number and a copy of the agency's response to the petition stating that an ANDA may be submitted. (Section 505(j)(2)(C) of the act prohibits an applicant from submitting an ANDA for a drug product that differs from a listed drug in one of the active ingredients, route of administration, dosage form, or strength, unless FDA has approved a petition for the change.) Ordinarily both an ANDA and a petition submitted under section 505(j)(2)(C) of the act must refer to a single listed drug. However, as discussed above at part V section C., a petition may, under limited circumstances, rely on more than one listed drug. The agency's response to a petition permitting submission of an ANDA will identify the listed drug or drugs relied on for approval of the petition. The listed drug referred to in an ANDA for which a suitability petition was approved must be the same as the listed drug relied on in the petition.

Currently, the agency uses one product as a reference standard for bioequivalence determinations. Usually that reference standard is the pioneer drug product. Applicants will be required to refer and show bioequivalence to the listed drug selected by the agency as the standard for bioequivalence determinations. Therefore, where there is more than one listed drug for the same drug product, prospective applicants are encouraged to consult with the Director, Division of

Bioequivalence before selecting a reference listed drug.

Under FDA's DESI program, each **Federal Register** notice announcing the effectiveness conclusions reached in the DESI review about a drug product first approved for marketing before October 10, 1962, has included, when appropriate, an FDA finding that an ANDA is the suitable mechanism by which manufacturers or suppliers of duplicate versions of the first approved drug product could obtain FDA approval. Similar findings may, under the DESI or related programs, be made by the agency in the future. Where the agency has made such a finding and there is no other approved NDA or ANDA at the time of submission of an ANDA, the listed drug referred to in the ANDA would be the agency's notice published in the **Federal Register**. If the ANDA is for a duplicate of a drug product that is subject to FDA's DESI review and there is a listed drug, the applicant would refer to the listed drug as the basis for submission of the ANDA unless FDA has selected a different drug product as the standard for bioequivalence determinations.

The applicant must also include a statement as to whether the reference listed drug is entitled to a period of marketing exclusivity as provided under section 505(j)(4)(D) of the act. Exclusivity information on listed drugs is published in the list. If the listed drug is entitled to 5 years of exclusivity under section 505(j)(4)(D)(ii) of the act, ANDA's that refer to the drug may not be submitted until the exclusivity expires. All remaining periods of exclusivity accorded by sections 505(j)(4)(D)(i), (iii), (iv), and (v) of the act do not bar an applicant from submitting an ANDA. Such exclusivity does, however, require the agency to delay the effective date of approval of an ANDA.

b. *Conditions of use.* The agency proposes to require in § 314.94(a)(4) that the ANDA include sufficient information to show that the conditions of use, which include, among other things, indications and dosage instructions for which the applicant is seeking approval, have been previously approved for the reference listed drug. Except in extraordinary circumstances, an applicant would be expected to seek approval for all of the indications previously approved for the reference listed drug except for those indications that are protected by patent or that have been accorded periods of exclusivity. Consistent labeling for duplicate versions of a drug product, insofar as this is possible, will avoid differences that might confuse health care professionals who prescribe and dispense prescription drug products or might create omissions of significant information.

An applicant, however, may not seek approval in an ANDA or through an ANDA suitability petition for an indication that has not been previously approved. Approval of a new indication requires investigations to demonstrate the safety and effectiveness of the drug product for the new indication, and thus may not be obtained through an ANDA or suitability petition.

The requirement that the applicant show that its proposed conditions of use have been previously approved for the reference listed drug is satisfied if the applicant includes in the ANDA: (1) a statement that the conditions of use for which the applicant is seeking approval and for which the drug product will be marketed have previously been approved for the reference listed drug; and (2) reference to the applicant's annotated proposed labeling and to the currently approved labeling for the reference listed drug contained elsewhere in the ANDA.

c. *Active ingredients.* The agency proposes to require in § 314.94(a)(5) that the applicant provide sufficient information to show that the active ingredients of the drug product for which the applicant seeks approval are the same as those of the reference listed drug. The agency interprets the requirement that the active ingredients in the proposed drug product be the same as those of the listed drug to mean that the active ingredients must be identical. For example, if the proposed drug product contained a different salt or ester of the active ingredient in the listed drug, the active ingredient in the proposed drug product would not be identical to the active ingredient in the listed drug, and could not, therefore, be approved in an ANDA. Active ingredient in this context means the active ingredient in the finished drug product prior to its administration.

In some cases, an applicant may petition the agency to permit the applicant to vary an active ingredient in a proposed combination drug product. If the reference listed drug has one active ingredient, then the active ingredient in the applicant's drug product must be identical to that of the listed drug. See section 505(j)(2)(A)(ii)(I) and (j)(3)(C)(i) of the act. If the reference listed drug has more than one active ingredient, then all of the active ingredients in the applicant's drug product must be identical to those in the listed drug, except that an applicant may seek to vary one of the active ingredients of a listed combination drug product by the ANDA suitability petition procedure.

Under proposed § 314.94(a)(5), the requirement that the active ingredients in the applicant's drug product be shown to be the "same as" those of the reference listed drug is satisfied if the applicant includes in its ANDA: (1) A statement that the active ingredients in its product are the same as that of the reference listed drug except for any different active ingredient in a combination drug product that has been the subject of an approved petition and (2) reference to the applicant's annotated proposed labeling and to the currently approved labeling for the reference listed drug contained elsewhere in the ANDA.

For a combination drug product with an active ingredient different from that of the listed drug, the applicant would be required to provide information to show that (1) The different active ingredient is an active ingredient of another listed drug or of a drug which does not meet the definition of "new drug" in section 201(p) of the act and (2) the other active ingredients of the drug product are the same as those of the reference listed drug by referring to the applicant's annotated proposed labeling and the reference listed drug's approved labeling contained in the ANDA. The applicant would also be required to provide any other information about the different active ingredient that FDA may require.

d. *Route of administration, dosage form, and strength.* Under proposed § 314.94(a)(6), the applicant would be required to include in an ANDA sufficient information to show that the route of administration, the dosage form and the strength of the drug product for which the applicant is seeking approval are identical to those of the reference listed drug. An applicant may vary the route of administration, dosage form or strength of its product from the reference listed drug only if the applicant has petitioned FDA for permission to submit an ANDA for the differing drug product and the agency has approved the petition. An applicant satisfies the requirement to show that the route of administration, dosage form, and strength of its drug product are the same as those of the reference listed drug except for differences that have been the subject of an approved petition if the applicant includes in its ANDA: (1) a statement that the route of administration, dosage form, and strength are the same as those of the reference listed drug and (2) reference to the applicant's annotated proposed labeling and to the currently approved

labeling for the reference listed drug contained elsewhere in the ANDA. If the applicant has obtained permission to vary the route of administration, dosage form, or strength of the proposed product, the application must contain any information about the change as FDA may require.

e. *Bioequivalence.* The agency proposes at § 314.94(a)(7)(i) to require the applicant to include in an ANDA information sufficient to show that the drug product for which the applicant is seeking approval is bioequivalent to the reference listed drug. In addition, the proposed rule provides that for each in vivo study, an applicant include in the ANDA a description of the analytical and statistical methods used and a statement with respect to the applicant's compliance with the institutional review board regulations under 21 CFR Part 56 and the informed consent regulations under 21 CFR Part 50.

Under this proposal, the agency would retain, with one modification, the current definitions of the terms "bioequivalence" and "bioavailability" under Subpart A of 21 CFR Part 320. These terms are similarly characterized in section 505(j)(7)(A) and (B) of the act. The language of section 505(j)(7)(A) and (B) of the act is adopted except for a minor wording difference as noted below. Thus, a drug product for which an applicant is seeking approval in an ANDA would be considered bioequivalent to the reference listed drug if: (1) the rate and extent of absorption of the applicant's drug product do not show a significant difference from the rate and extent of absorption of the reference listed drug when administered at the same molar dose of the active moiety under similar experimental conditions in either a single dose or multiple doses or (2) the extent of absorption of the applicant's drug product does not show a significant difference from the extent of absorption of the reference listed drug when administered at the same molar dose of the active moiety under similar experimental conditions in either a single dose or multiple doses and the difference from the reference listed drug in the rate of absorption of the drug product is intentional, is reflected in the proposed labeling, is not essential to the attainment of effective body drug concentrations on chronic use, and is considered medically insignificant for the drug product (21 CFR 320.1(e)). The second definition of bioequivalence in existing § 320.1(e) is similar to that proposed except that under the existing regulation a difference in rate of absorption must be: (1) Intentional and reflected in the labeling; (2) not essential to the attainment of effective body drug concentrations; or (3) considered medically insignificant for the particular drug. The language of section 505(j)(7)(B)(ii) of the act thus differs from the current regulatory definition in that a drug must now meet all three of the current criteria. FDA is proposing to adopt the statutory definition. (Also see part VI. Conforming Amendments.)

The second definition of the term bioequivalence may be applied, for example, in considering whether two controlled release products are bioequivalent. Therefore, for purposes of approval of an ANDA, if a controlled release dosage form of a drug product meets the four criteria in the second definition, it would be regarded as bioequivalent to the reference standard. However, for purposes of including the product in the list, FDA reserves the right to rate the product not "therapeutically equivalent" to any other listed drug containing the same active ingredient.

The term "bioavailability" means the rate and extent to which the active ingredient or active moiety is absorbed from a drug product (21 CFR 320.1(a)). The agency proposes to expand this definition to include a reference to drugs that are not intended to be absorbed.

Currently, the agency uses one product as a reference standard against which the bioequivalence of the applicant's product is compared. The agency intends to continue that practice. Usually that reference product is the innovator's product, which would also usually be the listed drug referred to by the applicant. However, if the listed drug chosen by the applicant is different from that chosen by the agency as the standard for bioequivalence determinations, the agency will require the applicant to amend its application to refer to the agency's bioequivalence reference standard as its listed drug. This policy is intended to assure that all generic products remain equivalent to a common standard and thus to each other.

The agency notes that the statutory definitions of "bioavailability" (section 505(j)(7)(A) of the act) and "bioequivalence" (section 505(j)(7)(B) of the act) use the phrase "therapeutic ingredient" rather than the phrase "therapeutic moiety," which is used in 21 CFR Part 320. FDA does not believe Congress intended a meaning different from that in 21 CFR Part 320 for drug products that are the subject of ANDA's, because the legislative history of the 1984 Amendments, in discussing the terms "bioavailability" and "bioequivalence," refers to 21 CFR 320.1 (a) and (e). See H. Rept. 98-857 Part 1, 98th Cong., 2d Sess. at 31 (1984). The agency, however, believes that the term "active moiety" is more appropriate and proposes to substitute this term for the term "therapeutic moiety" or "therapeutic ingredient" in defining the terms "bioavailability" and "bioequivalence.

Both the statutory definition of "bioequivalence" and the definition under § 320.1(e) describe a standard for demonstrating in vivo bioequivalence for systemically absorbed drug products. Some drug products are not intended for systemic absorption, e.g., a topically applied drug product, an antacid or a radiopaque medium. Nevertheless, the statute imposes a bioequivalence requirement on all drug products for which an applicant is seeking approval in an ANDA. Where the usual in vivo bioequivalence methods (blood level measurements) are not applicable, suitable alternative methods, such as measurement of acute pharmacologic effect or demonstration of equivalent clinical effectiveness (with appropriate confidence intervals), may be established where FDA determines that they are capable of demonstrating bioequivalence. FDA notes, however, that where no methodology capable of establishing bioequivalence has been shown to exist for a particular drug or class of drugs, ANDA's for the drug cannot be approved until adequate methodology becomes available. (See section 505(j)(3)(F) of the act.)

In vitro dissolution may also be determined by the agency to be an appropriate means of demonstrating bioequivalence, for example, where an in vitro test has been correlated with human in vivo bioavailability data. The list specifies whether an in vitro or in vivo bioequivalence study will be required for ANDA's that refer to a listed drug. One method of demonstrating bioequivalence will generally apply to all indications for which the listed drug is approved, unless there is more than one route of administration in which case it may be necessary to study bioequivalence by more than one route. If any person believes that a specified method demonstrates bioequivalence only for a certain indication, that person may raise the issue with the agency. The agency will decide each such issue on a case-by-case basis.

Before enactment of the 1984 Amendments, the agency deferred or waived the requirement for the submission of evidence of in vivo bioavailability for various drugs for a

number of reasons. For example, FDA deferred the requirement if adequate methodology were not available for in vivo testing. However, section 505(j)(2)(A)(iv) of the act requires that the applicant provide information to show that its drug product is bioequivalent to the listed drug referred to by the applicant. Thus, there is no statutory provision for deferral of the requirement. Therefore, in those situations where methodology for in vivo testing is not available, the applicant is required to develop adequate methodology for such testing, or to carry out clinical studies to assess therapeutic equivalence, unless the agency determines that in vitro methods can be used to demonstrate bioequivalence.

In some cases, the in vivo bioavailability of a drug product may be self-evident, e.g., for a drug product that is a solution intended for intravenous or oral administration. The regulations under 21 CFR Part 320 set forth the criteria for waiver of evidence of in vivo bioavailability. (Also see discussion about proposed revisions to the waiver criteria under part VI.) The agency does not believe Congress intended that unnecessary human research be conducted in cases where an applicant could demonstrate that a product is inherently bioequivalent to another product and therefore meets the statutory standard of bioequivalence. Therefore, the agency proposes to continue its policy that if an applicant can demonstrate that its proposed drug product falls in this category, such a demonstration would be considered adequate information to show bioequivalence to the reference listed drug, as required in proposed § 314.94(a)(7)(i). Likewise, if the agency concludes that bioequivalence can be demonstrated by in vitro tests, the agency proposes to require only such tests rather than in vivo studies. (See section 505(j)(6)(A)(i)(III) of the act.) The agency informs prospective applicants of whether in vivo or only in vitro tests will be required through its list. In addition, the agency may from time to time, prepare or modify existing guidance documents for conducting bioequivalence studies. To assure that all applicants receive the most up-to-date version of any available guidance documents on the types of studies recommended for establishing bioequivalence, FDA publishes a complete listing of the most current available guidance documents in the list.

Many applicants now submit bioequivalence protocols to obtain agency review and comment before beginning bioequivalence tests. The agency proposes to continue to permit the submission of these protocols. An ANDA that contains a bioequivalence protocol and the chemistry, manufacturing, and controls data required by § 314.94(a)(9) would be considered sufficiently complete to start the statutory 180-day review period. However, an applicant certifying patent invalidity or noninfringement must submit completed bioequivalence studies with the initial ANDA submission (see section 505(j)(2)(B) of the act).

f. *Therapeutic effect.* Under the petition procedure, an applicant may seek to substitute one of the active ingredients in its proposed combination drug product for one of the active ingredients in the reference listed combination drug. If FDA approves a petition permitting the submission of an ANDA for such a change, the ANDA must contain information to show that the different active ingredient in the proposed drug product is of the same pharmacological or therapeutic class as the ingredient in the reference listed drug that was changed and that the proposed drug product can be expected to have the same therapeutic effect as the reference listed drug when administered to patients for the conditions of use approved for the listed drug and for which the applicant is seeking approval. (See section 505(j)(2)(A)(iv) of the act.)

With respect to the requirement that the substituted active ingredient be "of the same pharmacological or therapeutic class" as that of the listed drug, FDA would view the different active ingredient as being of the same pharmacological or therapeutic class as that of the listed drug if the applicant can show that the different active ingredient in its proposed drug product has similar pharmacologic properties to the ingredient in the listed drug that has been changed. FDA would view a drug product as being expected to have the same therapeutic effect as the listed drug if the applicant can demonstrate that: (1) There is an adequate scientific basis for determining that substitution of the specific proposed dose of the different active ingredient for the dose of the member of the same pharmacological or therapeutic class in the reference listed drug will yield a resulting drug product of the same safety and effectiveness. This will ordinarily require a showing that there is general acceptance in the scientific community that the specified doses of the two ingredients are equipotent; (2) the unchanged active ingredients in the applicant's drug product are bioequivalent to those in the reference listed drug; and (3) the different active ingredient in the applicant's drug product is bioequivalent to an approved dosage form of a drug product containing that ingredient and approved for the same indication(s) as the proposed product or is bioequivalent to a drug product offered for that indication which does not meet the definition of "new drug" under section 201(p) of the act. This would demonstrate that the different active ingredient is as bioavailable from the combination drug product as it is when separate preparations of the active ingredient are given. During its review of the ANDA, FDA may request the submission of additional information to show that the proposed drug product can be expected to have the same therapeutic effect as the listed drug.

g. *Chemistry, manufacturing, and controls.* The agency proposes at § 314.94(a)(9)(i) to retain the current requirement of the submission of adequate chemistry, manufacturing, and controls information described under § 314.50(d)(1). Current agency practice permits applicants to submit this information and bioequivalence protocols before beginning bioequivalence tests of their drug products and submitting the results of these tests to FDA. Thus, applicants are able to obtain agency review and comment on their formulation data, bioequivalence protocols, and pilot studies before conducting bioequivalence tests. The agency intends to continue this practice, except that ANDA's that contain a section 505(j)(2)(A)(vii)(IV) patent certification must submit completed bioequivalence studies with the initial ANDA submission.

h. *Inactive ingredients.* The inactive ingredients or composition used in a generic drug product must not raise serious safety questions. (See discussion in part V section M., *infra.*) The agency intends to place more stringent limitations on the variations permitted in the inactive ingredients in the formulation of parenteral, ophthalmic, and otic drug products than on other dosage forms. This is because each parenteral, ophthalmic, and otic drug product represents an individual pharmaceutical system with its own characteristics and requirements. In the formulation of parenteral drug products, certain added substances are used to maintain solubility, stability, sterility, and to increase patient comfort (i.e., by adjusting toxicity and reducing tissue irritation). Added substances selected

for parenteral drug products must be known to be of the highest quality, must be known to not interfere with the therapeutic effectiveness of the product and must be known to be nontoxic in the quantities used. The sensitivity of inactive ingredients in parenteral drug products is reflected in regulations under 21 CFR 201.100 which require that certain added substances and their concentrations be listed on the label of the product. Similarly, added substances are used in the formulation of products intended for ophthalmic and otic use such as buffers, antimicrobial preservatives, chemicals to adjust toxicity, and thickening agents.

Generally, in an ANDA, the formulation of ingredients in parental, ophthalmic, and otic dosage forms must be identical to the formulation of the reference listed drug identified in the ANDA. For the reasons described above, the agency will presume any inactive ingredient in an applicant's proposed drug product different from that in the reference listed drug to be unsafe unless the applicant can rebut the presumption by demonstrating that the different inactive ingredient will not affect the safety of its proposed drug product. Differences from the reference listed drug in the types of added substances described above for parenteral, ophthalmic, and otic dosage forms may be permitted if the applicant includes in its ANDA an identification and characterization of the differences in added substances between the proposed drug product and reference listed drug and demonstrates that such differences will not affect the safety of the proposed drug product.

For all dosage forms, the applicant would be required to identify and characterize any differences between the formulation of its proposed drug product and that of the reference listed drug and include in the ANDA information to show that the inactive ingredient will not adversely affect the drug product's safety.

i. *Samples and labeling.* The agency proposes at § 314.94(a)(10) to: (1) retain the current requirement under § 314.50(e) that upon FDA's request, the applicant submit samples of the finished drug product, the drug substances used in the manufacture of the drug product, and reference standards and blanks and (2) retain the current requirement under § 314.50(e) with respect to the submission of analytical methods and descriptive information needed to perform the tests on the samples and to validate the applicant's analytical methods.

The agency also proposes at § 314.94(a)(8)(ii) to retain the current requirement under § 314.50(e)(2)(ii) for the submission of copies of the proposed or final printed label and labeling for the drug product for which the applicant is seeking approval, i.e., four copies of draft labeling or 12 copies of final printed labeling.

The agency proposes to add a new requirement with respect to the submission of labeling. The statutory provisions of section 505(j) of the act require that an applicant provide sufficient information to assure that a generic version of a previously approved drug product is the same as the listed drug in dosage form, strength, and route of administration, contains the same active ingredients, except for differences from the listed drug that have been the subject of an approved petition, and generally is recommended for administration under the same conditions of use. In addition, the act requires that an applicant include in the ANDA information adequate to show that the proposed labelling for its drug product is the same as that of the reference listed drug except for changes required because of differences approved under a petition or because the drug product and the reference listed drug are produced or distributed by different manufacturers. Thus, an applicant's proposed labeling might differ from that of the reference listed drug because: (1) the method of formulation (e.g., inactive ingredients) differs; (2) the applicant's product and the reference listed drug have different strengths (in the case of petition-approved drug products) or with respect to the "how supplied" section of the labeling, the generic manufacturer does not supply all strengths of the drug product; (3) the reference listed drug labeling does not reflect current agency labeling standards; for example, the agency may require a change in the labeling of a drug product to make available important new information about the safe use of a drug product, but the reference listed drug's labeling has not yet been updated to reflect this change; (4) the reference listed drug labeling includes conditions of use that are protected by a patent or are accorded a period of exclusive marketing; (5) the name and address of the manufacturers of the proposed and listed drug products vary; (6) the expiration dates for the proposed product and the reference listed drug differ; (7) the National Drug Code (NDC) number for the proposed product and the reference listed drug differ, if displayed on the label and in the labeling; and (8) there are differences in the color used in a tablet (e.g., the listed drug contains Yellow No. 5, which must be declared in the label, while the proposed product uses a different color).

FDA emphasizes that the exceptions to the requirement that a generic drug's labeling be the same as that of the listed drug are limited. The agency will not accept ANDA's for products with significant changes in labeling (such as new warnings or precautions) intended to address newly introduced safety or effectiveness problems not presented by the listed drug. Such labeling changes do not fall within the limited exceptions in sections 505(j)(2)(A)(v) and 505(j)(3)(G) of the act. Moreover, FDA does not believe that it would be consistent with the purpose of section 505(j) of the act, which is to assure the marketing of generic drugs that are as safe and effective as their brand-name counterparts, to interpret section 505(j)(2)(A)(v) of the act as permitting the marketing of generic drugs with diminished safety or effectiveness and concomitantly heightened labeled warnings. Thus, where a proposed change in a generic drug, e.g., in packaging or inactive ingredients or, for a petition-approved drug, in the approved change, would jeopardize the safe or effective use of the product so as to necessitate the addition of significant new labeled warnings, the proposed product would not satisfy the labeling requirements of sections 505(j)(2)(A)(v) and 505(j)(3)(G) of the act.

To assist the agency in determining if the applicant's proposed labeling is the "same as" that of the reference listed drug, except for the types of differences described above, FDA proposes in § 314.94(a)(8)(iv) to require the applicant to include in the ANDA a side-by-side comparison of the applicant's proposed labeling with the currently approved labeling for the listed drug referred to in the ANDA with all differences annotated and explained. Current approved labeling for any approved drug product may be obtained under 21 CFR Part 20 pursuant to the Freedom of Information Act. In addition, the proposed rule provides that an applicant must include in the ANDA a statement that the proposed labeling is the same as that of the listed drug except for those allowable differences specifically cited by the applicant. Where the agency has issued class labeling or another labeling standard, e.g., labeling requirements set forth in a DESI notice, and the applicant believes such labeling is more appropriate than the listed drug product's labeling, the applicant should refer to such labeling or standard and explain why it is more appropriate.

j. *Patent certification.* The statute prevents an ANDA from becoming

effective before all relevant listed product and use patents that have been filed for the listed drug have expired or, if the generic applicant asserts either that the generic product will not infringe the patent or that the patent is invalid, until the patent owner and listed drug holder have been notified and have had an opportunity to litigate the matter. Sections 505 (b) and (c) of the act require that applicants for all newly submitted or pending new drug applications and holders of all previously approved new drug applications submitted under section 505(b) of the act submit to FDA the patent number and the expiration date of any patent that claims the drug in the new drug application or that claims a method of using such drug with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, sale, or use of the drug product.

The patents covered by the statutory provisions for submission of patent information are those that claim the drug product for which approval is being sought, including an active ingredient in such product and use patents that claim a particular indication or method of using the drug product. The agency interprets the statutory language "any patent which claims the drug" to include formulation and composition patents that claim the drug product for which approval is being sought. The 1984 Amendments do not authorize the submission of information for patents that claim a method of manufacturing a listed drug or that claim drug products for which the applicant is not seeking or has not obtained approval. FDA is required to publish the required patent information submitted under section 505 (b) or (c) of the act. The patent information appears in the list.

i. *Patents requiring a certification or statement.* Proposed § 314.94(a)(12), which implements sections 505(j)(2)(A)(vii) and (viii) of the act, requires applicants to include in their original ANDA submission a certification or statement as to each patent that, in the opinion of the applicant and to the best of its knowledge, claims the reference listed drug or a use of the reference listed drug for which the applicant seeks approval. A certification under § 314.94(a)(12)(i) or statement under § 314.94(a)(12)(iii), as appropriate, must be submitted whenever an applicant believes that the reference listed drug is claimed by an ingredient patent, drug product patent (including a formulation and composition patent), or a method of use patent. In some instances, an applicant may have to make multiple certifications if there is more than one relevant patent on the listed drug. For example, if the active ingredient patent for the listed drug has expired but a valid formulation patent will not expire for 3 years, then the applicant would be required to certify, for example, that one patent has expired and the other will expire in 3 years.

The patent information submitted to FDA, whether or not published in the list, should be the basis of the applicant's certification. To assist the applicant in determining whether information on a relevant patent has been submitted to FDA, the agency will place copies of new patent submissions on approved drug products and, prior to its publication, a copy of the patent information supplement to the list on public display in the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857 Once a year, FDA conducts a review of the patent information published in the list and deletes all patents that have expired in the course of the year. Thus, an applicant should check the list for published patent information and FDA's Freedom of Information Office for patent information submitted to FDA but not yet published. FDA would also expect that an applicant would check the Patent Office for U.S. patents issued but not yet submitted to FDA. If the applicant is aware of a U.S. patent that claims the drug, drug product, or a method of using the drug that has been granted but not yet submitted to FDA, it must submit a certification under section 505(j)(2)(A)(vii)(I) of the act or, if applicable, a statement under section 505(j)(2)(a)(viii) of the act. If an applicant becomes aware, after submitting an ANDA, of a newly issued patent or if a patent is timely submitted after the submission of the ANDA, an appropriate new certification would be required in the form of an amendment to the pending ANDA.

ii. *Patent certifications or statement.* Under section 505(j)(2)(A)(vii)(I) of the act, an applicant must make a "paragraph I" certification if the applicant is aware, e.g., through a patent search, that a patent exists that claims the listed drug or that claims a use for such listed drug for which the applicant is seeking approval and for which patent information is required to be submitted, but for which the holder of the approved application for the listed drug has not submitted the information to FDA (proposed § 314.94(a)(12)(i)(A)(*1*)).

Under section 505(j)(2)(A)(vii)(II) of the act, an applicant must make a "paragraph II" certification if the applicant believes that there was a patent that claimed the listed drug or that claimed a use for such listed drug but that such patent has expired (proposed § 314.94(a)(12)(i)(A)(*2*)).

Under section 505(j)(2)(A)(vii)(III) of the act, an applicant must make a "paragraph III" certification if the applicant believes that there is an unexpired patent that claims the reference listed drug or that claims a use for such listed drug and the applicant does not want to certify that the patent is invalid or will not be infringed by the applicant's proposed drug product. The certification must state the date on which the patent will expire (proposed § 314.94(a)(12)(i)(A)(*3*)).

Under section 505(j)(2)(A)(vii)(IV) of the act, an applicant must make a "paragraph IV" certification if the applicant believes that there is a relevant unexpired patent that claims the listed drug or that claims a use for such listed drug, but also believes that the patent is invalid or will not be infringed by the applicant's proposed drug product. In addition, if the proposed drug product is a generic copy of a listed, patented drug and is the subject of a patent licensing agreement with the patent owner, the applicant would submit a paragraph IV certification. The agency proposes at § 314.94(a)(12)(i)(A)(*4*) that a paragraph IV certification be submitted to FDA in the following form:

> I, (*name of applicant*), certify that Patent No. ____(*is invalid or will not be infringed by the manufacture, use, or sale of) (name of proposed drug product*) for which this application is submitted.

The certification must be accompanied by the statement required by section 505(j)(2)(B)(i) of the act that the applicant will give the notice required by section 505(j)(2)(B)(ii) of the act and proposed § 314.95(a) to the patent owner or its representative and the holder of the approved application for the listed drug and by a statement that the applicant will comply with the requirements under proposed § 314.95(c) with respect to the content of the notice. A certification in any other form will not be accepted by the agency as a paragraph IV certification.

If, in the applicant's opinion and to the best of its knowledge, no relevant patents claim the listed drug or a method of using the listed drug, the agency proposes at § 314.94(a)(12)(ii) to require the applicant to include in its ANDA the following certification:

> In the opinion and to the best knowledge of (*name of applicant*), there are no patents that

claim the listed drug referred to in this application or that claim a use of the listed drug.

This will assist the agency in assuring that each applicant has complied with section 505(j)(2)(A)(vii) of the act. If a patent is removed from the list after an applicant has submitted one of the certifications described in § 314.94(a)(12)(i)(A), and the application is pending or has a delayed effective date, the applicant should submit an amended certification under § 314.94(a)(12)(ii) certifying that there are no relevant patents. The new certification should be submitted either as an amendment to a pending application or by letter to an approved application.

If there is a patent claiming a method of using the listed drug, and the labeling for the applicant's proposed drug product does not include any indications that are covered by the use patent, proposed § 314.94(a)(12)(iii) would require the applicant to submit a statement that the method of use patent does not claim any of the proposed indications. The applicant should not submit a certification under § 314.94(a)(12)(i)(A) for such a patent. If, however, the labeling of the proposed drug product includes an indication that, according to the patent information submitted to FDA under sections 505 (b) and (c) of the act or in the opinion of the applicant, is claimed by the use patent, the applicant must submit an applicable certification under § 314.94(a)(12)(i)(A).

If patent information is submitted on a listed drug and, if, as of the time FDA concludes that an ANDA that refers to that drug is approvable, the ANDA applicant has not submitted an appropriate certification or statement on the patent, FDA will notify the applicant of the existence of the submitted patent before approval. (Because the applicant will then have to comply with any applicable certification and notification requirements, possibly delaying approval, applicants should make every effort to keep themselves informed as to whether patent information has been submitted while their ANDA's are pending.) If, however, a patent on the listed drug is issued by the Patent Office after an ANDA is submitted to FDA, and the holder of the approved application for the listed drug does not submit patent information within 30 days of issuance of the patent as required by section 505(c) of the act, the agency is proposing that no recertification be required for a pending ANDA that refers to that drug, if the ANDA applicant has previously submitted an appropriate certification. If the approved application holder ultimately submits the information late, the applicant need not submit an amended certification. A generic applicant whose application is submitted *after* a late submission of patent information on the listed drug or whose application is pending but does not contain a previously submitted certification, must, however, certify as to that patent. (See proposed § 314.94(a)(12)(vi) and discussion at part V section Q.4, *infra*.)

iii. *Patent licensing agreements*. The agency proposes in § 314.94(a)(12)(i)(B) and (v) to implement the following patent certification rules where the proposed drug product or the listed drug is a copy of a patented drug and is the subject of a patent licensing agreement with the patent owner. If the proposed drug product is a generic copy of a patented drug and the applicant has obtained a licensing agreement with the patent owner, FDA proposes to require the applicant to submit a certification under section 505(j)(2)(A)(vii)(IV) of the act. In response to the notice of certification from the generic applicant to the patent owner, the patent owner may consent to an immediate effective date of approval of the generic applicant's application by providing FDA with a written statement that the patent owner and the applicant have entered into a patent licensing agreement and consent to an immediate effective date. In such cases, i.e., when the agency is informed by the patent owner of a licensing agreement, the agency may, if all other requirements are met, approve the ANDA before the 45-day statutory period has elapsed. The written statement from the patent owner should be in the following form:

(*Name of patent owner*), owner of Patent No. _____, and (*name of applicant*) have entered into a patent licensing agreement that authorizes (*name of applicant*) to engage in the manufacture and sale of (*name of proposed drug product*). (*Name of patent owner*) does not object if FDA makes the approval of (*name of applicant's*) ANDA for (*name of proposed drug product*) effective at any time on or after the date of this statement.

If an ANDA refers to a listed drug that is itself a licensed generic version of a patented pioneer drug, the ANDA must include a certification as to any relevant patent on the pioneer drug. Section 505(j)(2)(A)(vii) of the act requires an applicant to make a certification "* *with respect to each patent which claims the listed drug referred to in clause (i) or which claims a use for such listed drug for which the applicant is seeking approval* under [section 505(j)] and for which information is required to be filed under subsection (b) or (c) *" (emphasis added). Because, where a licensing agreement is necessary, the patent will claim both the pioneer drug product and generic copies of that drug product, an ANDA that refers to the licensed copy must include a certification as to any patent on the pioneer for which information was required to be filed under section 505 (b) or (c) of the act. When the agency is aware of a patent licensing agreement between the applicant of a listed generic drug and a patent owner, it will publish in the list information on the patent next to the listing for the licensed generic drug.

iv. *Amended certifications*. FDA is proposing to require an applicant who has made a paragraph IV certification to amend its patent certification if the applicant has a pending ANDA or an ANDA with a delayed effective date and one of the following occurs: (1) a final judgment is entered finding that the applicant's product infringes the patent, or (2) the patent is removed from the list for any reason other than because the patent has been declared invalid in a lawsuit brought by the patent owner within 45 days of the receipt of notice under section 505(j)(2)(B) of the act. Once amended, the application will not be considered to be one containing a paragraph IV certification for purposes of section 505(j)(4)(B)(iv) of the act.

A patent certification must also be amended if the applicant learns that its previous certification is incorrect, with two exceptions. First, as described above in part V section D.1.j.ii., an applicant who has made an appropriate certification would not be required to amend the certification if, following the first certification, the listed drug applicant submits information on a patent on the listed drug, but the submission is untimely.

Second, FDA is proposing not to require an amended certification if after an ANDA is approved, whether or not the approval is effective, the listed drug applicant submits information on a patent on the listed drug, whether the submission is timely or not. Once an ANDA becomes effective, new patents issued on a listed drug are not subject to the patent certification provisions of the 1984 Amendments; the patent holder may enforce such a patent under the patent provisions of Title 35 of the United States Code, but is not entitled to notice from the ANDA applicant or to a period during which the ANDA applicant is kept off the market while the patent issue is litigated. Any delay in an ANDA's effective date will be entirely unrelated to the timing of the issuance of a new patent on the listed

drug. Accordingly, FDA believes that requiring an amended certification if a patent is issued after approval of an ANDA but before its effective date would provide an unintended windfall to the listed drug applicant, who, but for the fortuitous delay in the ANDA's effective date, would not have reaped the benefits of the patent certification provisions of the 1984 Amendments. However, FDA specifically seeks comment on whether an amended certification should be required under these circumstances, and on the policies, if any, that would be served by requiring such an amendment.

2. *Review copy.* The agency proposes to retain the current requirement that, in addition to the complete archival copy, an applicant submit a review copy of an ANDA that contains two separately bound sections. One section would be required to contain a copy of the application form, the chemistry, manufacturing, and controls information described in proposed § 314.94(a)(9), the information described in proposed § 314.94(a)(3) (basis for ANDA submission), § 314.94(a) (4) through (6), (8), and (12), and one copy of the analytical methods and descriptive information needed by FDA's laboratories to perform tests on samples of the proposed drug product and to validate the applicant's analytical methods. The other section will contain a copy of the application form, the information described in § 314.94(a)(3) (basis for ANDA submission) and (7) (bioequivalence information) and a copy of the currently approved labeling for the reference listed drug and of the applicant's annotated proposed labeling.

E. Notice of Certification of Invalidity or Noninfringment of a Patent

Proposed § 314.95 incorporates the requirements of section 505(j)(2)(B) of the act with respect to notification of the patent owner and the holder of the approved application for the listed drug when an applicant certifies under section 505(j)(2)(A)(vii)(IV) of the act that a patent is invalid or will not be infringed. In addition, proposed § 314.95 describes the information to be included in the notice.

The act permits an applicant who wishes to market a generic version of a listed drug product to challenge a drug or use patent that the pioneer application holder identifies as precluding the marketing of the generic version. An applicant who submits an ANDA to FDA for the generic version of the listed drug and wishes to initiate such a challenge must certify that the relevant patent submitted by the pioneer application holder to the agency is invalid or will not be infringed. The applicant must then give notice of its certification to (1) the owner(s) of each relevant patent or the representative designated by the patent owner to receive such notice and (2) the holder of the approved application under section 505(b) of the act for the reference listed drug claimed by the patent or the holder's representative (attorney, agent, or other authorized official).

Under the proposal, an applicant is required to provide the notice of certification when it receives FDA's acknowledgment of the receipt of an ANDA that is acceptable for review. Although the legislative history states that Congress intended that the notice be sent simultaneously with submission to FDA of the ANDA, the statute requires the applicant to state in the notice that an application "has been submitted. Moreover, the statute requires the notice to state that the application contains data from bioavailability or bioequivalence studies. Receipt of the notice by the patent owner or its representative or the approved application holder triggers the start of the 45-day clock within which a patent owner or application holder must bring suit if it wishes to challenge an applicant's certification of patent invalidity or noninfringement. The statute and legislative history of Title I demonstrate that Congress did not intend incomplete application submissions to trigger legal action by a patent owner or approved application holder.

The agency therefore proposes that the notice be sent only upon submission of a "complete" application. An applicant must first submit an ANDA and certify in the application that it will provide the required notice to the patent owner or its representative and to the pioneer application holder. After receipt of the application, the agency will determine if the application is acceptable for review. An application containing a paragraph IV certification that does not contain the results of any required completed bioavailability or bioequivalence studies that meets an appropriate FDA guidance or that is reasonable in design, and that purports to show that the proposed drug is bioequivalent to the listed drug, would not be considered acceptable for review. Neither a protocol nor a pilot study will be considered acceptable. If, however, the ANDA is for a drug for which a bioequivalence study is not required, e.g., a parenteral product, the application may be considered acceptable for review if it contains a waiver of a bioequivalence study requirement. If the application is acceptable for review, FDA will notify the applicant in writing and provide the applicant with the ANDA number assigned by FDA. Immediately upon receipt by the applicant of FDA's acknowledgement letter, the applicant would be required to notify the persons described in the statute of the certification of invalidity or noninfringement, and amend the ANDA to include a statement certifying that the notice has been provided and that the notice contains the required information, described at § 314.95(c). If an abbreviated application is amended to include a paragraph IV certification because the applicant learns of a relevant patent after the abbreviated application is submitted and before its approval, the applicant would be required to notify the appropriate parties when the amendment is submitted to FDA. If a patent on a listed drug is issued after an abbreviated application is approved, the generic applicant need take no further action.

The agency does not propose to require the applicant to notify holders of approved applications for drugs other than the listed drug claimed by the product or use patent. If an ANDA refers to a licensed generic version of a patented pioneer drug and the applicant made a certification as to the patent on the pioneer drug, the applicant must notify the patent owner and the holder of the approved pioneer application of its certification.

An applicant may obtain the name and address of the patent owner or the attorney or agent designated to represent the patent owner in patent proceedings (attorney or agent of record) from the United States Patent and Trademark Office. The name and address of the holder of the approved application or the holder's attorney, agent, or authorized official (i.e., the person who signed the Form FDA 356h) may be obtained from FDA's Center for Drug Evaluation and Research, Division of Drug Information Resources (HFD-80).

The 45-day clock would start on the first day after the date of receipt of the notice by the patent owner or its representative or by the approved application holder if it is an exclusive patent licensee as documented by the applicant under proposed § 314.95(e). Although an applicant is required to provide the notice to the patent owner and approved application holder, FDA believes it is appropriate to rely solely on the patent owner to make decisions about bringing patent infringement actions, unless there is a patent license

agreement and the approved application holder is the exclusive patent licensee. In the latter situation, FDA would expect the exclusive licensee to bring suit for patent infringement. Therefore, the date of receipt of the notice by an application holder who is not an exclusive licensee for the patent will not trigger the start of the 45-day clock. The agency specifically seeks comment on this policy.

FDA will accept as adequate documentation of the date of receipt of the notice (1) a return receipt or (2) a letter acknowledging receipt from the patent owner and approved application holder. If an applicant wishes to rely on another form of documentation, the applicant should first check with the agency. The applicant would be required to amend the ANDA to include a copy of the return receipt or other such evidence of the date the notification was received by the patent owner and approved application holder.

Proposed § 314.95(c) lists the information to be included in the notice. Under the proposal, the notice would cite section 505(j)(2)(B)(ii) of the act as the relevant statutory authority for the notice and contain: (1) a statement that FDA has received an ANDA submitted by the applicant containing any required bioavailability or bioequivalence data or information, (2) the ANDA number assigned by FDA, (3) the established name, if any, of the drug product that is the subject of the ANDA, (4) the active ingredient, strength, and dosage form of the proposed drug product, (5) the patent number and expiration date, as submitted to the agency or as known to the applicant, of each patent alleged to be invalid or not infringed, (6) a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed, and (7) if the applicant does not reside or have a place of business in the United States, the name and address of an agent in the United States authorized to accept service of process for the applicant. With respect to the factual and legal basis for the applicant's certification, the agency proposes that for each claim of a patent noninfringement, the notice would be required to include an explanation of the alleged noninfringement. In addition, for formulation or composition patents, the notice would be required to include a description of a mechanism through which the applicant agrees to make the formulation or composition of the proposed drug product known to the patent owner or to a designated intermediary who will act as a referee. The agency believes that only by making the formulation or composition available to the patent owner or a designated third party will the patent owner have sufficient information to make an informed decision whether to sue for patent infringement. For each claim of patent invalidity, the notice would be required to include an explanation of the grounds supporting the allegation, including all statutory bases, affirmative defenses, reasoning, and evidence supporting the allegation, citing any relevant case precedent upon which the allegation is based, providing a copy of any patent or publication relied upon, and indicating that portion of each such patent or publication that is alleged to invalidate such claim and the reasons supporting such allegation.

Although the proposed regulations describe the information required by statute that an applicant must include in a notice, the applicant is not required to include a copy of the notice in its ANDA as suggested by the Pharmaceutical Manufacturers Association (PMA) (comments filed under Docket No. 85N-0214). Only a statement that such notice has been given by the applicant is required (21 U.S.C. 355(j)(2)(B)(i)). Determinations concerning the scope of patents are the province of the United States Patent and Trademark Office and of the courts. FDA does not have the expertise, nor is it required to review the notice as suggested by PMA. FDA proposes only to ensure that such notice has been sent and received. If the applicant meets the requirements under proposed § 314.95, which FDA believes will assure adequate notice, the agency will presume the notice to be complete and sufficient. Thus, the agency does not intend to intervene in cases where the patent owner or exclusive patent licensee claims that the notice was deficient. However, in cases where the notice was deemed inadequate by the patent owner or exclusive patent licensee and where the ANDA applicant subsequently amends the notice, the agency may, if the applicant amends its ANDA with a written statement that the date of receipt of the amended notification should be considered the date of receipt of notice, use the date of the amended notification to begin the 45-day statutory period for institution of an action for patent infringement.

F Amendments to an Unapproved ANDA

The agency proposes to revise its regulations regarding amendments to pending ANDA's.

Proposed § 314.96 would provide for extensions to the 180-day review clock under section 505(j)(4)(A) of the act only for evaluating major amendments (i.e., those requiring substantial FDA review time). Examples of such major amendments would involve amendments that contain data from a new bioequivalence study or stability or sterility study resulting from a drug product reformulation or change in the manufacturing or controls procedures, significant updated data from a change in the source of the drug substance or change in manufacturing facility, or data from a bioequivalence study where only a protocol was contained in the original submission. The agency would consider such an amendment, whether submitted on the applicant's own initiative or at the request of the agency, to constitute an agreement by FDA and the applicant to an extension of the review period under section 505(j)(4)(A) of the act. Any extension would start with the date of receipt by FDA of the amendment and would be limited to the time necessary for FDA to review the submission.

Under the proposal, an amendment that contains data and information to resolve substantial deficiencies in the ANDA as set forth in a not approvable letter under § 314.120 would extend the review period for 120 days from the date of receipt by FDA of the amendment. Although the agency now attempts to review these amendments quickly, the agency believes this is a reasonable period for review of an amendment to resolve substantial deficiencies and that establishing a uniform length of time for this review will eliminate the need to notify each applicant of the amount of time needed to review its amendment.

G. Other Applicant Responsibilities

1. *General.* The agency proposes to retain the current requirements for applicants under 21 CFR Part 314 regarding: (1) withdrawal by an applicant of an unapproved ANDA, (2) submission of supplements and other changes to an approved ANDA, (3) change in ownership of an ANDA, (4) submission of postmarketing reports, other than adverse drug experience reports, and (5) request for waiver of submission requirements.

2. *Postmarketing reports.* With respect to the requirements set forth under § 314.80 for reporting adverse drug experiences, the agency proposes in § 314.98 to require an applicant of an approved ANDA to comply with those requirements but only if the approval is effective under § 314.107 The objective of the adverse drug experience reporting requirements is to signal potential serious safety problems with marketed drugs, especially newly marketed drugs. An applicant cannot market a drug product before it has an effective

approval for its ANDA, so it is unlikely that the applicant, before this effective approval, would receive adverse drug experience information about other drug products through literature reports or unpublished scientific papers that would not also be received by the marketers of those drug products.

FDA is also proposing in § 314.98 the following changes in its adverse drug experience reporting requirements for applicants of ANDA's and abbreviated antibiotic applications. First, ANDA and abbreviated antibiotic application applicants would no longer be required to submit duplicate copies of adverse drug experience reports. This change is made possible by the centralization of FDA's processing of drug experience reports on generic versions of approved drug products in a single office in the Center for Drug Evaluation and Research that has the responsibility for ensuring the proper distribution and analysis of these reports. Ordinarily, the Division of Generic Drugs will not evaluate these reports and therefore no longer needs to receive a copy. Applicants should send one copy of each adverse drug experience report directly to the Division of Epidemiology and Surveillance (HFD-730).

Second, the proposed regulations would provide that an ANDA and abbreviated antibiotic application applicant submit to FDA periodic reports of adverse drug experiences only if (1) the applicant has received during the periodic reporting cycle adverse drug experiences not previously reported or (2) there are labeling changes initiated by the applicant.

FDA is also proposing the following revisions to § 314.80. First, the agency proposes to revise the definition of the term "adverse drug experience" by deleting the word "significant" in the phrase "any significant failure of expected pharmacological action. The word "significant" has been a source of confusion and ambiguity. FDA considers any report of failure of a drug to produce the expected pharmacological action to be significant. This proposed revision would unambiguously require that all reports of a therapeutic failure (lack of effect) be submitted to FDA. Second, the agency proposes to add the following new adverse drug experience reporting requirement. Under the proposal, applicants of both full and abbreviated applications would be required to review periodically (at least as often as the periodic reporting cycle) the frequency of reports of failure of a drug to produce the expected pharmacological action (lack of effect) received by an applicant and report any significant increase in frequency of therapeutic failure (lack of effect) to FDA within 15 working days of determining that an increase in frequency exists. Determinations of significant increases in frequency are to be based on FDA's "Guideline for Postmarket Reporting of Adverse Drug Reactions. Applicants would be required to submit these reports in narrative form (including the time period on which the increased frequency is based, the method of analysis, and the interpretation of results). These narrative reports would be required to be submitted under separate cover and not in a periodic report except for summary purposes. The intent of this proposed revision is to facilitate the identification of possible therapeutic failures with both generic and brand-name drug products, and to obtain evidence to confirm or refute reports of therapeutic inequivalence between generic drugs and their brand-name counterparts. (Also see part VI. Conforming Amendments.)

The agency proposes to retain the current requirement for the submission of other postmarketing reports under § 314.81, if applicable, upon approval of an ANDA, whether or not the approval is effective. For example, certain manufacturing and control changes not requiring a supplemental application under § 314.70(b) and (c) must be reported in an annual report, and advertising and promotional material must be submitted to FDA at the time of initial dissemination or initial publication.

3. *Waivers.* The agency proposes to retain the current requirement under § 314.90 under which an applicant may obtain a waiver of requirements for the submission of information in an application. The applicable sections are those set forth under new proposed Subpart C. FDA may not, however, waive statutory requirements.

H. Time Frames for FDA Actions on ANDA's

The agency proposes to revise its regulations regarding agency actions in receiving, reviewing, and approving or refusing to approve ANDA's to implement the provisions of section 505(j) of the act.

1. *Receiving and reviewing ANDA's.* Under section 505(j)(4)(A) of the act, within 180 days of the initial receipt of an ANDA, FDA must either approve or refuse to approve the ANDA, unless FDA and the applicant agree to an extension. If FDA refuses to approve the ANDA, it must give the applicant a notice of an opportunity for a hearing (NOOH) on whether the ANDA is approvable and will issue such a notice if the applicant elects to request a hearing rather than to amend or withdraw its application, see § 314.120.

Although the statute mentions "filing" an ANDA, filing does not trigger the statutory time period in which FDA must either approve or disapprove the ANDA. For an ANDA submitted to FDA under section 505(j) of the act, it is the time between the initial receipt of the ANDA and approval or disapproval. This differs from an application submitted under section 505(b) of the act, for which, within 180 days after filing an application, FDA must either approve the application or give the applicant a notice of opportunity for a hearing on whether the application is approvable, unless FDA and the applicant agree to an extension of time. For applications submitted under section 505(j) of the act, the agency considers the date of initial receipt of an ANDA to be the date FDA receives a submission that, on its face, is sufficiently complete to permit a substantive review. Such an ANDA may contain only the chemistry, manufacturing, and controls information required by § 314.94(a)(9) and a bioequivalence protocol unless the applicant certifies that a relevant patent is invalid or will not be infringed. In the latter case, the ANDA must contain also the results of any required bioequivalence studies.

Accordingly, the agency proposes revisions to § 314.101 to add the requirements for receipt of an ANDA. ANDA's will be reviewed for completeness when they are submitted. If an ANDA is not sufficiently complete to permit a substantive review, the applicant will be notified, normally by telephone. The applicant may then withdraw the application, amend the application to correct deficiencies, or take no action. FDA may elect to allow a deficiency to be corrected without a formal withdrawal of the ANDA and resubmission. If the applicant does not correct the deficiency, FDA will not consider the ANDA "received. If an ANDA is sufficiently complete to permit a substantive review, the application will be "received" and reviewed. (See proposed § 314.101(b).)

To clarify its applicability, the agency also proposes to revise the provision under § 314.101(e)(1) under which FDA will refuse to file an application if the drug product that is the subject of the submission is already covered by an approved application. The provision is intended to permit FDA to refuse to review spurious applications. For example, persons or firms who are

merely distributors of an already approved drug product do not need an approved application for the products they distribute. Therefore, the agency proposes to revise the provision to read, "The drug product that is the subject of the submission is already covered by an approved application and the applicant of the submission is merely a distributor and/or a repackager of the already approved drug product. The agency specifically seeks comment on whether there are appropriate exceptions or additions to this provision that should be expressly noted in the provision, e.g., for joint developers of a drug product, or distributors who engage in activities beyond that of a distributor because of a special relationship to the developer of the drug product.

2. *Approval of ANDA's.* Section 505(j)(3) of the act requires FDA to approve an ANDA if it finds that none of the statutory grounds for disapproval of the ANDA apply. The agency proposes to revise § 314.105 to state this requirement. Under the proposed revision, if FDA finds that none of the grounds in the statute for disapproval of an ANDA applies, the agency would approve the ANDA and send the applicant an approval letter. If only minor deficiencies exist in the applicant's draft labeling or if the applicant has not submitted final printed labeling to FDA and the application is otherwise approvable, FDA will send the applicant an approvable letter. The approvable letter will describe the information or material FDA requires and state a time period within which the applicant must respond. Unless the applicant corrects the deficiencies by amendment or submits final printed labeling within the specified time period, the agency would formally refuse to approve the application. The agency proposes to revise § 314.110 by adding a new paragraph (b) to state when FDA will send the applicant an approvable letter.

I. Applications Described by Section 505(b)(2) of the Act

Since 1977 FDA has permitted applicants who want to market generic copies of new drugs first approved after 1962 to file new drug applications that meet the "full reports" requirement of section 505 of the act with published reports in the medical literature establishing the generic drug's safety and effectiveness. FDA's policy of permitting approval of generic copies of approved drugs based on literature reports is commonly referred to as the "paper NDA policy, a complete description of which appears in the Federal Register of May 19, 1981 (46 FR 27396). The "paper NDA policy" applied only to duplicate drug products of post-1962 drugs, i.e., drug products which contained an active ingredient identical to an already marketed drug product first approved for marketing after 1962 in the same or closely related dosage form, and offered for the same indications as those of the already marketed drug product.

A paper NDA was a new drug application for a duplicate drug product submitted under section 505(b) of the act that satisfied the statutory criteria for a full application except that the full reports of investigations required by section 505(b) of the act to prove safety and effectiveness consisted entirely of references from the medical literature. A paper NDA differed from an abbreviated new drug application in that, in an abbreviated application, studies of safety and effectiveness (other than bioavailability) were not required to be submitted or identified by the applicant.

The 1984 Amendments to the act include provisions applicable to applications submitted under section 505(b)(1) of the act similar to those previously denominated paper NDA's. These new provisions, under sections 505(b)(2) and 505(c)(3) (D) of the act, describe an application submitted under section 505(b)(1) in which the investigations described in clause (A) of section 505(b)(1) of the act and relied upon by the applicant for approval of the application "were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. The requirement in clause (A) to which this provision refers mandates submission of "* full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use. Section 505(b)(2) of the act is significant because newdrug applications that contain full reports of investigations that were not conducted by or for the applicant or for which the applicant has not obtained a right of reference are subject to the patent certification and exclusivity provisions of the act. (See part V sections K. and L.)

Despite certain similarities between section 505(b)(2) of the act and the "paper NDA policy," the new statutory provision is broader than the paper NDA policy. Although the legislative history of the 1984 Amendments refers to "paper NDA's" in discussing the applications described in sections 505(b)(2) and 505(c)(3)(D) of the act, the language of these provisions does not limit the applications described to duplicates of already approved products. Instead, sections 505(b)(2) and 505(c)(3)(D) of the act, by their terms, apply to any application that relies on investigations which the applicant has not conducted, sponsored, or obtained a right of reference to, regardless of the similarity or dissimilarity of the drug product to an already approved drug product.

The agency therefore proposes, in accordance with the plain language of the statute, to interpret sections 505(b)(2) and 505(c)(3)(D) of the act to cover any application in which one or more of the investigations without which the application could not be approved, as described below, were not conducted or sponsored by the applicant or to which the applicant does not have a right of reference. Such applications may be for variations of approved drug products, or, rarely, for new chemical entities. (An application, however, for a new chemical entity would not be subject to any patent protection or exclusivity accorded a previously approved drug, because, by definition, there will be no applicable previously approved drug.)

Because the 1984 Amendments established a statutory scheme for the approval of all applications that, before the Amendments, would have been approved under the paper NDA policy, the agency believes that the policy is no longer necessary. For this reason, and to avoid confusion caused by the differences between the coverage of the paper NDA policy and the 1984 Amendments, FDA is hereby revoking the policy. FDA proposes to revise § 314.50 to delete the term "paper NDA wherever it now appears.

The agency does not, however, propose to treat all applications previously covered by the paper NDA policy as 505(b)(2) applications. Applications for duplicates of listed drugs eligible for approval under ANDA's will be treated as submitted under section 505(j) of the act rather than under section 505(b) of the act, even if such applications are supported by literature reports of safety and effectiveness. The agency intends to treat any application for a duplicate of a listed drug eligible for approval under an ANDA as an application under section 505(j) of the act because it believes that Congress intended the ANDA provisions to, among other things, assist the agency in avoiding duplicative reviews of safety and effectiveness information about already approved drugs. It would be inconsistent with this purpose to require FDA to

review safety and effectiveness information in 505(b)(2) applications when the statute also authorizes an abbreviated review under section 505(j) of the act. Moreover, because the patent certification and exclusivity provisions apply equally to applications described under section 505(b)(2) or 505(j) of the act, an applicant will not be disadvantaged by the review of its application under section 505(j) of the act rather than 505(b)(2) of the act.

The agency has considered expanding this policy to include applications for drug products that are modified versions of previously approved products, where the types of changes are those for which a section 505(j)(2)(C) petition could be approved permitting submission of an ANDA. As described above in part V section C., certain types of changes from an approved product, i.e., changes in dosage form, strength, route of administration and active ingredients, can be reviewed in a 505(j) application, if a petition under section 505(j)(2)(C) of the act is approved permitting the submission of an ANDA. Currently, an applicant can submit a 505(b)(2) application for a drug product with any of these types of changes rather than request permission to submit an ANDA through a 505(j)(2)(C) petition. Under an expanded policy, one option would be to treat a 505(b)(2) application for these types of changes as a 505(j)(2)(C) petition. Another option would be to return the 505(b)(2) application to the applicant and request the submission of a 505(j)(2)(C) petition. This expanded policy would also further assist the agency in avoiding reviews of safety and effectiveness information in a 505(b)(2) application for drug products for which the statute authorizes an abbreviated review under section 505(j) of the act. The agency specifically seeks comment on whether FDA should adopt such an expanded policy.

Applications described by sections 505(b)(2) and 505(c)(3)(D) of the act may therefore currently be submitted for: (1) drug products that could not be approved under section 505(j) of the act and (2) drug products with changes from an approved product that could be reviewed in an ANDA submitted pursuant to a 505(j)(2)(C) petition for which the applicant chose to submit a 505(b)(2) application rather than a petition. In practice, with respect to the first category of drug products, this means that 505(b)(2) applications will generally be submitted for never before approved changes in already approved drug products, where the change cannot be reviewed under section 505(j). As described above in part V section C., certain types of changes from an approved product, in dosage form, strength, route of administration and active ingredients, can be reviewed in a 505(j) application, as long as investigations are not necessary to evaluate the safety and effectiveness of the changed product. If such investigations are necessary, they can be reviewed only under the procedures applicable to 505(b) applications. Therefore, a 505(b)(2) application will be appropriately submitted for a drug product where the safety and effectiveness of the change must be, at least in part, established by investigations. Examples of such cases would be applications seeking approval of significantly different dosage forms or of new uses of already approved drugs. If it is necessary for FDA to review the results of investigations to approve the drug, but the applicant has not conducted, sponsored, or obtained a right of reference to one or more of the investigations necessary for approval of the application, the application will be treated as a 505(b)(2) application.

In addition to applications supported by literature reports or a combination of literature reports and new clinical investigations, FDA is proposing to treat as a 505(b)(2) application an application for a change in an already approved drug supported by a combination of literature or new clinical investigations and the agency's finding that a previously approved drug is safe and effective. (See part V section J., *infra.*)

The agency proposes to interpret the phrase "right of reference or use" as a right of reference to, or use of, the underlying raw data which provide the basis for the reports of investigations submitted in a 505(b)(2) application. Proposed revised § 314.3(b) incorporates this interpretation as the definition of the term "right of reference or use. A right of reference or use must be granted by the owner of the raw data. If the raw data are in the public domain, e.g., because they were developed in a publicly funded study, no express right of reference is necessary. FDA is proposing, under revised § 314.50(g), to require an applicant that has obtained a right of reference to, or use of, such raw data, to include in its application a written statement signed by the owner of the data that authorizes the applicant to use, in support of its submission to FDA, the raw data that provide the basis for each report of an investigation submitted in its application. Thus, the applicant must be able physically to make available the raw data for FDA audit, if necessary, or the data must be available for review by FDA in another application to which the applicant has a right of reference.

FDA proposes to interpret the phrase "investigations described in clause (A) and relied upon for approval" in sections 505(b)(2) and 505(c)(3)(D) of the act to mean any investigations without which the application could not be approved. Accordingly, an application is described by section 505(b)(2) of the act if the applicant has not conducted or sponsored or obtained a right of reference to every safety or effectiveness investigation without which the drug could not be approved. An application that contains one study conducted by the applicant but that relies on literature citations for the remainder of the safety and effectiveness data without rights of reference is thus considered an application described by section 505(b)(2) of the act.

In light of this interpretation, an applicant seeking to submit a so-called "full NDA and thereby avoid any exclusivity or patent rights attaching to a pioneer drug must conduct or sponsor the adequate and well-controlled investigations necessary to establish the effectiveness of the drug, or, if the applicant relies on literature for these studies, must obtain rights of reference to the data. The applicant must conduct, sponsor, or obtain rights of reference to these studies even if the pioneer applicant relied on literature citations. Similarly, the applicant must conduct, sponsor, or obtain a right of reference to all the safety tests without which the application could not be approved. In general, such tests will include animal carcinogenicity and reproduction studies, certain animal toxicity studies, and some clinical investigations. When a drug product has a U.S. marketing history, an analysis of the spontaneous adverse reaction reports may, in some cases, be substituted for some of the safety data described. Appropriate reliance on an analysis of these adverse reaction reports will not cause the application to be one described by section 505(b)(2) or 505(c)(3)(D) of the act.

This interpretation is consistent with Congress' intent to encourage the pharmaceutical industry to develop and seek approval of significant new therapies by conferring periods of exclusive marketing. If exclusivity could easily be avoided by an application containing only minimal data generated or purchased by the applicant, the incentive created by the availability of such exclusivity would decrease considerably.

The term "application" as defined in § 314.3 means both a full application submitted under section 505(b)(1) of the act that contains full reports of investigations conducted or sponsored by the applicant or for which the applicant has obtained a right of reference or use and an application submitted under section 505(b)(1) of the act that meets the description in section 505(b)(2) of the act, i.e., one or more of the investigations without which the application could not be approved relied on by the applicant for approval of the application were not conducted by or for the applicant and the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted.

Applications that meet the description in section 505(b)(2) of the act have been (under the "paper NDA policy"), and will continue to be, submitted under section 505(b)(1) of the act. They are therefore subject to the same statutory provisions that govern full new drug applications, except, of course, that the applicant has not conducted, sponsored, or obtained a right of reference to one or more of the investigations necessary to demonstrate safety and effectiveness. Thus, for example, 505(b)(2) applications may be entitled to periods of exclusivity and should submit any relevant information required under proposed § 314.50(j), and any relevant patent information required under § 314.53.

A new drug application that meets the statutory description in sections 505(b)(2) and 505(c)(3) of the act must satisfy patent certification requirements and is subject to any exclusivity accorded a relevant previously approved drug. The patent and exclusivity provisions applicable to 505(b)(2) applications are generally the same as those that apply to abbreviated new drug applications.

An applicant submitting a section 505(b)(2) application must make the same certifications with respect to patents as an applicant submitting an ANDA. (See part V section D.1.j., *supra*.) A 505(b)(2) applicant must make certifications with respect to each patent which, in the opinion of the applicant and to the best of its knowledge, claims the drug or drugs on which investigations that are relied upon by the applicant for approval of its application were conducted, or which claims a use for such drug or drugs. With respect to a use patent, if the labeling of the applicant's proposed drug product includes an indication that, according to the patent information submitted to FDA or in the opinion of the applicant, is claimed by the use patent, the applicant must submit to FDA an appropriate certification under section 505(b)(2)(A) of the act. If, however, there is a patent on a method of using the drug that was the subject of an investigation relies on in the application and the labeling for the applicant's proposed drug product does not include the indications that are covered by the use patent, the applicant must submit a statement under section 505(b)(2)(B) of the act that the method of use patent does not claim any of the proposed indications. As with ANDA's, if the applicant certifies that a patent is invalid or will not be infringed, the applicant is required to give notice to patent owners and holders of approved new drug applications. Applicants who have licensing agreements with patent owners will also be required to follow the same rules as licensed ANDA applicants. FDA proposes to revise § 314.50 by adding a new paragraph (i) that would contain the regulations implementing the statutory provision regarding the certification requirements and to add new § 314.52 to describe the notice requirements.

As with ANDA's, under proposed revised § 314.80, an applicant of an approved 505(b)(2) application would comply with the requirements for reporting adverse drug experiences only if the approval is effective under § 314.107

J. Applications for Changes in Approved Drug Products That Require the Review of Investigations

As described in part V section C., *supra*, an applicant may petition for permission to submit an ANDA for certain changes in the listed drug when the change does not require the review of investigations. An applicant may also wish to make a modification in an approved drug where the modification requires the submission of data that cannot be reviewed in an ANDA. For example, an applicant may wish to obtain approval of a new indication for a listed drug that is only approved for other indications. If the applicant has an approved ANDA for the approved indications, the applicant may of course submit a supplemental application that contains reports of clinical investigations needed to support approval of the new indication. (Because such a supplement would require the review of clinical data, FDA would process it as a submission under section 505(b) of the act.)

An applicant may also wish to seek approval of, for example, a new dosage form of a listed drug that requires the review of investigations but may have no interest in marketing the drug in its approved dosage form. The 1984 Amendments do not directly address the appropriate mechanism for obtaining approval of such a change, but permit several alternatives. The statute could be interpreted to require such an applicant to first obtain approval of an ANDA for the listed drug's approved dosage form, and then file a 505(b) supplement to the approved ANDA containing clinical data to obtain approval of the new dosage form. If the applicant did not first obtain an ANDA for the approved dosage form, the applicant could be required to submit a full new drug application under section 505(b) of the act for the new dosage form and duplicate the basic safety and effectiveness studies conducted on the listed drug. FDA has concluded that such an interpretation would be inconsistent with the legislative purposes of the 1984 Amendments because it would serve as a disincentive to innovation and could require needless duplication of research.

FDA believes that a more consistent, less burdensome interpretation of the 1984 Amendments is to allow a generic applicant to submit a 505(b) application for a change in an already approved drug that requires the submission and review of investigations, without first obtaining approval of an ANDA for a duplicate of the listed drug. Therefore, under proposed § 314.54, applications will be accepted for changes requiring the review of investigations, including changes in dosage form, strength, route of administration, and active ingredients (in a combination product), as well as new indications. Like similar supplements to approved ANDA's, these applications will rely on the approval of the listed drug together with the data needed to support the change. The applicant will thus be relying on the approval of the listed drug only to the extent that such reliance would be allowed under section 505(j) of the act: to establish the safety and effectiveness of the underlying drug. FDA notes, however, that it will not accept such an application for a drug that differs from the listed drug only in that its extent of absorption is significantly less than that of the listed drug. To allow such a drug to be approved under section 505(b)(2) would thwart Congress' clear intention to require that a duplicate of a listed drug be shown to be bioequivalent to that listed drug. (See section 505(j)(3)(F) of the act.)

FDA also believes that it would be inconsistent with the policies of the 1984 Amendments to allow these applications to rely on the approval of a listed drug unless they were subject to the listed

drug applicant's patent rights and exclusivity. Therefore, an application that relies in part on the approval of a listed drug, is, for this purpose, considered an application described in section 505(b)(2) and must make a certification as to any relevant patents that claim the listed drug. In addition, the date of submission and effective approval of these applications may, under section 505(c)(3), be delayed to give effect to any patent or period of exclusivity accorded the listed drug.

Because these submissions will be reviewed as applications under section 505(b) of the act, they will be subject to the statutory and regulatory requirements applicable to such applications, including the patent submission requirements of sections 505 (b) and (c) of the act, and may be eligible for 3 years of exclusivity under sections 505(c)(3)(D) (iii) and (iv) of the act. These applications should be directed to the address specified in § 314.440(a)(1). The agency proposes to revise § 314.440(a)(1) to so state.

K. Delay in the Effective Date of Approval of an ANDA and 505(b)(2) Application Because of the Existence of a Patent

The 1984 Amendments require an important change from previous practice for ANDA's and those 505(b)(2) applications previously handled as paper NDA's with respect to the effective date of their approval. The effective dates of approval of ANDA's and 505(b)(2) applications are dependent on the existence of any patents on the pioneer drug for which the generic applicant is seeking approval (sections 505(j)(4)(B) and 505(c)(3) of the act) and on any periods of exclusive marketing accorded the reference listed drug or other listed drug under the so-called "exclusivity" provisions of the act (sections 505(j)(4)(D) and 505(c)(3)(D) of the act). Thus, an ANDA or 505(b)(2) application may be approved with a delayed effective date, as specified by the agency in its approval letter. No new drug product may be introduced or delivered for introduction into interstate commerce under a full or abbreviated new drug application unless the approval of the application is effective (section 505(a) of the act). The agency proposes to add new § 314.107 to the regulations to codify the statutory requirements with respect to effective dates of approval of ANDA's and 505(b)(2) applications.

With respect to patent status, proposed § 314.107 provides that approval of an ANDA or 505(b)(2) application, if approval is otherwise warranted, would be made effective in accordance with the following conditions. First, if the applicant certified that there are no relevant patents, or the holder of the approved application for a drug product covered by a relevant patent did not submit to FDA any patent information, or that the relevant patents submitted to FDA have expired, approval of the ANDA or 505(b)(2) application would be made effective immediately.

Second, if the applicant certified that any relevant patents would expire on a certain future date, based on information submitted to FDA, approval of the ANDA or 505(b)(2) application would become effective on that date, unless that date had already passed, in which case the approval would be immediately effective.

Third, if the applicant certified that any relevant patent was invalid or would not be infringed, approval of the ANDA or 505(b)(2) application could be made effective 45 days from the date of the receipt of the notice of certification by the patent owner or the approved application holder who is an exclusive patent licensee, unless the patent owner or exclusive patent licensee filed an action for patent infringement before the 45 days have elapsed. As discussed in part V section D.1.j. above, FDA proposes to require that an applicant who has obtained a patent license to manufacture a generic copy of a patented drug certify under section 505(b)(2)(A)(iv) or 505(j)(2)(A)(vii)(IV) of the act that the relevant patent is invalid or will not be infringed. Although the statute does not expressly address the effect of patent licensing agreements on effective dates, FDA does not believe that Congress intended to interfere with such agreements between pioneer and generic drug manufacturers. See section 505(b)(1) of the act (defining applicable patents as those "to which a claim of patent infringement would reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug"). Accordingly, FDA proposes to make the approval of an ANDA or 505(b)(2) application effective immediately where the applicant submits (1) information establishing that the proposed drug is covered by a patent licensing agreement with the patent owner, and (2) a written statement from the patent owner consenting to an immediate effective date. FDA invites comment on this approach.

Even in the absence of a licensing agreement, the patent owner or exclusive patent licensee may waive its opportunity to file an action for patent infringement provided it submits a valid waiver to FDA before the 45 days elapses. Under proposed § 314.107(f)(3), if a patent owner or exclusive patent licensee does not intend to file action for patent infringement against the generic applicant within the 45-day time period and the applicant seeks an effective approval date before the 45-day period has elapsed, the patent owner or exclusive patent licensee must submit to FDA a waiver in the form prescribed in the proposed regulation.

1. *The 45-day clock.* Both the PMA and the Generic Pharmaceutical Industry Association (GPIA) offered FDA suggested regulatory language designed to ensure that the recipient of a notice of patent certification has the full 45 days in which to decide whether to bring a patent infringement suit. (PMA and GPIA comments filed under Docket No. 85N-0214.) FDA believes its proposed requirements under § 314.52 for an application submitted under section 505(b)(2) of the act and § 314.95 for an ANDA under section 505(j) of the act with respect to documentation of receipt of notice of certification and the proposed requirements in § 314.107 address the concerns of the PMA and GPIA. Under this proposal, the 45-day clock would begin on the day after the date of receipt by the patent owner or its representative or by the approved application holder if the holder is an exclusive patent licensee of the applicant's notice of certification. Thus, the applicant's return receipt or a letter acknowledging receipt from the patent owner or exclusive patent licensee would be deemed to be legal notice of receipt of the applicant's notification by the patent owner or its representative or exclusive patent licensee. Action would then have to be filed in federal court by the patent owner or exclusive patent licensee before the end of the 45th day.

In computing the 45 days, Saturdays, Sundays, and Federal holidays are included. When, however, the 45th day falls on Saturday, Sunday, or on a Federal holiday, the 45th day would be the next succeeding day that is not a Saturday, Sunday, or a Federal holiday. FDA intends to strictly apply the 45-day statutory time period. Therefore, unless FDA is notified in writing by the ANDA or 505(b)(2) applicant before the expiration of the 45-day time period or before the completion of the review period, whichever is later, of the commencement of legal action for patent infringement within the 45-day time period, approval of the ANDA or 505(b)(2) application may be made effective immediately upon expiration of the 45 days or upon completion of the review process, whichever is later. Even

if the commencement of legal action occurs before the ANDA is ready for approval but after the 45-day period has elapsed, the agency will approve the ANDA with an immediate effective date when the application review is complete and satisfactory. Notification by the generic applicant of the filing of a complaint alleging patent infringement shall include: (1) the ANDA or 505(b)(2) application number, (2) the ANDA or 505(b)(2) applicant's name, (3) established name of the drug, if any, strength, and dosage form, and (4) a certification that action to defend the patent, identified by number, has been filed in an appropriate court and the date of the filing. An ANDA applicant shall submit the notification to FDA's Division of Generic Drugs (HFD-230); a 505(b)(2) applicant shall submit the notification to the appropriate division in the Center for Drug Evaluation and Research reviewing the application.

If an action for patent infringement is filed before the expiration of the 45 days, FDA is precluded from making the approval of the ANDA or 505(b)(2) application effective for a period of 30 months while the matter is in litigation or until a date of a final decision determined by a court, with one exception. The exception is for a patented drug entitled to 5 years of marketing exclusivity under section 505(c)(3)(D)(ii) or (j)(4)(D)(ii) of the act, where the patent holder files an action for patent infringement during the 1-year period beginning 4 years after the date the patented drug was approved (and within 45 days of receiving the notice of patent certification). In this situation, FDA must extend the 30-month period by that amount of time required for 7½ years to elapse from the date of approval of the patented drug. Once the 30 months, or 7½ years where applicable, have expired, the applicant would have an effective approval of its drug product subject to the outcome of the pending litigation, unless the court itself orders otherwise.

If before the expiration of the 30-month or 7½-year period the court decides that any relevant patent is invalid or not infringed, approval of the ANDA or 505(b)(2) application would be made effective on the date that final judgment is entered by the court.

If before the expiration of the 30-month or 7½-year period the court decides that any relevant patent would be infringed, the approval would be made effective on the date the patent expires or on the date the court orders. If before the expiration of the 30-month or 7½-year period the court grants a preliminary injunction prohibiting an applicant from manufacture or marketing of its drug product until the court decides the issues of patent validity and infringement and if the court later decides that the patent is invalid or not infringed, approval would be made effective on the date the court enters final judgment on the merits.

For purposes of establishing the proper effective date for an ANDA or 505(b)(2) application approval in the above situations, FDA proposes that the applicant submit to the Division of Generic Drugs (HFD-230), within 10 working days of the entry of any relevant judgment, a copy of the court order. There is a potential ambiguity in the statutory language concerning what "court" decision triggers an effective date. The agency has interpreted that language as referring to the final decision of that court from which no appeal can be or has been taken by the affected party.

FDA will issue a revised approval letter stating the effective approval date. However, an applicant may begin marketing its approved drug product on the date that final judgment is entered by the court or on any other court ordered effective date whether or not the applicant has received a revised approval letter from FDA.

2. *The 180-day exclusivity period.* Finally, under the proposal and the statute, if any subsequent ANDA's for the same drug product as the first drug product to be involved in a patent infringement action also contain a certification of the invalidity or noninfringement of a patent, approval of those subsequent ANDA's would not become effective until 180-days after the first commercial marketing of the drug product under the first ANDA, or until 180 days after the court has determined that the patents in dispute are invalid or not infringed, whichever is earlier. (See section 505(j)(4)(B)(iv) of the act.) This provision does not apply to 505(b)(2) applications.

FDA has concluded that the 180-day delay of subsequent ANDA's is available only to a previous applicant who has been sued for patent infringement following its notification to the patent owner of the filing of a certification of invalidity and noninfringement. Although section 505(j)(4)(B)(iv) of the act can be interpreted in several ways, FDA believes that the structure of the provision reflects Congress' intention to provide to the first generic applicant who spends its resources to litigate the scope or validity of a patent a 180-day period free from generic competition.

The formula provided by section 505(j)(4)(B)(iv) of the act for calculating the date from which the 180-day period runs, and particularly the reference to "first commercial marketing, can be applied logically and consistently with the statutory scheme only if Congress intended the provision to apply only when the first ANDA applicant was actually sued for patent infringement. Every other exclusivity provision in the 1984 Amendments begins with date of approval of the application. Congress' decision to begin the 180-day period under section 505(j)(4)(B)(iv)(I) of the act from "the first commercial marketing of the drug, rather than from the effective date of the ANDA, serves a rational policy only if Congress contemplated a situation in which an approval of an ANDA is in effect but the applicant's decision not to market the drug deserves to be protected because a delay in marketing serves the public interest.

Such a situation occurs where, under the terms of section 505(j)(4)(B)(iii) of the act, an ANDA goes into effect 30 months after a lawsuit is filed, but the lawsuit is still pending. It serves the public interest to permit a prudent ANDA holder in that situation to stay off the market until the litigation is resolved, thereby minimizing potential damages.

As drafted, sections 505(j)(4)(B)(iv)(I) and (II) of the act carefully avoid providing an incentive for immediate marketing: the 180-day reward of exclusive marketing begins when the applicant wins the lawsuit or when the applicant actually begins marketing, "whichever is earlier. The applicant thus does not lose any of the 180-day period by electing to stay off the market until the lawsuit is over.

If, on the other hand, section 505(j)(4)(B)(iv) of the act is interpreted to apply even if the first applicant has not been sued, dating the 180-day period from "first commercial marketing" rather than from the effective date of the ANDA approval serves no purpose. Indeed, it might provide a counterproductive incentive to the first ANDA applicant to delay marketing so as to prolong the period during which other ANDA's may not be marketed. In contrast to the delay occasioned by a prudent plaintiff in a lawsuit, this delay serves no public interest. To remove this unproductive incentive for delay, the agency would therefore consider it necessary to read into section 505(j)(4)(B)(iv)(I) of the act various additional requirements and presumptions.

Section 505(j)(4)(B)(iv) can thus be applied straightforwardly only when an

applicant who seeks the 180-day period of exclusive marketing has been involved in a patent infringement lawsuit. To apply the section where there has been no lawsuit, requires either that the agency ignore the plain language of the section, essentially reading out the phrase "first commercial marketing, or that the agency assume, contrary to the goals of the 1984 Amendments, that Congress intended to create an incentive for delay in competition, without any countervailing benefit to society. Moreover, the policy embodied in the provision, of rewarding the applicant who devotes the considerable time and money necessary for patent litigation, is not served by providing 180 days of exclusive marketing to an applicant who avoids a lawsuit. Accordingly, proposed § 314.107(c) applies only when the first applicant has been sued.[1]

FDA has also concluded that the 180-day period of exclusivity delays approval of all generic copies of the same listed drug whose applications contain paragraph IV certifications. It has been suggested that where a formulation or composition patent is the subject of certification and lawsuit, the exclusivity granted under section 505(j)(4)(B)(iv) should delay the effective approval only of subsequent applications that raise claims of noninfringement identical or similar to those raised by the holder of the exclusivity. The legislative history of section 505(j)(4)(B)(iv) is silent as to the purpose of the provision and does not limit its applicability to subsequent applicants that receive a benefit from the first applicant's finding of noninfringement. The 180-day period can be interpreted as a reward not only for the benefit provided to subsequent ANDA applicants but for the benefit to the public of removing an obstacle to competition. Moreover, FDA lacks the expertise in patent law that would allow it to determine whether a subsequent applicant raised issues of noninfringement in common with the previous applicant. Therefore, the 180-day period is available to the applicant who resolves an issue of patent coverage, regardless of the judgment's applicability to subsequent ANDA applicants.

3. *Other provisions.* FDA proposes to implement other aspects of section 505(j)(4)(B)(iv) of the act as follows:

a. *Date of submission.* The date of submission of a prior application that contained a certification of invalidity or noninfringement will be considered the date on which the applicant submitted a substantially complete ANDA. In most cases, to be "substantially complete, an ANDA must contain data from any required bioavailability or bioequivalence studies. A required bioequivalence study is one that meets any FDA guidance document or is otherwise reasonable in design and purports to show that the drug product for which the applicant seeks exclusivity is bioequivalent to the listed drug. Neither a protocol nor a pilot study will satisfy these requirements. (An ANDA may be substantially complete without such studies only if such studies are not required to establish bioequivalence, i.e., where bioequivalence can be established through other information and the applicant has requested a waiver of the study requirements.) Although the provision could be read to permit the mere submission of the first certification of invalidity or noninfringement to delay the effective date of subsequent ANDA's, regardless of the completeness of the application, the legislative history of the 1984 Amendments makes clear that such an interpretation would be inconsistent with the purposes of the patent certification and notification scheme.

The purpose of section 505(j)(4)(B)(iv) of the act is to reward the first applicant to test the scope or validity of a patent by litigating an action for patent infringement. However, it is only the giving of notice to the patent owner under section 505(j)(2)(B)(ii) of the act, and not the filing of a certification of invalidity or noninfringement with FDA, that can initiate a lawsuit. The notice required by section 505(j)(2)(B)(ii) of the act must state that the applicant has submitted an ANDA "which contains data from bioavailability or bioequivalence studies. (Section 505(j)(2)(B)(ii) of the act.) The purpose of requiring a statement that the ANDA contains data from bioavailability or bioequivalence studies is to prevent applicants from testing an innovator's patent through the filing of "sham ANDA's or ANDA's that are substantially incomplete. H. Rept. 98 857 Part I, 98th Cong., 2d Sess. 24–5 (1984).

FDA believes that to fulfill the purposes of the patent provisions of the statute, the date of submission of a previous application under section 505(j)(4)(B)(iv) of the act must therefore be the date on which the previous applicant submitted a substantially complete ANDA, and thus was in a position to notify the patent owner. As described in part V section E., supra, an ANDA that contains a certification of invalidity or noninfringement will not be accepted for review unless it contains the results of any required bioequivalence studies.

b. *Delay when first application is not yet approved.* If the first ANDA applicant for a listed drug is sued for patent infringement and a subsequent ANDA for the drug is submitted before the first ANDA is approved, FDA will delay the effective date of approval of the subsequent ANDA only as long as the agency remains satisfied that the first applicant is actively pursuing approval of its ANDA.

c. *"First commercial marketing.* "First commercial marketing" is defined as the first date of introduction or delivery for introduction into interstate commerce outside the control of the manufacturer, except for investigational use under 21 CFR Part 312, but does not include transfer of a drug product for reasons other than sale within the control of the manufacturer or application holder.

d. *"Court decision."* Section 314.107(c)(1)(ii) specifies as one of the two dates from which the 180 days runs "the date of a decision of the court holding the patent invalid or not infringed. This date will be the date of a final decision of a court from which no appeal can or has been taken, or the date of a settlement order or consent decree signed by a Federal judge, which enters final judgment and includes a finding that the patent is invalid or not infringed. A final adjudication on the merits is not required to trigger the 180-day period.

e. *Amended certification after finding of infringement.* If a final judgment is entered in an action for patent infringement finding the patent to be infringed by a drug product that is the subject of an abbreviated new drug application, and the application contains a paragraph IV certification, the applicant should submit an amended certification, certifying under § 314.94(a)(12)(i)(A)(3) that the patent will expire on a specific date. The new certification should be submitted either as an amendment to a pending application or as a letter if the application is approved. Once the amendment or letter has been submitted, the application will no longer be considered to be one containing a paragraph IV certification.

f. *Amended certification after removal of a patent from the list.* If, after one or

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Note: Subsequent to the Commissioner's signing of this document, Federal district court reached contrary conclusion. See Inwood v. Young, No. 89-0845 (D.D.C. May 12, 1989). An appeal from that decision is under consideration.

more applicants have made paragraph IV certifications on a patent, that patent is removed from the list for any reason other than because that patent has been declared invalid in a lawsuit brought by that patent owner within 45 days of receiving notice under § 314.95 any applicant with a pending application or delayed effective date who has made such a certification should submit an amended patent certification, certifying under § 314.94(a)(12)(ii) if applicable, that no relevant patents claim the drug. If other relevant patents still claim the drug, the applicant should instead submit a request to withdraw the paragraph IV certification. Once the amendment or letter has been submitted, the application will no longer be considered to be an application containing a paragraph IV certification.

L. Exclusivity

1. *Exclusivity for certain approved drug products.* Sections 505(j)(4)(D) and 505(c)(3)(D) of the act partially protect certain listed drugs, or certain changes in listed drugs, from competition in the marketplace for specified periods by placing a moratorium on the submission of, or by delaying the effective date of approval of, ANDA's and 505(b)(2) applications for those listed drug products. (The exclusivity provisions of the act do not provide any protection from the marketing of a generic version of the same drug product if the generic version is the subject of a full new drug application submitted under section 505(b)(1) of the act.) These periods of exclusive marketing are independent of any marketing exclusivity accorded an orphan drug pursuant to section 527 of the act and of any protection a listed drug may have as a result of a patent. Proposed § 314.108 implements the exclusivity provisions of sections 505(j)(4)(D) and 505(c)(3)(D) of the act. The holder of a new drug application or supplemental new drug application submitted under section 505(b) of the act that was approved on or after January 1, 1982, may be entitled to a period of exclusive marketing (hereinafter referred to as "exclusivity") for the drug product subject to the approved application or supplemental application.

Briefly, the exclusivity provisions provide the following protection. Sections 505(c)(3)(D)(i) and 505(j)(4)(D)(i) grant a 10-year period of exclusivity to new chemical entities approved during a specified "window period": January 1, 1982, to September 24, 1984, the date of enactment of the 1984 Amendments. Sections 505(c)(3)(D)(ii) and 505(j)(4)(D)(ii) of the act grant a 5-year period of exclusivity to new chemical entities approved after September 24, 1984. Sections 505(c)(3)(D)(v) and 505(j)(4)(D)(v) of the act grant a 2-year period of exclusivity for non-new chemical entities, or for certain changes made to already approved products, approved during the "window period. (This 2-year period expired on September 24, 1986.) There is no requirement that an applicant have conducted clinical investigations to qualify a drug for exclusivity under the above three provisions. On the other hand, the remaining two exclusivity provisions, sections 505(c)(3)(D)(iii) and (iv) and 505(j)(4)(D)(iii) and (iv) of the act, which grant a 3-year period of exclusivity, specifically require that the applicant have "conducted or sponsored new clinical investigations essential to the approval" of the application, or the supplement.

With the exception of the 2-year exclusivity provision for non-new chemical entities or changes approved between January 1, 1982, and September 24, 1984 (sections 505(j)(4)(D)(v) and 505(c)(3)(D)(v) of the act), the exclusivity provisions are limited to new chemical entities, which by definition are innovative, and to those significant changes in already approved drug products, such as a new use, which require new clinical studies. Congress understood that the substantial economic rewards of exclusivity might well encourage drug companies to make minor and unimportant alterations in their marketed drug products or to conduct additional tests which they could claim provide important new information about a marketed drug product. To avoid rewarding such behavior, the 3-year provision includes the special criteria intended to restrict eligibility to significant innovations. See Cong. Rec. H9114, 9124 (daily edition September 6, 1984) (statement of Representative Waxman); Cong. Rec. S10505 (daily edition August 10, 1984) (statement of Senator Hatch).

The exclusivity provisions of section 505(j)(4)(D) of the act operate to prohibit the submission or delay the effective date of approval of (1) an ANDA submitted under section 505(j) of the act for a duplicate of a listed drug that is entitled to exclusivity and (2) an ANDA submitted under section 505(j) of the act pursuant to an approved petition under section 505(j)(2)(C) of the act for a drug product that is similar to a listed drug that is entitled to exclusivity. The exclusivity provisions of section 505(c)(3)(D) of the act affect applications described under section 505(b)(2) of the act and are essentially the same as those for abbreviated new drug applications. The legislative history of the 1984 Amendments makes clear that Congress intended the exclusivity provisions of section 505(c)(3)(D) of the act to delay submission or approval of applications described by section 505(b)(2) of the act to the same extent that section 505(j)(4)(D) of the act delays submission or approval of ANDA's. Section 505(c)(3)(D) of the act, however, unlike section 505(j)(4)(D) of the act, could be interpreted to apply only to those 505(b)(2) applications that are required to submit a patent certification. (See section 505(c)(3) of the act.) Under this interpretation, applications described by section 505(b)(2) of the act that were not required to submit a patent certification because, for example, the pioneer drug was unpatentable, would be exempt from the exclusivity provisions of section 505(c)(3)(D) of the act.

The agency does not believe that this interpretation is reasonable and intends to apply section 505(c)(3)(D) of the act to all 505(b)(2) applications. Although section 505(c)(3) of the act states that the delayed effective dates specified in section 505(c)(3)(A) through (D) apply to "an application filed under subsection (b) which contains a certification required by paragraph (2) of such subsection, patent certification is relevant only to section 505(c)(3)(A) through (C) of the act. These paragraphs delay an application's effective date on the basis of the patent status of the pioneer drug. Section 505(c)(3)(D) of the act, however, delays an effective date on the basis of exclusivity, which is entirely independent of the patent status of the pioneer drug. Indeed, in the floor debates preceding enactment of the 1984 Amendments, Congressman Waxman specifically stated that one of the purposes served by the exclusivity provisions was to supply needed incentives to develop new drugs where little or no patent life remains. Cong. Rec. H9113 (daily edition, September 6, 1984). It would thus be illogical and inconsistent with Congressional intent to apply the exclusivity provisions only to those 505(b)(2) applications required to make a patent certification.

Exclusivity provides the holder of an approved new drug application limited protection from new competition in the marketplace for the innovation represented by its approved drug product. Thus, if the innovation relates to a new active moiety or ingredient, then exclusivity protects the pioneer drug product from other competition from products containing that moiety or ingredient. If the innovation is a new dosage form or route of administration, then exclusivity protects only that

aspect of the drug product, but not the active ingredients. If the innovation is a new use, then exclusivity protects only that labeling claim and not the active ingredients, dosage form, or route of administration.

The language of sections 505(c)(3)(D) and 505(j)(4)(D) of the act is ambiguous as to which ANDA's or 505(b)(2) applications are affected by an innovator's exclusivity. The statutory language allows at least two interpretations. The narrower interpretation of the protection offered by exclusivity is that exclusivity covers only specific drug products and therefore protects from generic competition only the first approved version of a drug, or change in a drug. Under this interpretation, an innovator's exclusivity could lose its value as soon as FDA approved a second full new drug application for a version of the drug, because an ANDA could be approved by reference to the second approved version of the drug, which would not be covered by exclusivity.

The broader interpretation of the coverage of exclusivity is that it covers the active moieties in new chemical entities or changes in non-new chemical entities rather than covering only specific drug products. Thus exclusivity would protect the new active moiety of a new chemical entity or the innovative change in a non-new chemical entity from generic competition even after FDA had approved subsequent full new drug applications for subsequent versions of the drug. Under this theory, an ANDA or 505(b)(2) application for a drug with the same active moiety as the innovator's new chemical entity or as the innovator's change in a non-new chemical entity could not be approved until the innovator's exclusivity expired, even if the ANDA or 505(b)(2) application relied on another approved version of the innovator's drug.

The language of the five exclusivity provisions (similarly worded in both sections 505(c)(3)(D) and 505(j)(4)(D) of the act) is inconsistent on this issue, tending to support the narrower interpretation of the coverage of exclusivity for new chemical entities (sections 505(c)(3)(D) (i) and (ii) and 505(j)(4)(D) (i) and (ii) of the act and for drugs approved between January 1, 1982, and September 24, 1984 (sections 505(c)(3)(D)(v) and 505(j)(4)(D)(v) of the act), and the broader interpretation for innovative changes in already approved drugs (sections 505(c)(3)(D) (iii) and (iv) and 505(j)(4)(D) (iii) and (iv) of the act). Sections 505(c)(3)(D) (i), (ii), and (v) and 505(j)(4)(D) (i), (ii), and (v) of the act confer exclusivity by prohibiting submission or delaying approval of ANDA's or 505(b)(2) applications that "refer to the drug for which the [first approved] subsection (b) application was submitted. Depending upon the meaning of the phrase "refer to" and the word "drug, these provisions could be interpreted to allow ANDA's and 505(b)(2) applicants, once FDA approved subsequent new drug applications for different versions of the same drug, to circumvent the innovator's exclusivity by "referring to" the subsequent versions of the innovator's drug.

On the other hand, the two provisions that confer exclusivity on changes in already approved drugs delay the effective date of approval of all ANDA's or 505(b)(2) applications that have the same "conditions of approval" as the innovator's drug, without regard to whether the ANDA "refers to" the innovator's drug product or to another version of the same product for which a subsequent new drug application was approved.

FDA does not believe that Congress intended the exclusivity provisions to operate inconsistently, or that Congress intended the protection offered by the exclusivity for changes in approved drugs to be broader than the protection offered by exclusivity for new chemical entities. FDA therefore proposes to adopt a uniform interpretation of the scope of exclusivity. In addition, FDA has concluded that adopting the narrower interpretation of the scope of exclusivity for all types of exclusivity would seriously undermine its value, reducing the incentives for research and innovation in the pharmaceutical industry.

For example, if FDA adopted the narrower interpretation that exclusivity covers only a specific drug product and does not prevent ANDA s from copying subsequent versions of the innovative product, a manufacturer of a new chemical entity (entitled to 5 years of exclusivity), could not make improvements in the drug, e.g., by making a new dosage form of the drug, without destroying the value of its exclusivity. Approval of a new dosage form, and certain other changes in approved drugs, require the submission of a new drug application; once approved, the new dosage form would become a new drug product that an ANDA application could copy, without being subject to the exclusivity covering the original drug product.

For the same reasons, an innovator whose drug was entitled to exclusivity could not license another company to make a copy of the pioneer drug without losing the value of its exclusivity. Under the narrow theory of exclusivity, once the licensed company's product was approved, ANDA applicants could copy the licensed product, without regard to the innovator's exclusivity.

The agency does not believe that Congress intended the exclusivity provisions to discourage innovators from making improvements in their drug products nor from authorizing the marketing of competitive products. Accordingly, FDA has concluded that the broader interpretation of the scope of exclusivity should be applied to all types of exclusivity conferred by sections 505(c)(3)(D) and 505(j)(4)(D) of the act.

Therefore, when exclusivity attaches to an active moiety or to an innovative change in an already approved drug, the submission or effective date of approval of ANDA's and 505(b)(2) applications for a drug with that active moiety or innovative change will be delayed until the innovator's exclusivity has expired, whether or not FDA has approved subsequent versions of the drugs entitled to exclusivity, and regardless of the specific listed drug product to which the ANDA or 505(b)(2) application refers.

Proposed new § 314.108 implements the exclusivity provisions with respect to both ANDA's and 505(b)(2) applications.

a. *Definitions.* To understand how the agency intends to administer the exclusivity provisions of the act, it is necessary to define a number of terms that are used in those provisions. Some of those definitions have already been discussed; others are as follows:

i. *New chemical entity.* "New chemical entity" means a drug that contains no active moiety that has been approved by the Food and Drug Administration in any other application submitted under section 505(b) of the act. Thus, FDA interprets the statutory requirement that a drug (new chemical entity) contain "no [previously approved] active ingredient (including any ester or salt of the active ingredient)" to mean that the drug must not contain any previously approved active moiety. FDA bases this interpretation on the statutory language and on the definition of a "new molecular entity" or "Type 1" drug in FDA's IND/NDA classification scheme (which is used to classify new drugs by chemical type and therapeutic significance), which was in effect at the time the 1984 Amendments were under consideration in Congress. FDA's longstanding interpretation of the term "new molecular entity" is that it is a compound containing an entirely new

active moiety. FDA's interpretation of the scope of the 5-year exclusivity provision is also consistent with the legislative history, which reveals that Congress was aware of FDA s classification scheme and did not intend to confer significant periods of exclusivity on minor variations of previously approved chemical compounds. (See, e.g., Cong. Rec. H9124 (September 6, 1984) (statement of Representative Waxman); H. Rept. 857 Part I, 98th Cong., 2d Sess. 38 (1984).)

ii. *Active moiety.* The "active moiety" in a drug is the molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt (including a salt with hydrogen or coordination bonds) or other noncovalent derivative (such as a complex, chelate, or clathrate) of the molecule, responsible for the physiological or pharmacological action of the drug substance. A drug product will thus not be considered a "new chemical entity" entitled to 5 years of exclusivity if it contains a previously approved active moiety, even if the particular ester or salt (including a salt with hydrogen or coordination bonds) or other noncovalent derivative has not been previously approved. A compound (other than an ester) that requires metabolic conversion to produce an already approved active moiety is considered a "new molecular entity, however, and will be considered a new chemical entity entitled to 5 years of exclusivity. FDA will consider whether a drug contains a previously approved active moiety on a case-by-case basis. FDA notes that a single enantiomer of a previously approved racemate contains a previously approved active moiety and is therefore not considered a new chemical entity.

iii. *Date of approval.* An issue has arisen as to how the date of approval of a new drug application is determined. This issue is particularly important when an applicant is claiming that its new drug application was approved between January 1, 1982, and September 24, 1984, referred to in sections 505(c)(3)(D) (i) and (v) and 505(j)(4)(D) (i) and (v) of the act of the exclusivity provisions. The "date of approval" of the application as used in these provisions means the date on the approval letter sent by FDA to the applicant. A requirement in the approval letter for submission (but not for approval) of final printed labeling or other material that might delay the actual initiation of marketing of the product is not relevant to a determination of the date of approval, so long as the product could be legally marketed. Two cases have addressed FDA's interpretation of "date of approval. *Mead Johnson Pharmaceutical Group* v. *Bowen,* 838 F.2d 1332 (D.C. Cir. 1988), and *Norwich Eaton Pharmaceuticals, Inc.* v. *Bowen,* 808 F.2d 486 (6th Cir.), *cert. denied,* 108 S. Ct. 68 (1987). In these cases, two separate drug manufacturers challenged FDA's determinations that their products were not entitled to 10 years of exclusivity under sections 505(c)(3)(D)(i) and 505(j)(4)(D)(i) of the act, which grant such exclusivity to certain products approved between January 1, 1982, and September 24, 1984. FDA's determinations were based on its position that the two drugs were approved on the date the approval letters were issued, in both cases prior to January 1, 1982. The plaintiffs argued that the date of approval did not occur until the firms submitted final printed labeling. In both cases, the courts upheld FDA's position that the date an approval letter issues is the date of approval of a new drug application.

b. *Periods of exclusivity.* Drug products that are the subject of the following types of applications are eligible for specified periods of exclusivity.

i. Sections 505(c)(3)(D)(i) and 505(j)(4)(D)(i) of the act provide exclusivity for a drug product containing a new chemical entity that is the subject of a new drug application submitted under section 505(b) of the act and approved during the period beginning January 1, 1982, and ending on September 24, 1984. The approval of an ANDA or 505(b)(2) application for a drug product that contains the same active moiety as the listed drug may not become effective for 10 years after the date of approval of the listed drug entitled to exclusivity. Thus, a drug product covered by an ANDA or a 505(b)(2) application would be subject to a listed drug's 10-year exclusivity if it contains the active moiety in the listed drug.

A drug product is entitled to 10 years of exclusivity only if it does not contain an active moiety that has been part of a drug product previously approved under section 505(b) of the act either as a single ingredient or as one ingredient of a combination drug product. An application is one "approved under section 505(b)" if it was submitted under section 505(b) of the act and approved after the passage of the 1962 Amendments to the act or was "deemed approved" under section 107(c)(2) of the 1962 Amendments. Because the exclusivity conferred by this provision covers the active moiety of a drug, the exclusivity also protects a different ester or salt or other noncovalent derivative, or a different dosage form, strength, route of administration, or condition of use approved in a subsequent application or supplemental application for a drug product containing the same active moiety. Any modification in dosage form, strength, route of administration, or indication of a new chemical entity entitled to 10 years of exclusivity will be protected for the period of exclusivity remaining on the original application. Different salts, esters, or other changes that do not result in a change in active moiety are also protected. Significant changes to the drug product that occur after or toward the end of the initial 10 years of exclusivity and that independently qualify for exclusivity, e.g., a new use requiring new clinical investigations for approval (see discussion under provision d. below) may result in an additional period of exclusivity, but only for the change.

ii. Sections 505(c)(3)(D)(ii) and 505(j)(4)(D)(ii) of the act provide exclusivity for a drug product containing a new chemical entity that is the subject of a new drug application submitted under section 505(b) of the act and approved after September 24, 1984. No ANDA or 505(b)(2) application for a drug product that contains an active moiety in the listed drug may be submitted to FDA before the expiration of 5 years after the date of approval of the application for the listed drug entitled to exclusivity, except that an application challenging a patent that claims the listed drug may be submitted 4 years after approval of the listed drug. In the latter case, because this exclusivity provision blocks only submission of the ANDA or 505(b)(2) application, approval of the ANDA or 505(b)(2) application properly submitted after 4 years is not delayed by this provision, unless the patent owner initiates a lawsuit for patent infringement. Where litigation is initiated, the ANDA or 505(b)(2) application may not be made effective by FDA for a total of 7½ years after the approval of the reference listed drug, unless the court holds the patent invalid or not infringed at an earlier date. (See discussion under part V section K.)

As with sections 505(b)(3)(D)(i) and 505(j)(4)(D)(i) of the act, the agency interprets the exclusivity provided by this provision to cover any subsequent approval of an application or supplemental application for a different ester, salt, or other noncovalent derivative, or a different dosage form, strength, route of administration, or new

use of a drug product with the same active moiety. Any modification to the product will be protected for the period of exclusivity remaining on the original application, unless the change occurs after or toward the end of the initial 5 years of exclusivity and independently qualifies for exclusivity under another exclusivity provision. (See discussion under provision b.i. above.)

iii. Sections 505(c)(3)(D)(iii) and 505(j)(4)(D)(iii) of the act provide exclusivity for a drug product that does not contain a new chemical entity, is the subject of a new drug application submitted under section 505(b) of the act and approved after September 24, 1984, and which contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant. For example, a drug product containing a previously approved active ingredient may be approved for a new indication, dosage form, strength, or route of administration for which clinical studies are essential to approval. Exclusivity would be provided only if the clinical studies were "new, "essential to approval, and "conducted or sponsored by the applicant. If these requirements are met, approval of an ANDA or of a 505(b)(2) application for a duplicate drug product or an ANDA submitted pursuant to an approved petition under section 505(j)(2)(C) for a similar drug product that relies on the information supporting the new conditions of approval of the first-approved application, may not be made effective before the expiration of 3 years from the date of approval of the original new drug application.

iv. Sections 505(c)(3)(D)(iv) and 505(j)(4)(D)(iv) of the act provide exclusivity for a drug product that is the subject of a supplement to an approved application under section 505(b) approved after September 24, 1984, that contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the supplement and conducted or sponsored by the applicant. Approval of an ANDA submitted under section 505(j) of the act for a duplicate of, or submitted under section 505(j) of the act pursuant to an approved petition under section 505(j)(2)(C) of the act for a similar drug product that relies on the information supporting the new conditions of approval of a listed drug that is entitled to exclusivity or a 505(b)(2) application for a change approved in the supplemental application may not become effective for 3 years from the date of approval of the supplemental application. Under this provision, only the change approved in the supplemental application would be granted exclusivity and that exclusivity would be provided only if "new clinical investigations" were "essential to approval" of the change and the investigations were "conducted or sponsored by the applicant. The three requirements for exclusivity under this provision are identical to those of the third provision described above.

FDA expects that only those changes in an approved drug product that affect its active ingredient(s), strength, dosage form, route of administration or conditions of use would be granted exclusivity. These are the types of changes in a drug product that require prior approval by FDA before the change may be made (21 CFR 314.70).

To qualify for exclusivity under section 505(j)(4)(D) (iii) and (iv) of the act or section 505(c)(3)(D) (iii) and (iv) of the act, an application or supplemental application proposing a change to an already approved drug product must contain "reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant. All three of these criteria must be satisfied in order to qualify a drug product or change in a drug product for the exclusivity provided by these sections of the act.

Congress intended the term "clinical" to mean human studies, and intentionally excluded all animal studies, regardless of the purpose for which they are conducted. In *Zenith Laboratories, Inc.* v. *Heckler*, No. 85-3646 (D.N.J. May 19, 1986), Zenith Laboratories challenged the agency's interpretation of the term "clinical, arguing that clinical testing also includes animal testing. The court granted the government's motion for summary judgment, holding that FDA's interpretation was reasonable.

Further, Congress specifically excluded "bioavailability studies, which also may be clinical studies, to limit eligibility for exclusivity to changes in a drug product that are significant enough to require human safety or effectiveness studies for approval. The proposed regulations would, therefore, for purposes of exclusivity, define clinical investigation" to mean any experiment, other than a bioavailability study, in which a drug is administered or dispensed to, or used on, human subjects. The agency believes that most studies qualifying for exclusivity will be efficacy studies. There may, however, be occasional clinical investigations qualifying for exclusivity that establish that a product is safer than originally thought and that permit broader use of the drug. Studies that establish new risks will not be eligible for exclusivity because protection of the public health demands that all products' labeling contain all relevant warnings.

The legislative history makes clear that Congress intended to reward with 3 years of exclusivity only those investigations that require a considerable investment of time and money, see Cong. Rec. S10505 (daily edition August 10, 1984) (statement of Senator Hatch), and that are necessary for approval of important innovations requiring substantial study, such as significant new therapeutic uses, see Cong. Rec. H 9114, 9124 (daily edition September 6, 1984) (statements of Representative Waxman). The 3-year exclusivity provision, therefore, could be interpreted to confer exclusivity only for innovations requiring adequate and well-controlled trials in human subjects that meet the substantial evidence requirement for approval. Further, because the statutory language of this provision uses the term "clinical investigations" (plural) the provision could be interpreted to mean that more than one well-controlled trial is needed to support approval of the applicant's proposed change. The agency's interpretation of this exclusivity provision, however, is ordinarily to require only one clinical study and that it be of the type necessary to support approval of the proposed change.

The clinical investigations must be "new. Under this proposal, the agency would consider a clinical investigation "new" if the data from such a study (1) have not been relied on by the Food and Drug Administration to demonstrate substantial evidence of effectiveness of a previously approved drug for any indication or of safety for a new patient population and (2) do not duplicate the results of another investigation that was relied on by the agency to demonstrate the effectiveness or safety in a new patent population of a previously approved drug product. In this context, "new is intended to convey lack of prior use of this particular study or another similar study in successfully supporting the approval of the effectiveness of a drug product rather than any temporal requirement. The agency does not believe Congress intended to preclude use of data from a previously conducted study if such data provide important new information in support of the applicant's proposed change to its drug product. The agency would still consider to be "new data from a clinical investigation previously

submitted in a new drug application for use only in a comprehensive evaluation of the safety of a drug product but not to support the effectiveness of the drug product or safety in a specific new patient population.

Second, the studies referred to must also have been "conducted or sponsored by the applicant. PMA and GPIA submitted their views on this issue to the agency prior to publication of this proposal. (See Docket No. 85N-0214.) The PMA interpretation of "sponsored" would have that term apply whenever the applicant had provided financial, technical, or in kind support to the scientific studies, whether or not that support was the major funding of the investigations and whether or not it was received in advance of the performance of the investigations. GPIA disagreed, pointing out that the exclusivity provisions were intended to reward those who make a substantial investment and take the risk associated with clinical testing of a new drug or a new indication for a drug.

The Food and Drug Administration agrees that Congress intended these exclusivity provisions to reward only those who have made a substantial investment in new clinical studies. The underlying basis of exclusivity should, under the agency's policy, be transferable upon transfer of ownership of a company or rights to a drug. By making the product of the research more valuable, the agency believes this policy will foster and reward innovation and research to the full extent intended by Congress. However, the agency concludes that Congress did not intend that applicants qualify for exclusivity by simply collecting and submitting to FDA information from the literature, or buying the results of tests already done and submitting them to FDA. (See letter to Dr. Frank Young from Congressman Henry Waxman, August 5, 1985, on file in Docket No. 85N-0214.)

Therefore, in this proposal, the agency would consider an investigation "conducted or sponsored" by the applicant if, before or during the conduct of the investigation (1) the applicant was the sponsor of the IND under which the investigation was conducted, i.e., named as the sponsor of the IND in Form FDA-1571 filed with the agency, or (2) the applicant (or the applicant's predecessor in interest) provided substantial financial support for the study (see proposed § 314.108). For this purpose, the applicant's predecessor in interest may be a company the applicant purchased or merged with or a company that sold all rights to the drug to the applicant. Generally, if the applicant was the sponsor named in the Form FDA-1571 for a new clinical investigation that is essential to the approval, the applicant will be presumed to have conducted or sponsored that investigation. If the applicant was not the sponsor of the IND, e.g., because the study was conducted outside the United States, the applicant would be required to demonstrate sponsorship by showing that it provided substantial support for the study before it was completed. Ordinarily, to claim "substantial support, the applicant must have provided 50 percent or more of the cost of the study. In rare cases, the applicant may have provided less than 50 percent and still show "substantial support," if, for example, the study was extraordinarily expensive and the applicant's contribution to the total cost was significant. Merely supplying the drugs or providing other in kind support would not normally constitute "conducting or sponsoring" a study.

The applicant must show that its support for the study was provided before the study was conducted or while it was ongoing. The only exception to this rule is when, after completion of the study, the applicant purchased or merged with the company that sponsored or provided substantial support for the study or purchased all rights to the drug that is the subject of the application. Purchasing the study itself after the study has been completed does not constitute conducting or sponsoring a study. Under proposed § 314.50(j), an applicant would be required to include in its application (1) a statement that the applicant was the sponsor of the investigation named in Form FDA-1571 filed with the agency under the IND for the investigation, or (2) a certification with supporting information that the applicant or its predecessor in interest provided substantial support for the investigation. The agency acknowledges that it does not possess expertise and records essential to determining what elements should properly be considered in determining the cost of a study and what constitutes 50 percent funding of that study. The agency does not ordinarily intend to substitute its judgment for that of the applicant with respect to the 50 percent threshold. The agency will only look to see if the investigations were conducted under an IND in which the applicant was the sponsor or that the application contains the certification with supporting information. The agency specifically seeks comment on how to equitably interpret the term "sponsored by.

Third, the clinical studies must be "essential to the approval of the application. That is, without these new clinical studies, FDA would not have sufficient information to conclude that the drug product or change to a marketed drug product for which the applicant is seeking approval is safe and effective. Thus, to qualify for exclusivity, there must not be published reports of studies other than those conducted or sponsored by the applicant, or other information available to the agency sufficient for FDA to conclude that a proposed drug product or change to an already approved drug product is safe and effective. In addition, there must not be an already approved drug product for which the applicant could submit an ANDA or 505(b)(2) application. The agency disagrees with the suggestion by PMA that any "new information that will support the approvability of an application or supplement" is sufficient to satisfy this requirement. Rather, the studies must be truly "essential, rather than simply supportive, to qualify the application for exclusivity. A study will not be considered essential to approval merely because it was necessary for the applicant to conduct the study to avoid the exclusivity of the pioneer and obtain an immediate effective date of approval.

The PMA suggested regulatory language that it believed would help applicants to determine, in advance, the types of clinical investigations that would be considered "essential to the approval" of an application or supplemental application under section 505(b) of the act. The PMA urged FDA, upon request from a person planning to conduct or sponsor clinical tests on a proposed new drug, or upon submission of an IND, to examine a proposed testing protocol or general clinical outline to determine whether such clinical tests would be essential to approval of the new drug. PMA would have an investigation deemed essential unless FDA notified the applicant otherwise within 30 days following receipt of this information. GPIA opposed this PMA proposal.

What studies will be essential to the approval of an application cannot be determined, in each case, by a review of protocols without knowing what drugs have been approved and what is in the published literature at the time the application is approved. If published reports of investigations, other than those conducted or sponsored by the applicant, are sufficient to approve a drug product in a literature-supported application, no additional studies would be essential to the approval of that drug

product as of the date of approval. The agency encourages meetings between FDA and sponsors of clinical investigations to facilitate drug development and the approval process. However, the agency does not agree that it is possible to determine before approval which, if any, studies will be essential based on such discussions.

Under proposed § 314.50(j), an applicant would be required to include in its application a list of all published studies or publicly available reports of clinical investigations known to the applicant through a literature search that are relevant to the conditions for which the applicant is seeking approval. The list would be accompanied by a certification that the applicant has thoroughly searched the scientific literature and, to the best of the applicant's knowledge, the list is complete and accurate and, in the applicant's opinion, the listed studies or publicly available reports do not provide a sufficient basis for the approval of its application or supplement without reference to the new clinical investigation(s) in the application. The agency proposes that the applicant explain why the studies and reports are insufficient.

v. Sections 505(c)(3)(D)(v) and 505(j)(4)(D)(v) of the act provide exclusivity for a drug product that does not contain a new chemical entity and is the subject of a new drug application or supplemental application submitted under section 505(b) of the act and approved between January 1, 1982, and September 24, 1984. The approval of an ANDA or 505(b)(2) application that refers to the previously approved drug product or which refers to a change approved in a supplemental application may not be made effective before September 24, 1986. Because this date has passed, the proposed rule contains no reference to this provision.

Applications described in sections 505(b)(2) and 505(c)(3)(D) of the act present one issue not encountered with ANDA's. Because applications submitted under section 505(b) of the act may be entitled to exclusivity, there is an issue as to the treatment of concurrently pending 505(b)(2) applications for the same conditions of approval where the first approved 505(b)(2) application for a drug is entitled to exclusivity, and the approval of subsequent 505(b)(2) applications for that drug may be delayed. FDA proposes to interpret the exclusivity provisions with respect to competing 505(b)(2) applications in the following manner. Section 505(c)(3)(D)(ii), states that "* no application which refers to the drug for which the subsection (b) application [entitled to exclusivity] was submitted may be *submitted* (Emphasis added.) The agency intends to interpret this phrase to mean that any 505(b)(2) application submitted to FDA before the approval of another new drug application that qualifies for exclusivity under section 505(c)(3)(D)(ii) is not affected by this exclusivity provision. The agency believes, however, that an exception to this rule must be made where the first applicant to obtain approval and qualify for exclusivity publishes its data and the competing applicant amends its application to include the first applicant's published data. Where that data would be essential to the approval of the competing application, the second application will be deemed to refer to the first application. FDA is proposing to amend § 314.60 to ensure that the competing applicant cannot, without a right of reference, rely on the first applicant's data and at the same time avoid the first applicant's exclusivity.

Under proposed § 314.60(b), an amendment submitted by the competing applicant to include reports of investigations conducted or sponsored by the exclusivity holder, to which the competing applicant had not obtained a right of reference, and which would be essential to the approval of the competing application, would cause the application to be deemed withdrawn and resubmitted. Because an application for a drug entitled to 5 years of exclusivity cannot be submitted until the exclusivity expires, the resubmission would not be accepted until the exclusivity had expired (or until the expiration of 4 years from the date the first application was approved, where the competing applicant sought to challenge a patent on the first applicant's drug).

The exclusivity provisions of sections 505(c)(3)(D) (iii) and (iv) of the act delay the effective date of approval of any 505(b)(2) application that is for the conditions of use of a previously approved application that contained new clinical investigations essential for approval. Consequently, if two 505(b)(2) applications are under review at the same time and one is approved before the other, the effective date of approval of the second application to be approved will be delayed, regardless of the date of submission, if the first contained new clinical investigations essential for approval and thereby qualified for exclusivity.

The issue of competing applications under section 505(c)(3)(D)(i) of the act is moot. No 505(b)(2) applications were submitted for any of the drug products qualifying for exclusivity under this provision before the approval of the qualifying applications.

2. *Exclusion of DESI upgrades from exclusivity.* Under FDA's DESI review, if a manufacturer had an effective new drug application for a drug product before 1962, FDA reaffirmed its approval if the manufacturer submitted a supplemental new drug application to conform the product's indications for use to those determined to be effective in the DESI review. This is known as a DESI upgrade.

The agency believes as a matter of policy and statutory interpretation that a grant of exclusivity is inappropriate for any DESI upgrade. Except for the 2-year exclusivity provision (sections 505(j)(4)(D)(v) and 505(c)(3)(D)(v) of the act), Congress carefully limited the exclusivity provisions of the statute to new chemical entities, which by definition were innovative, and to those changes in already marketed drug products, such as a new use, which are important innovations. A DESI upgrade does not constitute a change in a marketed drug or a major innovation; rather it permits the continued marketing of an already existing product for an already existing indication. Thus, FDA does not believe that DESI upgrades qualify for exclusivity. Changes in DESI drugs that were not shown to be effective in the DESI review may, however, be entitled to exclusivity.

3. *Challenges to exclusivity determinations.* Drug products that qualify for exclusivity under one of the statutory provisions discussed above are identified in FDA's list and its monthly supplements, which state the expiration date of the period of exclusivity for any listed drug that FDA believes qualifies for exclusivity. The authority to make final exclusivity determinations has been delegated to the Center for Drug Evaluation and Research's Office of Drug Standards. (See 52 FR 10881; April 6, 1987.)

Interested persons may disagree with the agency's findings with respect to a period of exclusivity accorded or not accorded a drug product. An interested person should first informally contact the agency to determine that the conclusion represented in the list is real and not an error. Having established that the entry or lack of entry in the list represents an agency finding, the interested person who disagrees with the finding should petition the agency pursuant to 21 CFR 10.25 to include, exclude, or revise exclusivity information in the list if the petitioner believes the information in the list is

incorrect. The agency will generally publish in the **Federal Register** a notice of availability of any such petition it receives. Such publication is constructive notice to all interested persons who may be affected by the petition. Persons who may be affected include holders of approved new drug applications, approved ANDA's and approved 505(b)(2) applications, applicants with pending applications or potential applicants. (See also 50 FR 39177· September 27 1985.)

To resolve exclusivity issues as early as possible in the drug approval process, FDA proposes that, if an applicant believes its drug product or change to an already marketed drug product is entitled to exclusivity under the act, the applicant include this information in its new drug application. Under proposed § 314.50(j) for a new drug product and proposed § 314.70(e) for a change to an already marketed drug product, an applicant would be required to include: (1) a statement that the applicant is claiming exclusivity for its drug product or change, if approved; (2) a reference to the provision under proposed § 314.108 that supports the claim; (3) if the applicant is claiming exclusivity under § 314.108(b)(2), information to show that no drug product has previously been approved under section 505(b) containing any active moiety in the drug product for which the applicant is seeking approval and (4) if an applicant is claiming exclusivity under proposed § 314.108(b) (4) or (5), information to show that the application contains "new clinical investigations, "essential to approval, of the application or supplement and "conducted or sponsored by" the applicant. (See discussion at part V section L.1., *supra*.)

M. Refusal to Approve ANDA's

The statutory grounds for refusing to approve an ANDA in part parallel the ANDA submission requirements. Thus, under proposed § 314.127 the agency would deny approval of an ANDA if (1) the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of the drug product are inadequate to assure and preserve its identity, strength, quality, and purity; (2) information included in the ANDA is insufficient to show that each of the proposed conditions of use have been previously approved for the reference listed drug; (3) if the proposed drug product has one active ingredient, information in the ANDA is insufficient to show that the active ingredient is the same as that of the reference listed drug, or, if the proposed drug product is a combination product, (i) information in the ANDA is insufficient to show that the active ingredients are the same as those of the reference listed drug, or (ii) if one of the active ingredients differs, information in the ANDA is insufficient to show that the other active ingredients are the same as those of the reference listed drug, or that the differing active ingredient is an active ingredient of a listed drug or a drug that does not meet the requirements of section 201(p) of the act, or (iii) no petition to file an ANDA for the drug product with the different ingredient was approved under section 505(j)(2)(C) of the act; (4) information in the ANDA is insufficient to show that the route of administration, dosage form, or strength of the drug product are the same as those of the reference listed drug, or, if they are not the same, no petition to vary the changed elements was approved under section 505(j)(2)(C) of the act; (5) if the ANDA was filed pursuant to the approval of a petition to file an ANDA for a drug product with a different active ingredient, route of administration, dosage form, or strength, the ANDA did not contain the information required by FDA respecting the different active ingredient, route of administration, dosage form, or strength; (6) information in the ANDA is insufficient to show that the drug product is bioequivalent to the reference listed drug, or, if the ANDA was filed pursuant to an approved petition, the information is insufficient to show that the active ingredients of the drug product are of the same pharmacological or therapeutic class as those of the reference listed drug and that the drug product can be expected to have the same therapeutic effect as the reference listed drug when administered to patients for the same conditions of use; (7) information in the ANDA is insufficient to show that the labeling proposed for the drug product is the same as that for the reference listed drug except for changes required because of differences approved under a petition or because the drug product and reference listed drug are produced or distributed by different manufacturers.

1. *Inactive ingredients.* The statute also provides for denial of approval if information in the ANDA or any other information available to FDA shows that the inactive ingredients of the drug product are unsafe for use under the proposed conditions for use or that the composition of the drug product is unsafe under the proposed conditions of use because of the type or quantity of inactive ingredients in the drug product or the manner in which the inactive ingredients are included.

It is well-established that changing the inactive ingredients in a drug can adversely affect the drug's safety or effectiveness. Interpreting the act to require approval of generic drugs with potentially unsafe inactive ingredients would thwart one of the major purposes of the basic act, which was to prevent a repetition of the Sulfanilamide tragedy, in which the inactive ingredient of an untested drug was responsible for many deaths. The desire to avoid another such incident led to passage of the 1938 amendments to the act and the requirement that new drugs be shown to be safe. FDA is therefore proposing to consider inactive ingredients or composition "unsafe" if there is a reasonable basis to conclude that its inactive ingredients or composition raise serious questions about the drug's safety.

FDA's interpretation is consistent with the statutory scheme and with the purpose of the 1984 Amendments, which was to assure a supply of low cost generic drugs that are as safe and effective as their brand name counterparts.

Any other interpretation of section 505(j)(3)(H) of the act would produce absurd results when read in conjunction with the withdrawal provisions of section 505(e), which permit FDA to withdraw approval of an ANDA with less evidence of the hazard posed by an inactive ingredient than would be required to disapprove it. Section 505(e)(2) of the act permits FDA to withdraw approval of an application if there is evidence that shows that the drug "is not shown to be safe. FDA can invoke this provision if there is a reasonable basis from which to infer serious questions as to the safety of the drug, even if the agency lacks proof that the drug is unsafe. See Commissioner's Decision on DES, 44 FR 54852, 54861 (September 21, 1979), *aff'd, Rhone-Poulenc, Inc., Hess & Clark Div.* v. *FDA*, 636 F.2d 750 (D.C. Cir. 1980). Thus, if the agency believed that a new inactive ingredient was potentially dangerous but lacked proof that it was unsafe, and if section 505(j)(3)(H) of the act required proof that it was unsafe before it could disapprove the application, the agency would be required to approve the ANDA and then immediately initiate a proceeding to withdraw it.

The Supreme Court has held that in interpreting the Federal Food, Drug, and Cosmetic Act, the act must be given 'the most harmonious, comprehensive meaning possible' in light of the legislative policy and purpose, and must not 'impute to Congress a purpose to paralyze with one hand what it sought to promote with the other. It would be inconsistent with these

principles to interpret section 505(j)(3)(H) of the act as requiring either (1) a burden of proof on the agency that would allow approval of potentially unsafe drugs, or (2) a greater showing of unsafety to disapprove a drug than is required to withdraw it. Therefore, FDA proposes to harmonize section 505(j)(3)(H) of the act with other provisions of the act and therefore interprets that section as authorizing disapproval of an ANDA on the same basis as withdrawal under section 505(e)(2) of the act. Thus, an ANDA may be disapproved if there is a reasonable basis to conclude that one of its inactive ingredients or its composition raises serious questions about the drug's safety.

FDA is proposing to implement this interpretation in proposed § 314.127(h). That section provides that FDA will disapprove an ANDA if its inactive ingredients or composition raise serious questions of safety and cites examples of changes in inactive ingredients that FDA will consider to raise such serious questions. The examples reflect FDA's experience with types of changes in inactive ingredients that can adversely affect a drug's safety. The examples are not intended to be exhaustive, however, and FDA may conclude, on the basis of its experience or other information, that other types of changes raise serious questions about the safety of a drug. FDA solicits comments on additional types of changes in inactive ingredients and composition which create a reasonable basis from which to infer serious questions as to the drug's safety.

The agency lists in the regulations at proposed § 314.127(h)(2) examples of the types of changes in inactive ingredients that FDA will consider to raise serious questions about the safety of a drug product. In addition, for drug products intended for parenteral, ophthalmic, or optic use, the regulations identify the categories of added substances in which variations are not permitted and those in which variations may be permitted if the applicant demonstrates that the variation will not affect the safety of the product. (See discussion at part V section D.1.h.)

2. *Withdrawal or suspension of listed drug.* Section 505(j) of the act allows approval of ANDA's that refer to previously approved drugs, i.e., "listed drugs" within the meaning of 505(j)(2)(A)(i) and (6) of the act. The policy of allowing approval of generic copies of previously approved drugs would present significant problems if that policy allowed approval of generic copies of drugs whose approval had been withdrawn by FDA or that had been voluntarily withdrawn from sale for safety or effectiveness reasons. The statute seeks to assure that that will not happen by providing, in section 505(j)(6)(C) of the act, that a drug will be removed from listing, thus prohibiting approval of generic copies of that drug, if either of the above conditions occurs. In addition, section 505(j)(3)(I) bars the agency from approving an ANDA, even if the drug it refers to is still "listed, if there has been published a notice of opportunity for hearing on the withdrawal of approval of that listed drug. Section 505(j)(5) of the act, moreover, authorizes FDA to remove from the market, by withdrawal or suspension of approval, any generic copies already approved if the listed drug is removed from the market by FDA withdrawal or suspension of approval or is voluntarily withdrawn from sale for what the agency determines are safety or effectiveness reasons.

To assure that the intent of section 505(j)(3)(I) of the act is not evaded, the agency proposes to interpret this section broadly. Thus, § 314.162(a)(1) of the proposed rules is designed to deal with the following sequence of events: Drug A is approved under a full new drug application. Drug B is approved under an ANDA, and Drug A is the listed drug upon which it relies. The agency issues a notice of opportunity for hearing on withdrawal of approval of Drug A. Approval of Drug B will be withdrawn, in accordance with procedures discussed below, at the same time as that of Drug A. Section 505(j)(3)(I) of the act, by its terms, would prevent approval of an ANDA for Drug C that refers to Drug A as its listed drug after the notice of opportunity for hearing issues. Logically, that section should also prohibit approval of Drug C if it refers to Drug B as its listed drug, and the proposed regulation interprets the statutory language to produce that result.

A notice of opportunity for hearing is published only if the "listed" drug is being withdrawn under sections 505(e) or 505(j)(5) of the act. A drug must also be removed from the list when the agency determines that it has been voluntarily withdrawn from sale for safety or effectiveness reasons. To fulfill Congress' intent that new drugs not be approved pending the removal of a drug from the list, the agency will also refuse to approve an ANDA if the "listed" drug referred to in the ANDA was voluntarily withdrawn from sale and the agency has not determined that the withdrawal was not for safety or effectiveness reasons. (See proposed §§ 314.122 and 314.127(k).)

Where the listed drug is approved for more than one indication and the notice of proposed withdrawal proposes withdrawal of less than all of the approved indications, FDA will not approve an ANDA that includes an indication covered by the notice unless the applicant amends its ANDA with respect to labeling to remove the indication. Proposed § 314.127(i) would not apply if the ANDA seeks approval of the remaining indications only.

3. *Other grounds for disapproval.* Finally, FDA is authorized to disapprove an ANDA if the ANDA does not meet any other requirement of section 505(j)(2)(A) of the act, for example, does not contain the certifications regarding patents required in section 505(j)(2)(A)(vii) of the act, or the ANDA contains any untrue statement of material fact.

The agency proposes to add new § 314.127 to the regulations codifying the statutory reasons for disapproving an ANDA and to revise § 314.120 to state the administrative procedure governing this agency action. Under proposed revised § 314.120, if the agency concludes that there are grounds for denying approval of the ANDA, it will send the applicant a not approvable letter describing the deficiencies in the ANDA. The applicant must then either (1) withdraw its ANDA, (2) amend the ANDA incorporating already reviewed materials together with new information intended to correct all deficiencies identified in the not approvable letter, or (3) ask the agency to provide the applicant an opportunity for a hearing on the question of whether there are grounds for denying approval of the ANDA under section 505(j) of the act.

The regulations describing notices of opportunity for hearing on proposals to refuse to approve applications and abbreviated applications are set forth at § 314.200. The agency proposes to make editorial, but not substantive changes in these regulations. FDA will give an applicant written notice of opportunity for hearing on its refusal to approve an ANDA if the applicant asks the agency to provide it an opportunity for a hearing. The notice of opportunity for a hearing on a refusal to approve an ANDA would generally provide, as such notices now do, a detailed description and analysis of the specific facts resulting in the agency s refusal to approve the ANDA and would refer to specific requirements in the act and regulations under which the agency refused to approve the ANDA. An applicant would have, as it now does

under § 314.200, 30 days to respond to such notice. If the applicant requests a hearing, the hearing must begin not later than 90 days after the expiration of the 30-day period, unless both the agency and the applicant agree to a later date.

N. Withdrawal or Suspension of Approval of ANDA's

ANDA's may be withdrawn or suspended under two separate sections of the act. An ANDA may be withdrawn under section 505(e) of the act, on the same grounds that a full new drug application (NDA) may be withdrawn, or an ANDA may be withdrawn or suspended under section 505(j)(5) of the act, if a listed drug on which the approval of the ANDA depends is withdrawn or suspended by FDA or voluntarily withdrawn from sale for safety or effectiveness reasons. The agency proposes to retain its current regulations under § 314.150 stating the grounds for the withdrawal of approval of applications and abbreviated applications for new drugs under section 505(e) of the act. The agency proposes to add §§ 314.151 and 314.153, however, to describe the additional circumstances under which the agency will suspend or withdraw ANDA approval under section 505(j)(5) of the act.

The procedures to be followed when NDA's and ANDA's are withdrawn under section 505(e) of the act are specified by statute. Congress was silent, however, about the procedural requirements for the withdrawal or suspension of ANDA's under section 505(j)(5) of the act. The agency therefore proposes to establish procedures that will satisfy the requirements of due process.

Section 505(e) of the act requires the Secretary to provide "due notice and opportunity for hearing" when the agency proposes to withdraw approval of an NDA or an ANDA for grounds enumerated in that section. To satisfy this requirement, the agency currently affords an opportunity for a formal evidentiary hearing under 21 CFR Part 12 when it proposes to withdraw an NDA or an ANDA under section 505(e) of the act. FDA has tentatively concluded that different procedural safeguards are due an ANDA holder under section 505(j)(5) of the act than are due an NDA holder under section 505(e) of the act, for the reasons described below.

An ANDA for a generic drug exists legally and factually only by virtue of duplicating a previously approved listed drug. The investment in gaining approval of an ANDA is generally substantially less than the investment in gaining approval of an NDA. Unlike a full new drug application, an ANDA is not required to contain evidence of the safety and effectiveness of the drug entity for its intended use. Rather, the ANDA applicant relies on a prior agency finding of safety and effectiveness for approval. That prior agency finding is dependent on the evidence presented in a previously approved new drug application. The property rights and privileges that attach to an ANDA are therefore dependent and contingent upon the validity of the innovator drug manufacturer's NDA. Under the statutory scheme, an ANDA holder has no expectation of the continued marketing of its approved drug if approval of the underlying application for the reference drug is withdrawn or suspended. Accordingly, the agency concludes that the constitutionally protected interest of an ANDA holder is different than that of an NDA holder.

The agency recognizes, however, that ANDA holders may be entitled to more extensive procedural protections when the agency proposes to withdraw approval of their applications under sections 505(e) of the act rather than under 505(j)(5) of the act. This result is procedurally fair because of the different types of issues to be resolved under the two sections of the act. When the agency proposes to withdraw an ANDA under section 505(e) of the act, rather than section 505(j)(5) of the act, the basis for withdrawal will directly concern aspects of safety and effectiveness, labeling, or manufacturing that are specific to the ANDA holder's product; the basis for such a withdrawal will not be the safety and effectiveness of the underlying drug substance. In a 505(e) proceeding that concerns only a specific ANDA and not the underlying drug substance, therefore, the ANDA holder will be in the best position to present relevant evidence and to represent its interests. In many instances, an ANDA holder alone will possess the information essential to resolving factual issues necessary for the agency to make an informed judgment about whether or not approval of the application should be withdrawn or suspended for grounds specified under section 505(e) of the act.

In 505(j)(5) proceedings, on the other hand, the basis for the agency's decision to withdraw a reference listed drug will generally only indirectly concern the ANDA holder's product. Rather, the withdrawal will be based on the safety and effectiveness of the listed drug on which the ANDA approval depends. The issues in such a proceeding will usually involve the underlying safety and effectiveness data that supported the approval of the original full new drug application. For this reason, in 505(j)(5) withdrawal proceedings, an ANDA holder will not be uniquely able to present relevant evidence.

FDA notes that Congress did not amend section 505(e) of the act to require that ANDA holders be given an opportunity for hearing when the agency proposes to withdraw the listed drug to which the ANDA referred. Instead, Congress added new section 505(j)(5) of the act, which provides for the withdrawal or suspension of an ANDA when the approval of the listed drug on which the ANDA depends, is withdrawn or suspended. The agency believes this adds weight to its interpretation that ANDA's approved under section 505(j) of the act have different rights with respect to withdrawal proceedings. Section 505(j)(5) of the act does not require an opportunity for hearing.

1. *Type of hearing to be provided.* The agency has concluded that for withdrawals of ANDA approvals under section 505(j)(5), an opportunity for an oral hearing is not required. Where no hearing of any kind is required by statute, the agency believes procedural fairness requires adequate notice of the agency's position and an opportunity to respond to the agency's contentions, before a final determination. *Aeron Marine Shipping Co.* v. *United States,* 525 F Supp. 527 535 (D.D.C. 1981), *aff'd,* 695 F.2d 567 (D.C. Cir. 1982). Many courts, applying the Supreme Court's balancing test in *Mathews* v. *Eldridge,* 424 U.S. 319, 334–35 (1976), have held "paper hearing" procedures adequate where, in the total context of the process, they are deemed to ensure adequate notice and a genuine opportunity to explain one s case. See, e.g., *Carson Products* v. *Califano,* 594 F.2d 453, 459 (5th Cir. 1979); *Basciano* v. *Herkimer,* 605 F.2d 605 (2nd Cir. 1978), *cert. denied,* 442 U.S. 929 (1979); *Zotos Internat,l, Inc.* v. *Kennedy,* 460 F Supp. 268, 279 (D.D.C. 1978), following remand to agency, No. 82–1480 (D.D.C. August 14, 1986), *aff'g* Magis. Op. (filed August 21, 1985) (upholding FDA's written procedures for contesting agency determinations of trade secret status of certain ingredients). (See also *Geneva Towers Tenants Org.* v. *Federated Mortgage Investors,* 504 F.2d 483 (9th Cir. 1974).)

The agency has concluded that an oral hearing is not necessary to satisfy the requirements of due process for withdrawal or suspension of ANDA s under section 505(j)(5) of the act. As discussed above, the interests at stake and the nature of the issues to be resolved do not demand trial-type proceedings. Accordingly, the agency

intends to provide written due process safeguards that assure adequate notice, accurate fact-finding, and an opportunity to respond to agency findings.

Nevertheless, if the agency finds that there are dispositive factual issues about the reasons for the withdrawal of the listed drug that it cannot resolve on the basis of the written submissions alone, it will provide for a limited, informal oral hearing. The discretion to hold this hearing lies exclusively with the agency. The agency generally will not provide for an oral hearing unless it cannot make an informed determination without assessing the credibility and veracity of the witnesses.

The specific procedures afforded an ANDA holder under section 505(j)(5) of the act will depend on whether the ANDA is being withdrawn or suspended because (1) the listed drug referred to in the ANDA is being withdrawn or suspended by the agency for grounds described in the first sentence of section 505(e) of the act or under section 505(j)(5) of the act or (2) the manufacturer of the listed drug has voluntarily withdrawn its drug from sale for safety or effectiveness reasons. Section N.3. and 4. below discusses the procedures provided in each case.

2. *ANDA's subject to withdrawal or suspension.* Section 505(j)(5) of the act requires that the agency withdraw or suspend a drug approved under section 505(j) of the act that "refers in its application" to a listed drug that has been withdrawn or suspended by the agency or voluntarily withdrawn by its own manufacturer for safety or effectiveness reasons. Thus, the statute might be read to permit a withdrawal or suspension under section 505(j)(5) of the act only of generic drug A, which referred in its application to the listed drug, but not of generic drug B, which referred in its application to generic drug A. If this reading were correct, section 505(j)(5) would require the agency, following the withdrawal or suspension of generic drug A, to conduct a subsequent proceeding to withdraw or suspend generic drug B.

To avoid a series of repetitive proceedings, the agency proposes to include in a single proceeding under section 505(j)(5) of the act all applications for drug products that refer to any drug that would be withdrawn or suspended under section 505(j)(5) of the act, either immediately or sequentially, as a result of the withdrawal or suspension of the listed drug. Thus, if generic drug A refers in its application to the listed drug, generic drug B refers to drug A, and generic drug C refers to generic drug B, FDA will notify the manufacturers of drugs A, B, and C that it is proposing to withdraw or suspend their approvals and give each the opportunity to participate in a single proceeding, in accordance with the terms of either § 314.151 or § 314.153. (See section N.3. and 4. below.) It should be noted, however, that cases of generic drugs sequentially referring to different listed drugs are unlikely, because in most cases the agency would require all generic applicants to refer to a single listed drug to assure uniform labeling and bioequivalence continuity.

If, as a result of this policy, a large number of manufacturers elect to participate as nonparty participants in any hearing held under 21 CFR Part 12, the presiding officer is authorized to exclude repetitive submissions. (See 21 CFR 12.94.)

The agency notes that prospective ANDA applicants, i.e., persons without approved ANDA's, have no constitutionally protected interest in whether the pioneer drug remains on the list of approved drugs and thus are not entitled to participate in the decisionmaking process concerning withdrawal or removal of a drug from "listed" status.

3. *Withdrawal of approval of an ANDA when the listed drug is withdrawn for grounds described in section 505(e)(1) through (5) of the act.* If the agency proposes to withdraw a listed drug for grounds enumerated in the first sentence of section 505(e) of the act, the listed drug's manufacturer has a right to notice and an opportunity for a formal evidentiary hearing on the withdrawal of approval of the listed drug. Except for persons subject to notice and an opportunity for a hearing under 21 CFR 310.6, the holder of an abbreviated application that is dependent on the approval of the listed drug does not have an independent right to hearing. Such an ANDA holder may, however, submit written comments on the notice of opportunity for hearing issued on the proposed withdrawal of the listed drug. The agency recognizes that there may be rare cases in which the reason for the withdrawal of the listed drug product is not applicable to the ANDA holder's drug product. For example, a withdrawal caused by a problem related to a particular dosage form might not be relevant to the safety and effectiveness of a generic version of the drug which was marketed in a different dosage form, pursuant to an approved petition under section 505(j)(2)(C) of the act. In such a case, the burden would be on the ANDA holder to submit information establishing to the agency's satisfaction the inapplicability to the generic drug product of the grounds for withdrawal.

If a hearing is granted, any ANDA holder that submitted comments on the notice of opportunity for hearing may participate in the hearing as a nonparty participant as provided for in 21 CFR 12.89. (See proposed § 314.151.) If the listed drug is withdrawn without a hearing, any ANDA's whose holders did not submit comments will be withdrawn at the same time as the listed drug. If a hearing is requested but denied, each ANDA listed in the notice of opportunity for hearing will be withdrawn at the same time as the listed drug, unless the agency determines, pursuant to proposed § 314.151(d), that the grounds for withdrawal are not applicable to a specific ANDA.

If an affected ANDA holder that has commented on the notice of opportunity for hearing does not have an opportunity to participate in a 21 CFR Part 12 hearing because a hearing is not requested, or is settled, the ANDA holder will be provided the "paper hearing" procedures set forth in proposed § 314.151. If the drug has been suspended pursuant to § 314.153 (see discussion at section N.4. below), a hearing will be provided after the drug has been removed from the market. The published notice of opportunity for hearing on the withdrawal of the listed drug will serve as the written notice detailing the reasons for the proposed withdrawal of approval of affected ANDA's and providing a summary of the evidence that the agency considers most relevant.

ANDA holders will have had an opportunity, as described above, to comment on the agency's proposed withdrawal of the drug from "listed" status. An ANDA holder should submit evidence that directly challenges the accuracy of the information considered by the agency as well as the correctness of the agency's conclusions.

Any comments received will be considered by the agency. Where no 21 CFR Part 12 hearing is held, an initial decision on the withdrawal of the listed drug and related ANDA's, which responds to significant comments, will be sent to each ANDA holder that submitted comments. These ANDA holders will then have 30 days in which to object to the agency's initial determination, in the form of a written rebuttal. If necessary to resolve dispositive factual issues, the agency may, at its discretion, hold a limited informal oral hearing. If there are no objections to the initial decision, it will become final at the expiration of 30 days from the date of its issuance. If there are

objections to the initial decision, the written rebuttals will be reviewed and responded to in the final decision.

The Director will publish a notice announcing the availability of the final decision in the **Federal Register.** If the final decision withdraws approval of the listed drug, the published notice will also (1) remove the reference drug from the list and (2) withdraw approval of and remove from the list all ANDA's identified in the notice of opportunity for hearing. See proposed §§ 314.152 and 314.162.

4. *Suspension of approval of an ANDA when the "listed" drug is voluntarily withdrawn from sale for safety or effectiveness reasons.* When the agency proposes to suspend an ANDA because it determines that the listed drug on which the ANDA's approval depends was voluntarily withdrawn from sale by the manufacturer for safety or effectiveness reasons, the ANDA holder will have an opportunity to show that the withdrawal was not for safety or effectiveness reasons or that the reasons for the withdrawal are not applicable to the generic drug. By "voluntary withdrawal, the agency means any withdrawal from sale other than a withdrawal ordered under section 505(e) or 505(j)(5) of the act. A "paper hearing" procedure will be afforded affected ANDA holders for this purpose. (See proposed § 314.153.) If the drug has been suspended pursuant to § 314.153, a hearing will be provided after the drug has been removed from the market.

If a listed drug is voluntarily withdrawn from sale and the agency determines that the withdrawal from sale was for safety or effectiveness reasons, each affected ANDA holder will be sent a copy of the agency's initial decision setting forth the reasons for its determination and its intention to remove the listed drug from the list and suspend approval of the identified ANDA's. For a discussion of the factors the agency will consider in making this determination, see section O., *infra.*

ANDA holders will have 30 days from the date the initial decision is issued to present, in writing, comments on the agency's proposed decision. An ANDA holder may also submit evidence demonstrating that the reasons for the withdrawal of the listed drug are not applicable to the drug subject to the ANDA. The agency may, at its discretion, hold a limited informal oral hearing to resolve dispositive factual issues.

If no significant comments on the proposed decision are received, the initial decision will become final at the expiration of 30 days from the date the initial decision was issued. If significant comments are received, a final decision responding to them will be issued. The final decision will be in writing and will be sent to ANDA holders who submitted comments. If the final decision affirms the agency's initial decision, it will be published in the **Federal Register** and will remove the listed drug from the list and suspend approval of, and remove from the list, all ANDA's whose holders were notified of the proposed agency action. (See proposed § 314.153(b).) For a discussion of removal of drugs from the list, see section P *infra.*

The agency is using the term "suspended" rather than "withdrawn" to describe the status of ANDA's approved by reference to a listed drug that the agency determines has been voluntarily withdrawn from sale for safety or effectiveness reasons. Section 505(j)(5) of the act provides that an ANDA approval "shall be withdrawn or suspended for the period of [the listed drug's] withdrawal from sale, or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale is not for safety and effectiveness reasons. The agency believes that Congress intended that ANDA approval be reinstated immediately when either of these two conditions is met. The agency therefore intends to suspend rather than withdraw approval of ANDA's because once withdrawn, ANDA approval cannot be automatically reinstated. Instead, to regain approval of a withdrawn application, the ANDA applicant would have to obtain a new approval.

Therefore, to permit reinstatement of ANDA's, the agency proposes to suspend ANDA approval rather than withdraw it when the listed drug is determined to have been voluntarily withdrawn for safety or effectiveness reasons. Accordingly, if the approval of an ANDA depends on the approval of a drug that the agency determines is voluntarily withdrawn for safety or effectiveness reasons, the ANDA's approval will be suspended, i.e., the approval will cease to be in effect, for the period specified in section 505(j)(5)(B) of the act. The agency notes that the "imminent hazard" procedures in section 505(e) of the act do not apply to suspensions under section 505(j) of the act. The authority for "imminent hazard" suspensions cannot be delegated beyond the level of the Secretary of Health and Human Services, while no such statutory limitation applies to section 505(j) suspensions. Accordingly, the agency believes that Congress intended section 505(j) suspensions to be accomplished more expeditiously than section 505(e) suspensions.

ANDA approval will be reinstated if the agency has evidence or evidence is presented in a citizen petition demonstrating that the listed drug was not withdrawn for safety or effectiveness reasons and the agency therefore relists the withdrawn drug, or if evidence is presented in a citizen petition establishing that the basis for the withdrawal of the reference drug does not apply to the generic drug (proposed § 314.161(e)).

5. *Imminent public health hazards.* If the agency determines that a drug approved under section 505 of the act presents an unacceptable hazard to the public health, approval of its new drug application may be suspended pursuant to the "imminent hazard" provision of section 505(e) of the act. The holder of an abbreviated new drug application drug whose approval rests on a listed drug that is the subject of an "imminent hazard" proceeding will be permitted to participate in the proceeding. If approval of the listed drug is suspended as an imminent hazard, the approval of ANDA's whose approval rests on the listed drug will be suspended immediately (proposed § 314.153(a)(1)).

To assure that ANDA's for all drug products affected by an imminent hazard proceeding are suspended immediately, proposed § 314.153(a)(1) provides for the suspension of any ANDA that refers in its application to a listed drug suspended under authority of section 505(e) of the act or under authority of § 314.153(a)(1). Thus, if Drug B refers to Drug A and Drug A refers to a listed drug that is suspended in an imminent hazard proceeding under 505(e) of the act, Drug A will be suspended under § 314.153(a)(1) because its reference listed drug was suspended under authority of section 505(e) and Drug B will be suspended because its reference listed drug (Drug A) was suspended under authority of § 314.153(a)(1).

The holder of an ANDA suspended because a listed drug is found to be an "imminent hazard" will also be permitted to participate as a nonparty participant in any subsequent hearing on withdrawal of approval of the listed drug, as described above in section N.3.

If a listed drug is voluntarily withdrawn from sale for safety or effectiveness reasons and the agency concludes that the drug presents an unacceptable risk to the public, the proposed regulations also provide for the immediate suspension of ANDA approval of any drug whose approval rests on the approval of the withdrawn drug (proposed § 314.153(a)(2)). As discussed in section N.4. above, the

agency does not believe that the imminent hazard provisions of section 505(e) of the act apply to suspensions under section 505(j) of the act.

O. Determination That a Listed Drug Was Withdrawn for Safety or Effectiveness Reasons

The 1984 Amendments do not specify procedures to be followed in determining whether a drug that is voluntarily withdrawn from sale by its manufacturer is withdrawn for safety or effectiveness reasons. The statute does not require that the agency make this determination for every drug that is voluntarily withdrawn from sale, nor does it specify at what point after a voluntary withdrawal such a determination can or must be made. Many drugs are withdrawn from the market every year, and it would be a needless expenditure of resources for the agency to determine the reason for each such withdrawal. The agency is therefore interpreting section 505(j)(5) of the act to permit it to determine whether a drug is withdrawn for safety or effectiveness reasons at any time after it has ceased to be marketed.

The agency anticipates that a determination of the reasons for withdrawal of a listed drug will generally be made either when there are existing approved ANDA's that depend upon the approval of the listed drug, see § 314.153(b), when an ANDA applicant seeks to refer to a listed drug that has been voluntarily withdrawn from sale, see proposed § 314.122, or when an interested person petitions for a determination under §§ 10.25 and 10.30. The agency may, however, also make the determination at any other time on its own initiative. (See proposed § 314.161.)

The agency may determine whether a listed drug was withdrawn from sale for safety or effectiveness reasons, as required by section 505(j)(5) of the act, by attempting to focus on the intent of its manufacturer. Often, however, there will be more than one reason for the withdrawal of a drug from market by the manufacturer. Withdrawals are often accompanied by statements from the drug s manufacturer that the firm continues to have confidence in the safety and effectiveness of the product but is acting for business purposes. Drug manufacturers have also sometimes stated that the product was withdrawn from the market due to unwarranted product liability.

Because Congress did not provide the agency with subpoena power to call as witnesses the persons who made the decision to withdraw a product from sale, Congress cannot have expected the agency to discern the actual intent of the decisionmakers by direct evidence. The legislative history of this provision does make clear, however, Congress' intent that the agency examine whether the manufacturer had safety or effectiveness concerns about the withdrawn drug independent of the reasons given by the manufacturer for the withdrawal. (H. Rept. 857 Part I, at 30.) Congress, therefore, must have expected the agency to rely upon circumstantial evidence and logical inference to determine the actual intent of those who decided to withdraw the product from the market. The agency's inquiry, therefore, will focus on whether there were sufficient concerns about safety and effectiveness to make a withdrawal from sale likely and reasonable.

A determination on this issue by the agency will be based in part on the assumption that a pharmaceutical manufacturer would not cease distribution of a profitable drug if safety or effectiveness concerns had not arisen. If the withdrawn drug accounted for significant sales of the company withdrawing it, in the absence of convincing evidence to the contrary, that would be persuasive evidence that safety or effectiveness concerns prompted the manufacturer to withdraw the drug from sale. As a means of implementing the statute, the agency may establish the following rebuttable presumption. If a drug manufacturer withdraws a drug from the market which accounted for significant sales to that manufacturer, and there is no evidence to the contrary, it will be presumed that the withdrawal was for safety or effectiveness reasons. FDA seeks comments on a sales figure or other methodology that would be appropriate to establish this presumption.

The agency will also consider other factors in determining whether a market withdrawal was for safety and effectiveness reasons, such as increases in the number of adverse drug reactions reported on the drug and published or unpublished studies of the drug questioning its safety or effectiveness.

If the agency makes a final decision, pursuant to § 314.153(b) or § 314.161, determining that a listed drug is withdrawn for safety or effectiveness reasons, the agency will publish a notice of the determination in the **Federal Register** (proposed § 314.161). The notice will also serve to remove the drug from the list (proposed § 314.162).

At any time after a drug is removed from the list under proposed § 314.162(a)(2), the drug may be relisted if the agency determines that the drug was not withdrawn for safety or effectiveness reasons. The agency may make this determination on its own initiative or in response to a petition submitted under §§ 10.25(a) and 10.30. If the agency decides on the basis of evidence before it that the drug was not withdrawn for safety or effectiveness reasons, it will publish a notice in the **Federal Register** announcing its determination. (See proposed § 314.161(e).) The notice will announce that the drug is relisted and serve to reinstate approval of ANDA's that were suspended when the agency published its final decision removing the listed drug from the list.

1. *Submitting an application or a suitability petition that refer to a listed drug that is no longer marketed.* Because there are many instances each year in which a drug company decides not to continue selling a drug, FDA normally will not determine whether the drug was withdrawn for safety or effectiveness reasons simply because it learns that the product was voluntarily withdrawn from sale. To assure that generic versions of unsafe or ineffective drugs do not remain on the market, the agency will, however, promptly determine the reasons for the withdrawal of a listed drug if the agency has approved ANDA's that referred to the listed drug. The agency will require persons who wish to submit ANDA's for those listed drugs that have been withdrawn from sale and for which no ANDA's have been approved or who wish to submit suitability petitions that rely on those listed drugs to show that the withdrawals from sale were not for safety or effectiveness reasons. For purposes of sections 505(j)(5) and 505(j)(6)(C) of the act, a drug shall be considered to have been "withdrawn from sale" if the applicant has ceased its own distribution of the drug, whether or not it has ordered recall of previously distributed lots of the drug. A routine, temporary interruption in the supply of a drug product would not be considered a withdrawal from sale, however, unless triggered by safety or effectiveness concerns.

Persons who wish to submit an ANDA or a suitability petition that relies on a listed drug that has been voluntarily withdrawn from the market must petition the agency with supporting documentation that the withdrawal from sale was not for safety or effectiveness reasons (proposed § 314.122). If the agency receives an ANDA or a suitability petition for such a drug unaccompanied by a petition with supporting documentation, it will refuse to approve the ANDA or suitability

petition until it can determine that the listed drug is not withdrawn for safety or effectiveness reasons (proposed §§ 314.93(e)(v) and 314.127(k)).

2. *Informing FDA of withdrawals.* The agency proposes to require holders of approved applications to notify FDA in writing when commercial distribution of a drug has been discontinued. Section 510(j)(2)(B) of the act requires the reporting of this information to FDA semi-annually as part of updating drug listing information. However, section 505(j)(6)(C) of the act requires FDA to remove a drug from the list immediately if the drug has been withdrawn from sale for safety or effectiveness reasons. Under current regulations, a manufacturer that has voluntarily withdrawn a drug from sale may, at its discretion, report the information when the discontinuance occurs (§ 207.30).

To permit FDA to satisfy its obligations under 505(j)(6)(C) of the act and to assure that ANDA's will not be approved for generic copies of listed drugs that have been voluntarily withdrawn from sale for safety or effectiveness reasons, the agency is proposing to revise § 314.81 to require the applicant to tell the agency as soon as commercial distribution of a listed drug ceases, other than for temporary interruptions in the supply of the drug. The proposed revision would require an applicant to submit to FDA on Form FDA-2657 (Drug Product Listing) a report whenever the applicant discontinues commercial marketing of an approved drug, other than for routine, temporary interruptions in the supply of the drug not caused by safety or effectiveness concerns. The report would have to be submitted within 15 working days of the discontinuance and include the following information: (1) the National Drug Code (NDC) number; (2) the identity of the drug product by established name and any proprietary name; (3) the new drug application (NDA) or abbreviated new drug application (ANDA) number; and (4) the date of discontinuance. The applicant may state the reason for its decision to withdraw the drug from sale. The proposed regulation would require the report to be submitted to the Drug Listing Branch (HFD-315), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857

P Removing Drugs from the List

Section 505(j)(6)(C) of the act requires that FDA remove from the list any drug that was withdrawn or suspended for grounds described in the first sentence of section 505(e) or in section 505(j)(5) of the act, or that the agency determines was voluntarily withdrawn for safety or effectiveness reasons. The statute requires that removal occur immediately after the agency orders suspension or withdrawal or upon the agency's determination that the drug was voluntarily withdrawn for safety or effectiveness reasons. The only procedural requirement imposed by the statute is that the agency publish a notice in the **Federal Register** announcing the removal.

The agency is proposing to combine the procedures for removal of drugs from the list with the procedures already in place for the withdrawal and suspension of listed drugs, and for a determination of the reasons for a voluntary withdrawal. The publication in the **Federal Register** of the agency's final decision withdrawing or suspending a listed drug, or of the agency's decision determining that the drug was voluntarily withdrawn for safety or effectiveness reasons will also announce the removal of the drug from the list (proposed §§ 314.152, 314.153(b)(5), and 314.161).

Q. Patent Information in Full New Drug Applications and Supplements

1. *Introduction.* Sections 505(b)(1) and 505(c)(2) of the act require that an NDA applicant "file with its application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. This provision requires that an applicant submit information about any patent that meets the statutory description whether or not the applicant owns or is licensed under such a patent. Required patent information must be submitted with all original applications submitted under section 505(b) of the act, including applications described in section 505(b)(2) of the act and with certain supplemental applications. Upon approval of the application, the statute requires that FDA publish patent information submitted under section 505(b) of the act. Patent information on unapproved products or on patents beyond the scope of the act (i.e., process patents) will not be published. Proposed new § 314.53 would contain the regulations implementing the statutory provision requiring the submission of patent information. FDA also proposes to revise § 314.50 by designating paragraph (h) as paragraph (k) and adding a new paragraph (h) that would refer to the requirements of proposed new § 314.53.

2. *Patents for which information must be submitted.* The patents that FDA regards as covered by this statutory provision are those that claim the drug (active ingredient or ingredients) or drug product, and use patents for a particular indication or method of using the product. The agency has concluded that formulation and composition patents are drug product patents within the meaning of this statutory provision about which information must be submitted to and published by FDA. Process patents (patents that claim a method of manufacturing) are not covered by the statute and information on these patents are not to be submitted and will not be published by FDA.

The agency will not accept patent information that pre-dates an official notice by the United States Patent and Trademark Office that a patent has been granted. Thus, an applicant should not anticipate the granting of a patent. The applicant may informally notify the agency of an impending patent, but no official action will be taken in response to such notice.

3. *Reporting requirements.* The agency proposes in § 314.53(c) that each required submission of patent information contain the patent number, the date on which the patent will expire, a statement as to whether the patent is a drug patent, drug product patent, or use patent, and the name of the patent owner. Identifying the type of patent will assist the agency in assuring that those types of patents that require a certification by a generic applicant have such certification and that use patents are clearly identified for publishing in the list. Under this proposal, if the patent owner or applicant does not reside or have a place of business in the United States, the application would be required to include the name of an agent (representative) of the patent owner or applicant who resides or maintains a place of business within the United States authorized to receive notice of patent certification under sections 505(b)(3) and 505(j)(2)(B) of the act.

As noted above, information will be published in the list only on patents that claim approved drug products or that claim approved indications or other conditions of use. Therefore, to assist the agency in ensuring that only appropriate patents are published for patents that claim a drug, drug product, or method of use an applicant would submit information only on those patents that claim an approved drug product or approved method of using such drug product, or drug product or a

method of using such drug or drug product for which the applicant has submitted an application to obtain FDA approval. The patent information for each formulation or composition (drug product) patent would be required to include the following certification:

The undersigned certifies that the drug and the formulation or composition of (*name of drug product*) is claimed by Patent No. _____. This product is (*currently approved under section 505 of the Federal Food, Drug, and Cosmetic Act*) [*or*] (*the subject of this application for which approval is being sought*).

Under the proposal, an applicant would, before approval of the application, submit a certification for each formulation or composition patent that claimed the drug product for which the applicant was seeking approval. Because formulations are often changed during the approval process, within 30 days after the date of approval of the application, if the original application submission included a certification about a formulation or composition patent, the applicant would be required to submit an amended certification identifying the patents that claim the approved formulation or composition of the drug product. If an approved formulation is changed by an applicant through the submission and approval of a supplemental application and an existing formulation patent no longer claims the new approved formulation, the new drug application holder must notify FDA so that the patent can be removed from the list. Similarly, FDA should be notified if a patent holder no longer intends to enforce a patent, for example, because the patent is no longer valid. This will assist the agency in maintaining accurate patent information in its list and generic applicants in complying with the patent certification requirements under sections 505(b)(2) and 505(j) of the act.

With respect to a use patent, the agency proposes to require an applicant to submit a certification that identifies each patent that claims indications or conditions of use that are approved or are the subject of the application for which the applicant is seeking approval. Because all indications or conditions of use for which an applicant sought approval may not be approved, within 30 days after the date of approval of the application; if the original application submission included a certification about a method of use patent, the applicant would be required to submit an amended certification identifying the approved indications or conditions of use and the patents that claim those uses. The purpose of this requirement is to provide some guidance to applicants required to submit either a patent certification under section 505(b)(2)(A) or 505(j)(2)(A)(vii) or a statement under section 505(b)(2)(B) or 505(j)(2)(A)(viii) of the act (proposed § 314.94(a)(12)). When a generic applicant concludes that a use patent does not claim the use for which the applicant seeks approval, the applicant is required only to submit a statement under section 505(b)(2)(B) or 505(j)(2)(A)(viii) so stating to FDA. The applicant is not required to notify the patent owner of the applicant's intent to market a copy of the patented drug. If the patent owner does not specify which approved indications or conditions of use are covered by its patent, the generic applicant may interpret the scope of the patent more narrowly than would the patent owner, thereby avoiding the certification and notification provisions of the statute.

FDA's experience implementing the patent certification provisions suggests that where the patent owner and generic applicant disagree as to the applicability of a use patent, the patent owner may seek to have FDA intervene, by alleging that the generic applicant has not complied with the patent certification and notification provisions of the act. Because FDA has no expertise in the field of patents, the agency has no basis for determining whether a use patent covers the use sought by the generic applicant. Nor does FDA believe that Congress intended the patent provisions of Title I of the 1984 Amendments to require the agency to make such determinations. On the contrary, the 1984 Amendments are plainly structured to allow any patent disputes to be litigated in federal court. To ensure that FDA is not required to determine the scope of a use patent, the agency can either require the applicant to make a certification as to the covered approved indications and require generic applicants to file patent certifications as to those indications, or the agency can allow the generic applicant complete discretion to interpret the scope of any relevant use patent. The agency believes that the first approach more fairly implements Congress' intent that patent owners receive preapproval notice of potentially infringing products.

FDA therefore proposes that after approval of an application submitted under section 505 of the act that contained a certification that a method of use patent covered an indication for which the applicant sought approval, the applicant would be required to amend its certification to identify the specific indications or conditions of use that have been approved and the patents that claim those uses. If the applicant is not the patent owner, the applicant should obtain this amended certification from the patent owner, because the applicant has the responsibility for providing FDA with the required patent information. Upon approval of an application, the agency will publish in the list all use patents that claim an approved indication and for each patent identify the approved indications or conditions of use covered by the patent.

The proposal also would require that if an applicant believes that there are no patents that claim the drug or drug product, nor that claim an approved method of using the drug product and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product, the applicant would include in its application a certification stating this belief.

Finally, under proposed § 314.53, a certification required under the section must be signed by the applicant or patent owner, or the applicant's or patent owner's attorney, agent (representative), or other authorized official.

4. *When and where to submit patent information.* If a patent is issued on a drug or drug product or on a method of using a drug product before an application is filed with FDA, information on the patent must be submitted with the application. If a patent is issued after an application is filed with FDA but before the application is approved, the applicant must submit the required patent information in an amendment to the application under § 314.60. If a patent is issued after the application has been approved, the applicant must submit the required patent information by letter within 30 days of the date of issuance of the patent.

The act and proposed regulations contemplate amendment of an application when a patent is issued after submission, and before approval, of a full application. If a patent has not been submitted to FDA by the time FDA determines that an abbreviated new drug application or a 505(b)(2) application can be approved, and the generic applicant certifies that it is unaware of any relevant patents, the agency will not delay approval of the application. If the holder of a new drug application submits patent information after the application for the generic drug has already been approved, FDA will not attempt to rescind or withdraw approval.

Holders of or applicants for ANDA s or 505(b)(2) applications who are

licensed under a patent are encouraged to submit information concerning the patent license so that information on the patent can be listed with their products as well as with the patent owner's product, thus assuring that the patent protection features of the act are preserved for that patent. Licensees are also required to submit information concerning a patent licensing agreement if they wish to avoid a delayed effective date. (See proposed § 314.107(b)(1).)

In general, supplements are subject to the same patent submission requirements as original applications. Many supplements, however, are for changes that could not be patented. Rather than require patent submissions for every supplement, the agency proposes to require that patent information be submitted only for the following types of changes for which applicants must submit supplements: (1) changes in formulation; (2) new indications or other conditions of use, including a change in route of administration; (3) changes in strength; or (4) any other patented changes. FDA recognizes that there are formulation changes that are unpatentable and could be specifically excluded from the requirement of submitting patent information. However, FDA does not have the expertise to identify such unpatentable formulation changes. FDA solicits comments on this policy of requiring patent information only for certain supplements, and on the types of supplements for which patent information should be required.

Under the proposal, if new patents or existing patents cover the changes for which approval is sought in a supplement, the applicant would be required to submit the required patent information with the supplement. If existing patents for which information has already been submitted claim the change, the applicant would be required to submit a certification with the supplement identifying the patents that claim the change. If the applicant submits a supplement for one of the changes listed above and no patents, including previously submitted patents, claim the change, the applicant would be required to so certify. The patent information and certifications would be required to be submitted by letter separate from, but at the same time as, the supplement.

The agency proposes to require an applicant to submit two copies of each submission of patent information; an archival copy and a copy for the chemistry, manufacturing and controls section of the review copy of an application or supplement. The regulations would require the applicant to submit patent information to the Central Document Room, Center for Drug Evaluation and Research, Food and Drug Administration, Park Bldg., Rm. 214, 12420 Parklawn Dr., Rockville, MD 20857 Each submission of patent information, except information submitted with an original application, and its mailing cover would be required to bear prominent identification as to its contents, i.e., "Patent Information" or, if submitted after approval of the application, "Time Sensitive Patent Information.

5. *Untimely submission.* PMA suggested regulatory language designed to allow a pioneer holder to update, at any time, its patent information. FDA does not believe that specific regulatory language is necessary. If patent information on a patent issued after approval of an application is not timely submitted, i.e., is submitted more than 30 days after issuance of the patent, the agency could refuse to publish in the list the untimely information, or could withdraw approval of the new drug application if its applicant failed to respond within 30 days to a notice from the agency (21 U.S.C. 355(e)(4)). FDA has concluded, however, that while Congress clearly intended to enforce timely submission, a less severe penalty for late submission would effectuate Congress' intent without eliminating all statutory patent protection or withdrawing approval of the new drug application itself. Therefore, if a new drug application applicant submits required patent information on an approved drug product more than 30 days after issuance of the patent, FDA will publish the untimely information but will not require ANDA and 505(b)(2) applicants with pending applications who have previously submitted a certification, i.e., those applicants who would be prejudiced by the late submission, to recertify as to the new patent. Only applicants who initially submit ANDA's or 505(b)(2) applications after the submission of the patent information or whose pending applications do not contain a valid certification at the time of the submission would be required to submit a certification as to that patent. (See proposed §§ 314.50(i)(4) and 314.94(a)(12)(vi).)

The date that the patent information is received by the Central Document Room will generally be considered the date the information was submitted. Determining the date on which patent information is submitted is important because ANDA and 505(b)(2) applicants are required to notify a patent owner of the submission of an application for a potentially infringing drug product only if information on the patent has been submitted to FDA before approval of the ANDA or 505(b)(2) application. If questions arise as to whether patent information has been submitted, FDA will review the archival records in the Central Document Room. If there is no evidence then that patent information has been submitted, no patent information will be considered to have been submitted.

6. *Submission errors.* In deciding whether a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug, the agency will defer to the information submitted by the NDA applicant. If any interested person disputes the accuracy or relevance of patent information submitted by an NDA applicant and published by FDA in the list, or believes that an applicant has failed to submit required patent information, that person should first notify the agency informally, stating the grounds for the disagreement by writing to the Director, Office of Drug Standard (HFD-200), 5600 Fishers Lane, Rockville, MD 20857 The agency will contact the new drug application holder requesting that the correctness of the submission or omission be confirmed. Unless the new drug application holder withdraws or changes the patent submission, the agency will not change the patent information in the list. If there is no change to the patent information in the list, a section 505(b)(2) or 505(j) application submitted for the drug must, despite any disagreement, contain a certification for each listed patent and any patent challenge must then be pursued through private legal action under the patent laws.

The agency proposes to revise § 314.125 to add an additional reason for refusing to approve a new drug application. Under section 505(d)(6) of the act, the agency is obligated to refuse to approve an application if the application failed to contain the required patent information.

The agency proposes to revise § 314.150 to add an additional ground for the withdrawal of approval of a new drug application. As noted above, the statute provides that the agency is obligated to withdraw approval of an application if the application fails to contain the required patent information within 30 days after receipt of a written notice from FDA specifying the failure to provide such information. Although ordinarily the agency intends to invoke a less severe penalty for late submissions (see discussion under

section 0.5., FDA has the authority to withdraw approval of an application if an applicant has been notified of its failure to provide required patent information and the applicant does not respond within 30 days.

R. Public Disclosure of Safety and Effectiveness Data

Section 505(l) of the act specifies when safety and effectiveness data submitted as part of a new drug application are publicly disclosable. Those provisions were implemented by the agency's final rule published in the **Federal Register** of February 22, 1985 (50 FR 7452) that revised 21 CFR Part 314 governing the approval for marketing of new drugs and antibiotic drugs for human use. No changes to those provisions are being made by this proposed rule.

VI. Conforming Amendments

21 CFR 310.305 requires adverse drug experience reporting for marketed prescription drugs not the subject of approved new drug or abbreviated new drug applications. Those rules were patterned after the adverse drug experience reporting provisions under 21 CFR 314.80. To ensure consistency between these two sets of rules, the agency is proposing to revise § 310.305 to adopt changes identical to those proposed in this document for § 314.80 concerning the definition of the term "adverse drug experience" and reports on increased frequency of therapeutic failure (lack of affect).

The provisions of the 1984 Amendments with respect to bioequivalence, FDA's followup to the Bioequivalence Hearing held September 29 through October 1, 1986, and current agency policy necessitate changes in the regulations in 21 CFR Part 320.

In 21 CFR Part 320, FDA proposes to revise the table of contents to reflect the changes described below.

In § 320.1, FDA proposes to (1) revise the definition of "bioavailability" to add a reference to drugs that are not intended to be absorbed, (2) restate the definition of "bioequivalence, and (3) remove the definition of "bioequivalence requirement.

In § 320.21, FDA proposes to restate the requirements for submission of bioavailability and bioequivalence data.

In § 320.22, FDA proposes to revise paragraph (b)(1) to restate the waiver provision and to remove the automatic waiver of evidence of in vivo bioavailability for topically applied preparations (§ 320.22(b)(2)) and oral dosage forms not intended to be absorbed (§ 320.22(b)(3)) because the agency believes the in vivo bioavailability of such products should not be considered self-evident in every case. Variations in the manufacturing process (including a change in product formulation) used by each individual manufacturer may result in differences in the bioavailability of these drug products. Therefore, the agency intends to review each product on a case-by-case basis to determine if an in vivo bioavailability study is necessary.

It should be emphasized, however, that although the automatic waiver provisions under § 320.22 would no longer apply to topical drug products and oral dosage forms not intended to be absorbed, the agency may, in appropriate cases, waive the in vivo requirement.

In § 320.22(b)(4)(i) (proposed § 320.22(b)(2)), FDA proposes to delete the words "or vapor. These words have been inaccurately interpreted by applicants to apply to aerosol drug products.

In § 320.22(b)(5)(ii) (proposed § 320.22(b)(3)), FDA proposes to require that the active drug ingredient be in the same concentration and dosage form. This change conforms to current agency policy.

Current § 320.22(c)(1) states that FDA shall waive the requirement of in vivo bioavailability testing for a solid oral dosage form (other than an enteric-coated or controlled release dosage form) of a drug product determined to be effective for at least one indication in a DESI notice, if the drug is not on the list of so-called "bioproblem drugs" codified in § 320.22(c)(1). The waiver embodied in this provision resulted from the DESI review. During the review, because of the need to evaluate large numbers of products in a short time and in light of FDA's long experience with these drugs, FDA developed criteria for determining whether products approved before 1962 could be found bioequivalent on the basis of in vitro rather than in vivo data. (These criteria are codified in current § 320.52, proposed § 320.32.) If, after applying the criteria, FDA determined that a drug presented an actual or potential bioequivalence problem, it was placed on the list of bioproblem drugs, and in vivo data were required for approval. Those drugs that did not present such a problem could satisfy the bioavailability/bioequivalence requirements by meeting an appropriate in vitro standard.

There is no evidence that the policy of waiver of in vivo bioavailability for those DESI oral dosage forms that do not present an actual or potential bioequivalence problem has resulted in the approval of products that are not bioequivalent. FDA has therefore concluded that there is no reason to change the policy at this time. Proposed § 320.22(d) will thus continue to provide for a waiver of in vivo studies for DESI oral dosage forms that do not present an actual or potential bioequivalence problem. The list of bioproblem drugs currently codified in the regulation, however, is no longer necessary. The 1984 Amendments provide that FDA shall publish in the list of approved drugs a statement of whether, for each drug, in vitro or in vivo studies are required to show bioequivalence. (See section 505(j)(6)(III) of the act.) FDA satisfies this requirement through the use of therapeutic equivalence codes in the list. Thus, for each DESI product (as well as for each post-1962 product), the list provides notice of FDA's determination whether the drug presents an actual or potential bioequivalence problem, requiring an in vivo study. Consequently, FDA's implementation of the requirement in section 505(j)(6)(III) of the act makes the codified list of bioproblem drugs in § 320.22(c)(2) superfluous.

In addition, the list of bioproblem drugs, which has not been amended since 1981, does not include all pre-1962 products that FDA currently believes present an actual or potential bioequivalence problem. For example, a complete list of bioproblem drugs would also include products that are "identical, related, or similar" to those products on the list (See current § 320.22(c)(1)). In addition, since 1981, the agency has publicly identified, e.g., through **Federal Register** notices, additional drug products covered by the DESI review that the agency has determined present actual or potential bioequivalence problems, and that therefore require in vivo studies.

FDA is therefore proposing to remove the list of bioproblem drugs from existing § 320.22(c)(1), and to provide notice of in vitro or in vivo study requirements for particular DESI drugs through the list. As proposed, § 320.22(d) (formerly § 320.22(c)(1)) will continue to require FDA to waive in vivo studies for those DESI oral dosage forms that FDA determines do not present an actual or potential bioequivalence problem, but those determinations will appear in the list rather than in the regulation. If FDA determines that a DESI product previously considered a nonbioproblem drug should be reclassified as a bioproblem drug, FDA will provide notice of its tentative conclusion in a monthly supplement to the list and solicit comment. After considering any comments received, FDA will make a final determination, which will be

reflected in a subsequent monthly supplement.

In § 320.22, FDA proposes to remove paragraphs (c)(3) and (d)(1) because they are no longer relevant. FDA no longer intends to establish separate bioequivalence requirements for bioproblem drug products.

In proposed § 320.22(e) (formerly § 320.22(d)), FDA proposes to revise paragraph (4) to clarify that the differences in color, flavor, or preservative could not affect the bioavailability of the reformulated product.

In proposed § 320.22(e) (formerly § 320.22(d)), FDA proposes to remove paragraph (d)(5). The agency has no evidence to show that in vitro data alone are regularly sufficient to assure bioequivalence. In vitro testing can be used for drugs where there is a known in vivo/in vitro correlation, and has been used for pre-1962 drugs not suspected of having, or not likely to have, a bioavailability problem. For all other drug products, an in vivo bioequivalence study on the product is required to support at least one strength of the product. Notice of FDA's determination whether in vivo or in vitro studies are required to show bioequivalence is published in the list.

In proposed § 320.22(f), FDA proposes to modify the provision to clarify that deferral of a requirement for the submission of evidence of in vivo bioavailability is applicable only to full new drug applications. Under the 1984 Amendments, there is no authority to defer a showing of bioequivalence for abbreviated new drug applications.

In § 320.22, FDA proposes to add new paragraph (g) to state that FDA, for good cause, may require evidence of in vivo bioavailability for any drug product if the agency determines that any difference between a proposed drug product and a listed drug may affect the bioavailabilty of the proposed drug product. For example, the generic applicant may use a manufacturing process (including a formulation change) different from that used by the manufacturer of the listed drug, a difference that may affect the proposed product's bioavailability.

In § 320.23, FDA proposes to revise the provision to refer to the statutory standard for bioequivalence.

In § 320.24, FDA proposes to state the methods that may be used to meet an in vivo or in vitro testing requirement.

In § 320.30, FDA proposes to revise the provisions to apply both to inquiries about bioavailability and bioequivalence requirements.

In § 320.31, FDA proposes to clarify when an "Investigational New Drug Application" is required for an in vivo bioavailability or bioequivalence study.

Because the 1984 Amendments impose a bioequivalence requirement on all drug products that are the subject of ANDA's, FDA no longer intends to establish separate bioequivalence requirements for bioproblem drug products. Therefore, FDA proposes to amend its regulations in 21 CFR Part 320 under Subpart C by removing the subpart heading and those regulations that apply to establishing a bioequivalence requirement, and to revise the remaining regulations to delete any reference to establishing a bioequivalence requirement. The agency proposes to retain, move to Subpart B, and redesignate § 320.52 (proposed § 320.32) *Criteria and evidence to assess actual or potential bioequivalence problems,* § 320.55 (proposed § 320.33) *Requirements for batch testing and certification by the Food and Drug Administration,* § 320.56 (proposed § 320.34) *Requirements for in vitro testing of each batch,* and § 320.62 (proposed § 320.35) *Requirements for maintenance of records of bioequivalence testing.* In addition, elsewhere in this issue of the **Federal Register**, FDA is withdrawing 11 proposed rules that would have established bioequivalence requirements for certain drug products listed under existing § 320.22(c).

VII. Economic Assessment

The agency has considered the economic impact of this rule, and the relationship of the requirements in this rule with Pub. L. 98–417 The provisions in Title I of Pub. L. 98–417 that eliminated unnecessary regulatory barriers for duplicate products have demonstrated a capacity to achieve their intended economic consequences. Generic competition has already commenced on many important post-1962 drugs. Recent public reports of generic drug sales estimate their market share at nearly 25 percent of total prescription drug sales. At least half of these generic sales may be post-1962 drugs that would not have benefited from the price savings of multisource competition without enactment of Pub. L. 98–417 Thus, this increased competition is already saving consumers hundreds of millions of dollars per year. The agency concludes that these impacts are directly attributable to the statute. This rule will not affect the pace or magnitude of these already evident economic impacts. The procedures and interpretations provided by the rule will clarify and facilitate implementation of Title I, but the rule by itself does not create a significant economic impact.

Thus, the agency concludes that this rule is not a "major rule" as defined by Executive Order 12291 and does not require a regulatory impact analysis. Similarly, the agency certifies that this rule will not have a significant economic impact on a substantial number of small entities, and therefore, does not require a regulatory flexibility analysis under the Regulatory Flexibility Act of 1980 (Pub. L. 96–354).

VIII. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(8) that this proposed 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.

IX. Paperwork Reduction Act of 1980

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

Title: Abbreviated New Drug Application Regulations.

Description: The information requirements contained in the proposed rule would collect information from persons who must obtain FDA approval prior to marketing generic copies of previously approved drugs. These persons must submit information in the form of applications, notices, and certifications. FDA will use the information submitted to determine whether the proposed generic drug is eligible for consideration, under what provisions an application would be considered, and whether the proposed drug is identical to the pioneer drug it purports to copy.

Description of Respondents: Businesses.

ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDEN

Section	Annual number of respondents	Annual frequency	Average burden per response	Annual burden hours
314.50(g)	1	1	1 hour	1
314.50(i)	8	1	2 hours	16
314.50(j)	50	1	2 hours	100
314.52	30	1	8 hours	240
314.53	200	1	1 hour	200
314.54	10	1	80 hours	800
314.80, 310.305	40	1	8 hours	320
314.81	700	1	10 minutes	119
314.93	82	1	10 hours	820
314.94	850	1	160 hours	136,000
314.95	30	1	16 hours	480
314.107	10	1	8 hours	80
314.110	10	1	40 hours	400
314.122, 314.161	1	1	10 hours	10
Total				139,586

The agency has submitted a copy of this proposed rule to OMB for its review of these information collections. Interested persons are requested to send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to, FDA's Dockets Management Branch (address above), and to the Office of Information and Regulatory Affairs, OMB, Rm. 3208, New Executive Office Bldg., Washington, DC 20503, Attn: Desk Officer for FDA.

X. Request for Comments

Interested persons may, on or before October 10, 1989, submit to the Dockets Management Branch (address above) written comments regarding this proposal. 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 10

Administrative practice and procedure, News media.

21 CFR Part 310

Administrative practice and procedure, Drugs, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 314

Administrative practice and procedure, Drugs, Reporting and recordkeeping requirements.

21 CFR Part 320

Drugs, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner, it is proposed that Parts 10, 310, 314, and 320 be amended as follows:

PART 10—ADMINISTRATIVE PRACTICES AND PROCEDURES

1. The authority citation for 21 CFR Part 10 is revised to read as follows:

Authority: Sec. 201 *et seq.*, Pub. L. 717 52 Stat. 1040 as amended (21 U.S.C. 321 *et seq.*); sec. 1 *et seq.*, Pub. L. 410, 58 Stat. 682 as amended (42 U.S.C. 201 *et seq.*); sec. 4, Pub. L. 91-513, 84 Stat. 1241 (42 U.S.C. 257a); sec. 301 *et seq.*, Pub. L. 91-513, 84 Stat. 1253 (21 U.S.C. 821 *et seq.*); sec. 409(b), Pub. L. 242, 81 Stat. 600 (21 U.S.C. 679(b)); sec. 24(b), Pub. L. 85-172, 82 Stat. 807 (21 U.S.C. 467f(b)); sec. 2 *et seq.*, Pub. L. 91-597 84 Stat. 1620 (21 U.S.C. 1031 *et seq.*); secs. 1-9, Pub. L. 625, 44 Stat. 1101-1103 as amended (21 U.S.C. 141-149); secs. 1-10, Ch. 358, 29 Stat. 604-607 as amended (21 U.S.C. 41-50); sec. 2 *et seq.*, Pub. L. 783, 44 Stat. 1406 as amended (15 U.S.C. 401 *et seq.*); sec. 1 *et seq.*, Pub. L. 89-755, 80 Stat. 1296 as amended (15 U.S.C. 1451 *et seq.*); sec. 101, Pub. L. 98-417 98 Stat. 1585 (21 U.S.C. 355).

2. Section 10.30 is amended by revising the introductory text of paragraph (e)(2) and by adding a new paragraph (e)(4) to read as follows:

§ 10.30 Citizen petition.

(e)

(2) Except as provided in paragraph (e)(4) of this section, the Commissioner shall furnish a response to each petitioner within 180 days of receipt of the petition. The response will either:

(4) The Commissioner shall furnish a response to each petitioner within 90 days of receipt of a petition filed under section 505(j)(2)(C) of the act. The response will either approve or disapprove the petition. Agency action on a petition shall be governed by § 314.93 of this chapter.

3. Section 10.45 is amended by revising the introductory text of paragraph (d) to read as follows:

§ 10.45 Court review of final administrative action; exhaustion of administrative remedies.

(d) The Commissioner's final decision constitutes final agency action (reviewable in the courts under 5 U.S.C. 701 et seq. and, where appropriate, 28 U.S.C. 2201) on a petition submitted under § 10.25(a), on a petition for reconsideration submitted under § 10.33, on a petition for stay of action submitted under § 10.35, on an advisory opinion issued under § 10.85, on a guideline issued under § 10.90, on a matter involving administrative action which is the subject of an opportunity for a hearing under § 16.1(b) of this chapter, or on the issuance of a final regulation published in accordance with § 10.40, except that the agency's response to a petition filed under section 505(j)(2)(C) of the act and § 314.93 of this chapter will not constitute final agency action until any petition for reconsideration submitted by the petitioner is acted on by the Commissioner.

PART 310—NEW DRUGS

4. The authority citation for 21 CFR Part 310 continues to read as follows:

Authority: Secs. 501, 502, 503, 505, 701, 704, 705, 52 Stat. 1049-1053 as amended, 52 Stat.

1055–1056 as amended, 67 Stat. 477 as amended, 52 Stat. 1057–1058 (21 U.S.C. 351, 352, 353, 355, 371, 374, 375); 5 U.S.C. 553; 21 CFR 5.10 and 5.11.

5. Section 310.305 is amended by revising paragraph (a), by removing the word "significant" in paragraph (b)(2), by revising the first sentence in paragraph (c)(4) and by removing the words "(Drug Experience Report)" and replacing them with "(Adverse Reaction Report)" in paragraph (d)(1), to read as follows:

§ 310.305 Records and reports concerning adverse drug experiences on marketed prescription drugs for human use without approved new drug applications.

(a) *Scope.* FDA is requiring manufacturers, packers, and distributors of marketed prescription drug products that are not the subject of an approved new drug or abbreviated new drug application to establish and maintain records and make reports to FDA of:

(1) All serious, unexpected adverse drug experiences associated with the use of their drug products,

(2) Any significant increase in the frequency of a serious, expected adverse drug experience, and

(3) Any significant increase in the frequency of therapeutic failure (lack of effect).

These reports will enable FDA to protect the public health by helping to monitor the safety of marketed drug products and to assure that these drug products are not adulterated or misbranded.

(c)

(4) Each person identified in paragraph (c)(1) of this section shall review periodically (at least once each year) the frequency of reports of adverse drug experiences that are both serious and expected and reports of therapeutic failure (lack of effect), received or otherwise obtained, and report any significant increase in frequency as soon as possible but in any case within 15 working days of determining that a significant increase in frequency exists.

PART 314—APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG OR AN ANTIBIOTIC DRUG

6. Part 314 is amended by redesignating existing Subparts C, D, E, and F as Subparts D, E, F and G, respectively, by adding new Subpart C, consisting of §§ 314.92 through 314.99, and by revising the table of contents and the authority citation to read as follows:

Subpart A—General Provisions

Sec.
314.1 Scope of this part.
314.2 Purpose.
314.3 Definitions.

Subpart B—Applications

314.50 Content and format of an application.
314.52 Notice of certification of invalidity or noninfringement of a patent.
314.53 Submission of patent information.
314.54 Procedure for submission of an application requiring investigations for approval of a new indication for, or other change from, a listed drug.
314.60 Amendments to an unapproved application.
314.65 Withdrawal by the applicant of an unapproved application.
314.70 Supplements and other changes to an approved application.
314.71 Procedures for submission of a supplement to an approved application.
314.72 Change in ownership of an application.
314.80 Postmarketing reporting of adverse drug experiences.
314.81 Other postmarketing reports.
314.90 Waivers.

Subpart C—Abbreviated Applications

314.92 Drug products for which abbreviated applications may be submitted.
314.93 Petition to request a change from a listed drug.
314.94 Content and format of an abbreviated application.
314.95 Notice of certification of invalidity or noninfringement of a patent.
314.96 Amendments to an unapproved abbreviated application.
314.97 Supplements and other changes to an approved abbreviated application.
314.98 Postmarketing reports.
314.99 Other responsibilities of an applicant of an abbreviated application.

Subpart D—FDA Action on Applications and Abbreviated Applications

314.100 Time frames for reviewing applications and abbreviated applications.
314.101 Filing an application and an abbreviated antibiotic application and receiving an abbreviated new drug application.
314.102 Communications between FDA and applicants.
314.103 Dispute resolution.
314.104 Drugs with potential for abuse.
314.105 Approval of an application and an abbreviated application.
314.106 Foreign data.
314.107 Effective date of approval of a 505(b)(2) application or abbreviated new drug application under section 505(j) of the act.
314.108 New drug product exclusivity.
314.110 Approvable letter to the applicant.
314.120 Not approvable letter to the applicant.
314.122 Submitting an application for, or a 505(j)(2)(C) petition that relies on, a listed drug that is no longer marketed.
314.125 Refusal to approve an application or abbreviated antibiotic application.
314.126 Adequate and well-controlled studies.
314.127 Refusal to approve an abbreviated new drug application.
314.150 Withdrawal of approval of an application or abbreviated application.
314.151 Withdrawal of approval of an abbreviated new drug application pursuant to section 505(j)(5) of the act.
314.152 Notice of withdrawal of approval of an application or abbreviated application for a new drug.
314.153 Suspension of approval of an abbreviated new drug application.
314.160 Approval of an application or abbreviated application for which approval was previously refused, suspended, or withdrawn.
314.161 Determination of reasons for voluntary withdrawal of a listed drug.
314.162 Removal of a drug product from the list.
314.170 Adulteration and misbranding of an approved drug.

Subpart E—Hearing Procedures for New Drugs

314.200 Notice of opportunity for hearing; notice of participation and request for hearing; grant or denial of hearing.
314.201 Procedure for hearings.
314.235 Judicial review.

Subpart F—Administrative Procedures for Antibiotics

314.300 Procedure for the issuance, amendment, or repeal of regulations.

Subpart G—Miscellaneous Provisions

314.410 Imports and exports of new drugs and antibiotics.
314.420 Drug master files.
314.430 Availability for public disclosure of data and information in an application or abbreviated application.
314.440 Addresses for applications and abbreviated applications.
314.445 Guidelines.

Authority: Secs. 501, 502, 503, 505, 506, 507 701, 52 Stat. 1049–1053 as amended, 1055–1056 as amended, 98 Stat. 1585, 55 Stat. 851, 59 Stat. 463 as amended (21 U.S.C. 351, 352, 353, 355, 356, 357 371); 21 CFR 5.10, 5.11.

§ 314.1 [Amended]

7 Section 314.1 *Scope of this part* is amended in paragraphs (a)(1) and (2) by adding the phrase "or abbreviated application" after the word "application"

8. Section 314.3 is amended by revising paragraph (b) to read as follows:

§ 314.3 Definitions.

(b) The following definitions of terms apply to this part:

Abbreviated application" means the application described under § 314.94, including all amendments and supplements to the application.

Abbreviated application" applies to both an abbreviated new drug

application and an abbreviated antibiotic application.

Act" means the Federal Food, Drug, and Cosmetic Act (sections 201–901, 52 Stat. 1040 et seq., as amended (21 U.S.C. 301–392)).

Applicant" means any person who submits an application or abbreviated application or an amendment or supplement to them under this part to obtain FDA approval of a new drug or an antibiotic drug and any person who owns an approved application or abbreviated application.

Application" means the application described under § 314.50, including all amendments and supplements to the application.

Approvable letter" means a written communication to an applicant from FDA stating that the agency will approve the application or abbreviated application if specific additional information or material is submitted or specific conditions are met. An approvable letter does not constitute approval of any part of an application or abbreviated application and does not permit marketing of the drug that is the subject of the application or abbreviated application.

Approval letter" means a written communication to an applicant from FDA approving an application or an abbreviated application.

"Drug product" means a finished dosage form, for example, tablet, capsule, or solution, that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients.

"Drug substance" means an active ingredient that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or any function of the human body, but does not include intermediates used in the synthesis of such ingredient.

"FDA means the Food and Drug Administration.

"Listed drug" means a new drug product that has been approved for safety and effectiveness under section 505(c) or approved under section 505(j) of the act, the approval of which has not been withdrawn or suspended under section 505(e) (1) through (5) or (j)(5) of the act, and which has not been withdrawn from sale for what FDA has determined are reasons of safety or effectiveness. Listed drug status is evidenced by the drug product's inclusion in the current edition of FDA's Approved Drug Products with Therapeutic Equivalence Evaluations" (the list) or any current supplement to the list. A drug product is deemed to be included in the list on the date of approval of the application or abbreviated application for that drug product. For a drug product that is subject to FDA's Drug Efficacy Study Implementation (DESI) program, FDA will consider the applicable DESI notice published in the **Federal Register** a listed drug until a drug product subject to the notice meets the conditions for approval of effectiveness set forth in the notice and becomes a listed drug.

"Not approvable letter" means a written communication to an applicant from FDA stating that the agency does not consider the application or abbreviated application approvable because one or more deficiencies in the application or abbreviated application preclude the agency from approving it.

"Reference listed drug" means the listed drug identified in an abbreviated new drug application or identified by FDA as the drug product upon which an applicant relies in seeking approval of its abbreviated application.

"Right of reference or use" means the authority to rely upon, and otherwise use an investigation for the purpose of obtaining approval of an application, including the ability to make available the underlying raw data from the investigation for FDA audit, if necessary.

"The list" means the current edition of FDA's publication Approved Drug Products with Therapeutic Equivalence Evaluations" and any current supplement to the publication.

"505(b)(2) application" means an application submitted under section 505(b)(1) of the act for a drug for which the investigations described in section 505(b)(1)(A) and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted.

9. Section 314.50 is amended by revising the first and fifth sentences in the introductory paragraph, paragraph (a)(2), the second sentence in paragraph (c)(1), by adding new paragraph (g)(3), by redesignating existing paragraph (h) as paragraph (k), and by adding new paragraphs (h), (i), and (j) to read as follows:

§ 314.50 Content and format of an application.

Applications and supplements to approved applications are required to be submitted in the form and contain the information, as appropriate for the particular submission, required under this section. These include an application of the type described in section 505(b)(2) of the act, an amendment, and a supplement.

(a)

(2) A statement whether the submission is an original submission, a 505(b)(2) application, a resubmission, or a supplement to an application under § 314.70.

(c) *Summary.* (1) The summary is not required for supplements under § 314.70.

(g)

(3) If an applicant who submits a new drug application under section 505(b) of the act obtains a "right of reference or use, as defined under § 314.3(b), to an investigation described in clause (A) of section 505(b)(1) of the act, the applicant shall include in its application a written statement signed by the owner of the data from each such investigation that the applicant may rely on in support of the approval of its application, and provide FDA access to, the underlying raw data that provide the basis for the report of the investigation submitted in its application.

(h) *Patent information.* The application is required to contain the patent information described under § 314.53.

(i) *Patent certification*—(1) *Contents.* A 505(b)(2) application is required to contain the following:

(i) *Patents claiming drug, drug product, or method of use.* (*a*) Except as provided in paragraph (i)(2) of this section, a certification with respect to each patent issued by the United States Office of Patent and Trademark that, in the opinion of the applicant and to the best of its knowledge, claims the drug or drugs on which investigations that are relied upon by the applicant for approval of its application were conducted or that claims an approved use for such drug or drugs and for which information is required to be filed under section 505 (b) and (c) of the act and § 314.53. For each such patent, the applicant shall provide the patent number and certify, in its opinion and to the best of its knowledge, one of the following circumstances:

(*1*) That the patent information has not been submitted to FDA. The applicant shall entitle such a certification "Paragraph I Certification"·

(*2*) That the patent has expired. The applicant shall entitle such a certification "Paragraph II Certification"·

(*3*) The date on which the patent will expire. The applicant shall entitle such a

certification "Paragraph III Certification"· or

(*4*) That the patent is invalid or will not be infringed by the manufacture, use, or sale of the drug product for which the application is submitted. The applicant shall entitle such a certification "Paragraph IV Certification. This certification shall be submitted in the following form:

I, (*name of applicant*), certify that Patent No. (*is invalid or will not be infringed by the manufacture, use, or sale of*) (*name of proposed drug product*) for which this application is submitted.

The certification shall be accompanied by a statement that the applicant will comply with the requirements under § 314.52(a) with respect to providing a notice to each owner of the patent or their representatives and to the holder of the approved application for the drug product which is claimed by the patent or a use of which is claimed by the patent and with the requirements under § 314.52(c) with respect to the content of the notice.

(*b*) If the drug on which investigations that are relied upon by the applicant were conducted is itself a licensed generic drug of a patented drug first approved under section 505(b) of the act, the appropriate patent certification under this section with respect to each patent that claims the first-approved patented drug or that claims an approved use for such drug.

(ii) *No relevant patents.* If, in the opinion of the applicant and to the best of its knowledge, there are no patents described in paragraph (i)(1)(i) of this section, a certification in the following form:

In the opinion and to the best knowledge of (*name of applicant*), there are no patents that claim the drug or drugs on which investigations that are relied upon in this application were conducted or that claim a use of such drug or drugs.

(iii) *Method of use patent.* (*a*) If information that is submitted under section 505 (b) or (c) of the act and § 314.53 is for a method of use patent, and the labeling for the drug product for which the applicant is seeking approval does not include any indications that are covered by the use patent, a statement explaining that the method of use patent does not claim any of the proposed indications.

(*b*) If the labeling of the drug product for which the applicant is seeking approval includes an indication that, according to the patent information submitted under section 505 (b) or (c) of the act and § 314.53 or in the opinion of the applicant, is claimed by a use patent, the applicant shall submit an applicable certification under paragraph (i)(1)(i) of this section.

(2) *Method of manufacturing patent.* An applicant is not required to make a certification with respect to any patent that claims only a method of manufacturing the drug product for which the applicant is seeking approval.

(3) *Licensing agreements.* If a 505(b)(2) application is for a drug or method of using a drug claimed by a patent and the applicant has a licensing agreement with the patent owner, the applicant shall submit a certification under paragraph (i)(1)(i)(*a*)(*4*) of this section ("Paragraph IV Certification") as to that patent and a statement that it has been granted a patent license. If the patent owner consents to an immediate effective date upon approval of the 505(b)(2) application, the application shall contain a written statement from the patent owner that it has a licensing agreement with the applicant and that it consents to an immediate effective date.

(4) *Late submission of patent information.* If a patent described in paragraph (i)(1)(i)(*a*) of this section is issued and the holder of the approved application for the patented drug does not submit the required information on the patent within 30 days of issuance of the patent, an applicant who submitted a 505(b)(2) application that before the submission of the patent information contained an appropriate patent certification is not required to submit an amended certification. An applicant whose 505(b)(2) application is filed after a late submission of patent information or whose 505(b)(2) application was previously filed but did not contain an appropriate patent certification at the time of the patent submission shall submit a certification under paragraph (i)(1)(i) or (ii) or a statement under paragraph (i)(1)(iii) of this section as to that patent.

(5) *Disputed patent information.* If an applicant disputes the accuracy or relevance of patent information submitted to FDA, the applicant may seek a confirmation of the correctness of the patent information in accordance with the procedures under § 314.53(f). Unless the patent information is withdrawn or changed, the applicant must submit an appropriate certification for each relevant patent.

(6) *Amended certifications.* A certification submitted under paragraphs (i)(1)(i) through (iii) of this section may be amended at any time before the effective date of the approval of the application. An applicant shall submit an amended certification as an amendment to a pending application or by letter to an approved application. Once an amendment or letter for the change in certification has been submitted, the application will no longer be considered to be one containing the prior certification.

(i) *After finding of infringement.* An applicant who has submitted a certification under paragraph (i)(1)(i)(*a*)(*4*) of this section and is sued for patent infringement within 45 days of the receipt of notice sent under § 314.52, shall amend the certification if a final judgment in the action is entered finding the patent to be infringed. In the amended certification, the applicant shall certify under paragraph (i)(1)(i)(*a*)(*3*) of this section that the patent will expire on a specific date.

(ii) *After removal of a patent from the list.* If a patent is removed from the list for any reason other than because the patent has been declared invalid in a lawsuit brought within 45 days of a notice issued under § 314.52, after one or more applicants have made certifications under paragraph (i)(1)(i)(*a*)(*4*) of this section on that patent, any applicant with a pending application or delayed effective date who has made such a certification shall amend the certification. In the amended certification, the applicant shall certify under paragraph (i)(1)(ii) of this section, if applicable, that no patents described in paragraph (i)(1)(i) of this section claim the drug. If other relevant patents claim the drug, the applicant shall instead submit a request to withdraw the certification under paragraph (i)(1)(i)(*a*)(*4*) of this section.

(iii) *Other amendments.* (*a*) Except as provided in paragraphs (i)(4) and (i)(6)(iii)(*b*) of this section, an applicant shall amend a submitted certification if, at any time before the effective date of the approval of the application, the applicant learns that the submitted certification is no longer accurate.

(*b*) An applicant is not required to amend a submitted certification when information on an otherwise applicable patent is submitted after the 505(b)(2) application is approved, whether or not the approval of the abbreviated application is effective.

(j) *Claimed exclusivity.* A new drug product, upon approval, may be entitled to a period of marketing exclusivity under the provisions of § 314.108. If an applicant believes its drug product is entitled to a period of exclusivity, it shall submit to the new drug application prior to approval the following information:

(1) A statement that the applicant is claiming exclusivity.

(2) A reference to the appropriate paragraph under § 314.108 that supports its claim.

(3) If the applicant claims exclusivity under § 314.108(b)(2), information to show that no drug has previously been approved under section 505(b) of the act containing any active moiety in the drug for which the applicant is seeking approval.

(4) If the applicant claims exclusivity under § 314.108(b)(4) or (5), the following information to show that the clinical investigations in its application are "new clinical investigations, "essential to approval of the application or supplement, and were "conducted or sponsored by the applicant".

(i) "*New clinical investigations.* A certification that to the best of the applicant's knowledge the clinical investigations included in the application meet the definitions of "new" and "clinical investigations" set forth in § 314.108(a).

(ii) "*Essential to approval.*" A list of all published studies or publicly available reports of clinical investigations known to the applicant through a literature search that are relevant to the conditions for which the applicant is seeking approval, a certification that the applicant has thoroughly searched the scientific literature and, to the best of the applicant's knowledge, the list is complete and accurate and, in the applicant's opinion, such published studies or publicly available reports do not provide a sufficient basis for the approval of the conditions for which the applicant is seeking approval without reference to the new clinical investigation(s) in the application, and an explanation as to why the studies or reports are insufficient.

(iii) "*Conducted or sponsored by.* If the applicant was the sponsor named in the Form FDA-1571 for an investigational new drug (IND) under which the new clinical investigation(s) that is essential to the approval of its application was conducted, identification of the IND by number. If the applicant was not the sponsor of the IND under which the clinical investigation(s) was conducted, a certification that the applicant or its predecessor in interest provided substantial support for the clinical investigation(s) that is essential to the approval of its application, and information supporting the certification.

10. New §§ 314.52, 314.53, and 314.54 are added to Subpart B to read as follows:

§ 314.52 Notice of certification of invalidity or noninfringement of a patent.

(a) For each patent which claims the drug or drugs on which investigations that are relied upon by the applicant for approval of its application were conducted or which claims a use for such drug or drugs and which the applicant certifies under § 314.50(i)(1)(i)(*a*)(*4*) that a patent is invalid or will not be infringed, the applicant shall send notice of such certification by registered or certified mail, return receipt requested to each of the following persons:

(1) Each owner of the patent that is the subject of the certification or the representative designated by the owner to receive the notice. The name and address of the patent owner or its representative may be obtained from the United States Patent and Trademark Office; and

(2) The holder of the approved application under section 505(b) of the act for each drug product which is claimed by the patent or a use of which is claimed by the patent and for which the applicant is seeking approval, or, if the application holder does not reside or maintain a place of business within the United States, the application holder's attorney, agent, or other authorized official. The name and address of the application holder or its attorney, agent, or authorized official may be obtained from the Division of Drug Information Resources (HFD-80), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857

(3) This paragraph does not apply to a use patent that claims no uses for which the applicant is seeking approval.

(b) The applicant shall send the notice required by paragraph (a) of this section when it receives from FDA an acknowledgment letter stating that its application has been filed. At the same time, the applicant shall amend its application to include a statement certifying that the notice has been provided to each person identified under paragraph (a) of this section and that the notice met the content requirement under paragraph (c) of this section.

(c) *Content of a notice.* In the notice, the applicant shall cite section 505(b)(3)(B) of the act and shall include, but not be limited to, the following information:

(1) A statement that a 505(b)(2) application submitted by the applicant has been filed by FDA.

(2) The application number.

(3) The established name, if any, as defined in section 502(e)(3) of the act, of the proposed drug product.

(4) The active ingredient, strength, and dosage form of the proposed drug product.

(5) The patent number and expiration date, as submitted to the agency or as known to the applicant, of each patent alleged to be invalid or not infringed.

(6) A detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed. The applicant shall include in the detailed statement:

(i) For each claim of a patent alleged not to be infringed, an explanation of why the claim is not infringed.

(ii) For each claim of a patent alleged to be invalid, an explanation of the grounds supporting the allegation, including all statutory bases, affirmative defenses, reasoning, and evidence supporting the allegation, citing any relevant case precedent upon which the allegation is based, providing a copy of any patent or publication which is alleged to invalidate such claim and the reasons supporting such allegation.

(iii) For formulation or composition patents, a description of a mechanism through which the applicant agrees to make the formulation or composition of the proposed drug product known to the patent owner or to a designated intermediary who will act as a referee.

(7) If the applicant does not reside or have a place of business in the United States, the name and address of an agent in the United States authorized to accept service of process for the applicant.

(d) *Amendment to an application.* If an application is amended to include the certification described in § 314.50(i), the applicant shall send the notice required by paragraph (a) of this section at the same time that the amendment to the application is submitted to FDA.

(e) *Documentation of receipt of notice.* The applicant shall amend its application to document receipt of the notice required under paragraph (a) of this section by each person provided the notice. The applicant shall include a copy of the return receipt or other similar evidence of the date the notification was received. FDA will accept as adequate documentation of the date of receipt a return receipt or a letter acknowledging receipt by the person provided the notice. An applicant may rely on another form of documentation only if FDA has agreed to such documentation in advance. A copy of the notice itself need not be submitted to the agency.

(f) If the above requirements are met, the agency will presume the notice to be complete and sufficient, and it will count the day following the date of receipt of the notice by the patent owner or its representative or by the approved application holder if the holder is an exclusive patent licensee as the first day

of the 45-day period provided for in section 505(c)(3)(C) of the act.

§ 314.53 Submission of patent information.

(a) *Who must submit patent information.* This section applies to any applicant who submits to FDA a new drug application or an amendment to it under section 505(b) of the act and § 314.50 or a supplement to an approved application under § 314.70, except as provided in paragraph (d)(2) of this section.

(b) *Patents for which information must be submitted.* An applicant described in paragraph (a) of this section shall submit information on each patent that claims the drug or a method of using the drug that is the subject of the new drug application or amendment or supplement to it and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product. For purposes of this part, such patents consist of drug (ingredient) patents, drug product (formulation and composition) patents, and method of use patents. Process patents are not covered by this section and information on process patents may not be submitted to FDA. For patents that claim a drug or drug product, the applicant shall submit information only on those patents that claim an approved drug product or a drug product for which the applicant has submitted an application to obtain FDA approval. For patents that claim a method of use, the applicant shall submit information only on those patents that claim approved indications or other conditions of use or that claim indications or other conditions of use for which the applicant is seeking approval in an application.

(c) *Reporting requirements.* (1) *General requirements.* An applicant described in paragraph (a) of this section shall submit the following information for each patent described in paragraph (b) of this section:

(i) Patent number and the date on which the patent will expire.

(ii) Type of patent, i.e., drug, drug product, or method of use.

(iii) Name of the patent owner.

(iv) If the patent owner or applicant does not reside or have a place of business within the United States, the name of an agent (representative) of the patent owner or applicant who resides or maintains a place of business within the United States authorized to receive notice of patent certification under sections 505(b)(3) and 505(j)(2)(B) of the act and §§ 314.52 and 314.95.

(2) *Formulation or composition patents.* (i) *Original certification.* For each formulation or composition patent, in addition to the patent information described in paragraph (c)(1) of this section the applicant shall submit the following certification:

The undersigned certifies that the drug and the formulation or composition of *(name of drug product)* is claimed by Patent No. _____. This product is *(currently approved under section 505 of the Federal Food, Drug, and Cosmetic Act) [or] (the subject of this application for which approval is being sought).*

(ii) *Amendment of patent information upon approval.* Within 30 days after the date of approval of its application, if the application contained a certification required under paragraph (c)(2)(i) of this section, the applicant shall by letter amend the certification to identify each patent that claims the formulation and composition that has been approved.

(3) *Method of use patents.*—(i) *Original certification.* For a patent that claims a method of using the drug product, the patent information described in paragraph (c)(1) of this section shall be accompanied by the following certification that identifies each relevant patent that claims indications or other conditions of use that are approved or are the subject of the application for which approval is being sought:

The undersigned certifies that Patent No. _____ covers the use of *(name of drug product)* that is *(approved) [or] (the subject of this application for which approval is being sought):*

_____

(ii) *Amendment of patent information upon approval.* Within 30 days after the date of approval of its application, if the application contained a certification required under paragraph (c)(3)(i) of this section, the applicant shall by letter amend the certification to identify the specific indications or other conditions of use that have been approved and each patent that claims the approved indications or other conditions of use.

(4) *No relevant patents.* If the applicant believes that there are no patents which claim the drug or the drug product or which claim a method of using the drug product and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product, it shall so certify.

(5) *Authorized signature.* The certifications required by this section shall be signed by the applicant or patent owner, or the applicant's or patent owner's attorney, agent (representative), or other authorized official.

(d) *When and where to submit patent information.*—(1) *Original application.* An applicant shall submit with its original application submitted under this part, including an application described in section 505(b)(2) of the act, the information described in paragraph (c) of this section on each drug (ingredient), drug product (formulation and composition), and method of use patent issued before the application is filed with FDA and for which patent information is required to be submitted under this section. If a patent is issued after the application is filed with FDA but before the application is approved, the applicant shall submit the required patent information in an amendment to the application under § 314.60.

(2) *Supplements.* (i) If a patent is issued for a drug, drug product, or method of use after an application is approved, the applicant shall submit to FDA the required patent information within 30 days of the date of issuance of the patent.

(ii) An applicant shall submit patent information required under paragraph (c) of this section for a patent that claims the product or method of using the product for which approval is sought in any of the following supplements:

(A) To change the formulation;

(B) To add a new indication or other condition of use, including a change in route of administration;

(C) To change the strength;

(D) To make any other patented change.

(iii) If the applicant submits a supplement for one of the changes listed under paragraph (d)(2)(ii) of this section and existing patents for which information has already been submitted to FDA claim the changed product, the applicant shall submit a certification with the supplement identifying the patents that claim the changed product.

(iv) If the applicant submits a supplement for one of the changes listed under paragraph (d)(2)(ii) of this section and no patents, including previously submitted patents, claim the changed product, it shall so certify.

(v) The applicant shall comply with the requirements for amendment of formulation or composition and method of use patent information under paragraphs (c)(2)(ii) and (3)(ii) of this section.

(3) The applicant shall submit two copies of each submission of patent information, an archival copy and a copy for the chemistry, manufacturing and controls section of the review copy, to the Central Document Room, Center

for Drug Evaluation and Research, Food and Drug Administration, Park Bldg. (Rm. 214), 12420 Parklawn Dr., Rockville, MD 20857 The applicant shall submit the patent information by letter separate from, but at the same time as, submission of the supplement.

(4) Patent information shall be considered to be submitted to FDA as of the date the information is received by the Central Document Room.

(5) Each submission of patent information, except information submitted with an original application, and its mailing cover shall bear prominent identification as to its contents, i.e., "Patent Information, or, if submitted after approval of an application, "Time Sensitive Patent Information.

(e) *Public disclosure of patent information.* FDA will publish in the list the patent number and expiration date of each patent that is required to be, and is, submitted to FDA by an applicant, and for each use patent, the approved indications or other conditions of use covered by a patent and any unapproved indications or condition of use to which the applicant certified. FDA will publish such patent information upon approval of the application, or, if the patent information is submitted by the applicant after approval of an application as provided under paragraph (d)(2) of this section, as soon as possible after the submission to the agency of the patent information. Patent information submitted by the last working day of a month will be published in that month's supplement to the list. Patent information received by the agency between monthly publication of supplements to the list will be placed on public display in FDA's Freedom of Information Staff. A request for copies of the file shall be sent in writing to the Freedom of Information Staff (HFI-35), Food and Drug Administration, Rm. 12A-16, 5600 Fishers Lane, Rockville, MD 20857

(f) *Correction of patent information errors.* If any person disputes the accuracy or relevance of patent information submitted to the agency under this section and published by FDA in the list, or believes that an applicant has failed to submit required patent information, that person must first notify the agency in writing stating the grounds for the disagreement. Such notification should be directed to the Office of Drug Standards (HFD-200), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. The agency will then request of the applicable new drug application holder that the correctness of the patent information or omission of patent information be confirmed. Unless the application holder withdraws or amends its patent information in response to FDA's request, the agency will not change the patent information in the list. If the new drug application holder does not change the patent information submitted to FDA, a 505(b)(2) application or an abbreviated new drug application under section 505(j) of the act submitted for a drug that is claimed by a patent for which information has been submitted must, despite any disagreement as to the correctness of the patent information, contain an appropriate certification for each listed patent.

§ 314.54 Procedure for submission of an application requiring investigations for approval of a new indication for, or other change from, a listed drug.

(a) The act does not permit approval of an abbreviated new drug application for a new indication, nor does it permit approval of other changes in a listed drug if investigations, other than bioavailability or bioequivalence studies, are essential to the approval of the change. Any person seeking approval of a drug product that represents a modification of a listed drug (e.g., a new indication or new dosage form) and for which investigations, other than bioavailability or bioequivalence studies, are essential to the approval of the change may, except as provided in paragraph (b), submit a 505(b)(2) application. This application need contain only that information needed to support the modification(s) of the listed drug.

(1) The applicant shall submit a complete archival copy of the application that contains the following:

(i) The information required under § 314.50(a), (b), (c), (d)(1) and (3), (e), and (g).

(ii) The information required under § 314.50(d)(2), (4) (if an anti-infective drug), (5), and (6), and (f) as needed to support the safety and effectiveness of the drug product.

(iii) Identification of the listed drug for which FDA has made a finding of safety and effectiveness and on which finding the applicant relies in seeking approval of its proposed drug product by established name, if any, proprietary name, dosage form, strength, route of administration, name of listed drug's application holder, and listed drug's approved application number.

(iv) If the applicant is seeking approval only for a new indication and not for the indications approved for the listed drug on which the applicant relies, a certification so stating.

(v) Any patent information required under § 314.53 with respect to any patent which claims the drug for which approval is sought or a method of using such drug and to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product.

(vi) Any patent certification or statement required under § 314.50(i) with respect to any relevant patents that claim the listed drug or that claim any other drugs on which investigations relied on by the applicant for approval of the application were conducted, or that claim a use for the listed or other drug.

(vii) If the applicant believes the change for which it is seeking approval is entitled to a period of exclusivity, the information required under § 314.50(j).

(2) The applicant shall submit a review copy that contains the technical sections described in § 314.50(d)(1) and (3), and the technical sections described in § 314.50(d)(2), (4), (5), and (6), and (f) when needed to support the modification. Each of the technical sections in the review copy is required to be separately bound with a copy of the information required under § 314.50(a), (b), and (c) and a copy of the proposed labeling.

(3) The information required by § 314.50(d)(2), (4) (if an anti-infective drug), (5), (6), and (f) for the listed drug on which the applicant relies shall be satisfied by reference to the listed drug under paragraph (a)(1)(iii) of this section.

(b) An application may not be submitted under this section for a drug product whose only difference from the reference listed drug is that the extent to which its active ingredient(s) is absorbed or is otherwise made available to the site of action is less than that of the reference listed drug.

§ 314.55 [Removed]

11. Section 314.55 *Abbreviated application* is removed.

§ 314.56 [Removed]

12. Section 314.56 *Drug products for which abbreviated applications are suitable* is removed.

12a. Section 314.60 is amended by redesignating the existing paragraph as paragraph (a) and by revising the first sentence, and by adding a new paragraph (b) to read as follows:

§ 314.60 Amendments to an unapproved application.

(a) Except as provided in paragraph (b) of this section, the applicant may submit an amendment to an application that is filed under § 314.100, but not yet approved.

(b)(1) An unapproved application may not be amended if all of the following conditions apply:

(i) The unapproved application is for a drug for which a previous application has been approved and granted a period of exclusivity under § 314.108(b)(2) that has not expired;

(ii) The applicant seeks to amend the unapproved application to include a published report of an investigation that was conducted or sponsored by the applicant entitled to exclusivity for the drug;

(iii) The applicant has not obtained a right of reference to the investigation described in paragraph (b)(1)(ii) of this section; and

(iv) The report of the investigation described in paragraph (b)(1)(ii) of this section would be essential to the approval of the unapproved application.

(2) The submission of an amendment described in paragraph (b)(1) will cause the unapproved application to be deemed to be withdrawn by the applicant under § 314.65 on the date of receipt by FDA of the amendment. The amendment will be considered a resubmission of the application, which may not be accepted except as provided under § 314.108(b)(2).

13. Section 314.70 is amended by adding new paragraphs (e) and (f) to read as follows:

§ 314.70 Supplements and other changes to an approved application.

(e) *Claimed exclusivity.* If an applicant claims exclusivity under § 314.108 upon approval of a supplemental application for a change to its previously approved drug product, the applicant shall include with its supplemental application the information required under § 314.50(j).

(f) *Patent information.* The applicant shall comply with the patent information requirements under § 314.53(d)(2).

14. Section 314.71 is amended in paragraph (b) by revising the first sentence to read as follows:

§ 314.71 Procedures for submission of a supplement to an approved application.

(b) All procedures and actions that apply to an application under § 314.50 also apply to supplements, except that the information required in the supplement is limited to that needed to support the change.

15. Section 314.80 is amended by removing the word "significant" under Adverse drug experience" in paragraph (a), by revising paragraph (b), the first sentence in paragraph (c)(1)(ii), and the last sentence in paragraph (d)(1) to read as follows:

§ 314.80 Postmarketing reporting of adverse drug experiences.

(b) *Review of adverse drug experiences.* Each applicant having an approved application under § 314.50 or in the case of a 505(b)(2) application, an effective approved application under § 314.107 shall promptly review all adverse drug experience information obtained or otherwise received by the applicant from any source, foreign or domestic, including information derived from commercial marketing experience, postmarketing clinical investigations, postmarketing epidemiological/surveillance studies, reports in the scientific literature, and unpublished scientific papers.

(c)

(1)

(ii) The applicant shall review periodically (at least as often as the periodic reporting cycle) the frequency of reports of adverse drug experiences that are both serious and expected and reports of therapeutic failure (lack of effect), regardless of source, and report any significant increase in frequency as soon as possible but in any case within 15 working days of determining that a significant increase in frequency exists.

(d) *Scientific literature.* (1) The 15-day reporting requirements in paragraph (c)(1)(ii) of this section (i.e., a significant increase in frequency of a serious, expected adverse drug experience or of a therapeutic failure) apply only to reports found in scientific and medical journals either as the result of a formal clinical trial, or from epidemiological studies or analyses of experience in a monitored series of patients.

16. Section 314.81 is amended in paragraph (a) by removing "505(j)" and replacing it with "505(k)" and by adding new paragraph (b)(3)(iii) to read as follows:

§ 314.81 Other postmarketing reports.

(b)

(3)

(iii) *Withdrawal of approved drug product from sale.*

(*a*) The applicant shall submit on Form FDA 2657 (Drug Product Listing), within 15 working days of the withdrawal from sale of a drug product, the following information:

(*1*) The National Drug Code (NDC) number.

(*2*) The identity of the drug product by established name and by proprietary name.

(*3*) The new drug application or abbreviated application number.

(*4*) The date of withdrawal from sale. It is requested but not required that the reason for withdrawal of the drug product from sale be included with the information.

(*b*) The applicant shall submit each Form FDA-2657 to the Drug Listing Branch (HFD-315), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857

(*c*) Reporting under paragraph (b)(3)(iii) of this section constitutes compliance with the requirements under § 207.30(a) to report "at the discretion of the registrant when the change occurs."

17 New Subpart C consisting of §§ 314.92 to 314.99 is added to read as follows:

Subpart C—Abbreviated Applications

§ 314.92 Drug products for which abbreviated applications may be submitted.

(a) Abbreviated applications are suitable for the following drug products within the limits set forth under § 314.93:

(1) Drug products that are the same as a listed drug. A "listed drug" is defined in § 314.3. For determining the suitability of an abbreviated new drug application, the term "same as" means identical in active ingredient(s), dosage form, strength, route of administration, and conditions of use, except that conditions of use for which approval cannot be granted because of exclusivity or an existing patent may be omitted. If a listed drug has been voluntarily withdrawn from or not offered for sale by its manufacturer, a person who wishes to submit an abbreviated new drug application for the drug shall comply with § 314.122.

(2) Drug products that meet the monograph for an antibiotic drug for which FDA has approved an application.

(3) Drug products for which FDA made a finding that an abbreviated new drug application was suitable and such finding was announced by notice in the **Federal Register**.

(4) Drug products that have been declared suitable for an abbreviated new drug application submission by FDA through the petition procedures set forth under § 10.30 of this chapter and § 314.93.

(b) FDA will publish in the list listed drugs for which abbreviated applications may be submitted. The list is available from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402, 202-783-3238.

§ 314.93 Petition to request a change from a listed drug.

(a) The only changes from a listed drug for which the agency will accept a petition under this section are those changes described in paragraph (b). Petitions to submit abbreviated new drug applications for other changes from a listed drug will not be approved.

(b) A person who wants to submit an abbreviated new drug application for a drug product which is not identical to a listed drug in route of administration, dosage form, and strength, or in which one active ingredient is substituted for one of the active ingredients in a listed combination drug, must first obtain permission from FDA to submit such an abbreviated application.

(c) To obtain permission to submit an abbreviated new drug application for a change described in paragraph (b) of this section, a person must submit and obtain approval of a petition requesting the change. A person seeking permission to request such a change from a reference listed drug shall submit a petition in accordance with § 10.20 of this chapter and in the format specified in § 10.30 of this chapter. The petition shall contain the information specified in § 10.30 of this chapter and any additional information required by this section. If any provision of § 10.20 of this chapter or § 10.30 of this chapter is inconsistent with any provision of this section, the provisions of this section apply.

(d) The petitioner shall identify a listed drug and include a copy of the proposed labeling for the drug product that is the subject of the petition and a copy of the approved labeling for the listed drug. The petitioner may, under limited circumstances, identify more than one listed drug, for example, when the proposed drug product is a combination product with one different active ingredient than the combination reference listed drug and the different active ingredient itself is a listed drug. The petitioner shall also include information to show that:

(1) The active ingredients of its proposed drug product are of the same pharmacological or therapeutic class as those of the reference listed drug.

(2) The drug product can be expected to have the same therapeutic effect as the reference listed drug when administered to patients for each condition of use in the reference listed drug's labeling for which the applicant seeks approval.

(3) If the proposed drug product is a combination product with one different active ingredient, including a different ester or salt, from the reference listed drug, that the different active ingredient has previously been approved in a listed drug or is a drug that does not meet the definition of "new drug" in section 201(p) of the act.

(e) No later than 90 days after the date a petition that is permitted under paragraph (a) of this section is submitted, FDA will approve or disapprove the petition.

(1) FDA will approve a petition properly submitted under this section unless it finds that:

(i) Investigations must be conducted to show the safety and effectiveness of the drug product or of any of its active ingredients, its route of administration, dosage form, or strength which differs from the reference listed drug; or

(ii) For a petition that seeks to change an active ingredient, the drug product that is the subject of the petition is not a combination drug; or

(iii) For a combination drug product that is the subject of the petition and has an active ingredient different from the reference listed drug:

(A) The drug product may not be adequately evaluated for approval as safe and effective on the basis of the information required to be submitted under § 314.94; or

(B) The petition does not contain information to show that the different active ingredient of the drug product is of the same pharmacological or therapeutic class as the ingredient of the reference listed drug that is to be changed and that the drug product can be expected to have the same therapeutic effect as the reference listed drug when administered to patients for each condition of use in the listed drug's labeling for which the applicant seeks approval; or

(C) The different active ingredient is not an active ingredient in a listed drug or a drug that meets the requirements of section 201(p) of the act; or

(D) The remaining active ingredients are not identical to those of the listed combination drug; or

(iv) Any of the proposed changes from the listed drug would jeopardize the safe or effective use of the product so as to necessitate significant new labeling changes to address the newly introduced safety or effectiveness problem; or

(v) FDA has determined that the reference listed drug has been withdrawn from sale for safety or effectiveness reasons under § 314.161, or the reference listed drug has been voluntarily withdrawn from sale and the agency has not determined whether the withdrawal is for safety or effectiveness reasons.

(2) For purposes of this paragraph, "investigations must be conducted" means that information derived from animal or clinical studies is necessary to show that the drug product is safe or effective. Such information may be contained in published or unpublished reports.

(3) If FDA approves a petition submitted under this section, the agency's response may describe what additional information, if any, will be required to support an abbreviated new drug application for the drug product. FDA may, at any time during the course of its review of an abbreviated new drug application, request additional information required to evaluate the change approved under the petition.

§ 314.94 Content and format of an abbreviated application.

Abbreviated applications are required to be submitted in the form and contain the information required under this section. Two copies of the application are required, an archival copy and a review copy. FDA will maintain guidelines on the format and content of applications to assist applicants in their preparation.

(a) *Abbreviated new drug applications.* Except as provided in paragraph (b) of this section, the applicant shall submit a complete archival copy of the abbreviated new drug application that includes the following:

(1) *Application form.* The applicant shall submit a completed and signed application form that contains the information described under § 314.50(a) (1), (3), (4), and (5). The applicant shall state whether the submission is an abbreviated application under § 314.94 or a supplement to an abbreviated application under § 314.97

(2) *Table of contents.* The archival copy of the abbreviated new drug application is required to contain a table of contents that shows the volume number and page number of the contents of the submission.

(3) *Basis for abbreviated new drug application submission.* An abbreviated new drug application must refer to a

listed drug. Ordinarily that listed drug will be the drug product selected by the agency as the reference standard for conducting bioequivalence testing. The application shall contain:

(i) The name of the reference listed drug, including its dosage form and strength. For an abbreviated new drug application based on an approved petition pursuant to § 10.30 of this chapter or § 314.93, the reference listed drug must be the same as the listed drug referred to in the petition. If the abbreviated new drug application is submitted on the basis of an FDA finding published by notice in the **Federal Register** that an abbreviated new drug application is suitable for the product that is the subject of the abbreviated application, and there is no listed drug, the **Federal Register** notice will be considered the listed drug, and the application must contain a reference to the **Federal Register** citation.

(ii) A statement as to whether according to the information published in the list, the reference listed drug is entitled to a period of marketing exclusivity under section 505(j)(4)(D) of the act.

(iii) For an abbreviated new drug application based on an approved petition pursuant to § 10.30 of this chapter or § 314.93, a reference to FDA-assigned docket number for the petition and a copy of FDA's correspondence approving the petition.

(4) *Conditions of use.* (i) A statement that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the drug product have been previously approved for the reference listed drug.

(ii) A reference to the applicant's annotated proposed labeling and to the currently approved labeling for the reference listed drug provided under paragraph (a)(8) of this section.

(5) *Active ingredients.* (i) For a single-active-ingredient drug product, information to show that the active ingredient is the same as that of the reference single-active-ingredient listed drug, as follows:

(A) A statement that the active ingredient of the proposed drug product is the same as that of the reference listed drug.

(B) A reference to the applicant's annotated proposed labeling and to the currently approved labeling for the reference listed drug provided under paragraph (a)(8) of this section.

(ii) For a combination drug product, information to show that the active ingredients are the same as those of the reference listed drug except for any different active ingredient that has been the subject of an approved petition, as follows:

(A) A statement that the active ingredients of the proposed drug product are the same as those of the reference listed drug, or if one of the active ingredients differs from one of the active ingredients of the reference listed drug and the abbreviated application is submitted pursuant to the approval of a petition under § 314.93 to vary such active ingredient, information to show that the other active ingredients of the drug product are the same as the other active ingredients of the reference listed drug, information to show that the different active ingredient is an active ingredient of another listed drug or of a drug which does not meet the definition of "new drug" in section 201(p) of the act, and such other information about the different active ingredient that FDA may require.

(B) A reference to the applicant's annotated proposed labeling and to the currently approved labeling for the reference listed drug provided under paragraph (a)(8) of this section.

(6) *Route of administration, dosage form, and strength.* (i) Information to show that the route of administration, dosage form, and strength of the drug product are the same as those of the reference listed drug except for any differences that have been the subject of an approved petition, as follows:

(A) A statement that the route of administration, dosage form, and strength of the proposed drug product are the same as those of the reference listed drug.

(B) A reference to the applicant's annotated proposed labeling and to the currently approved labeling for the reference listed drug provided under paragraph (a)(8) of this section.

(ii) If the route of administration, dosage form, or strength of the drug product differs from the reference listed drug and the abbreviated application is submitted pursuant to an approved petition under § 314.93, such information about the different route of administration, dosage form, or strength that FDA may require.

(7) *Bioequivalence.* (i) Information which shows that the drug product is bioequivalent to the reference listed drug upon which the applicant relies or to the standard identified in an applicable **Federal Register** notice permitting the submission of an abbreviated new drug application for the drug product, or

(ii) If the abbreviated new drug application is submitted pursuant to a petition to vary an active ingredient, approved under § 314.93, the results of any bioavailability or bioequivalence testing required by the agency, and any other information required by the agency to show that the different active ingredient is of the same pharmacological or therapeutic class as that of the changed ingredient in the reference listed drug, and that the proposed drug product can be expected to have the same therapeutic effect as the reference listed drug. FDA will consider a proposed drug product to have the same therapeutic effect as the reference listed drug if the applicant provides information demonstrating that:

(A) There is an adequate scientific basis for determining that substitution of the specific proposed dose of the different active ingredient for the dose of the member of the same pharmacological or therapeutic class in the reference listed drug will yield a resulting drug product of the same safety and effectiveness.

(B) The unchanged active ingredients in the proposed drug product are bioequivalent to those in the reference listed drug.

(C) The different active ingredient in the proposed drug product is bioequivalent to an approved dosage form containing that ingredient and approved for the same indication as the proposed drug product or is bioequivalent to a drug product offered for that indication which does not meet the definition of "new drug" under section 201(p) of the act.

(iii) For each in vivo bioequivalence study contained in the abbreviated new drug application, a description of the analytical and statistical methods used in each study and a statement with respect to each study that it either was conducted in compliance with the institutional review board regulations in Part 56 of this chapter, or was not subject to the regulations under § 56.104 or 56.105 of this chapter and that each study was conducted in compliance with the informed consent regulations in Part 50 of this chapter.

(8) *Labeling*—(i) *Listed drug labeling.* A copy of the currently approved labeling for the listed drug referred to in the abbreviated new drug application, if the abbreviated new drug application relies on a reference listed drug.

(ii) *Proposed labeling.* Copies of the label and all labeling for the drug product (4 copies of draft labeling or 12 copies of final printed labeling).

(iii) A statement that the applicant's proposed labeling is the same as the labeling of the reference listed drug except for differences annotated and explained under paragraph (a)(8)(iv) of this section.

(iv) A side-by-side comparison of the applicant's proposed labeling with the approved labeling for the reference listed drug with all differences annotated and explained. Labeling (including the container label and package insert) proposed for the drug product must be the same as the labeling approved for the reference listed drug, except for changes required because of differences approved under a petition filed under § 314.93 or because the drug product and the reference listed drug are produced or distributed by different manufacturers. Such differences between the applicant's proposed labeling and labeling approved for the reference listed drug may include differences in expiration date, formulation, bioavailability, or pharmacokinetics, labeling revisions made to comply with current FDA labeling guidelines or other guidance, or omission of an indication protected by patent or accorded exclusivity under section 505(j)(4)(D) of the act.

(9) *Chemistry, manufacturing, and controls.* (i) The information required under § 314.50(d)(1).

(ii) *Inactive ingredients.* If an applicant seeks approval of a drug product which differs from the reference listed drug in one or more inactive ingredients or composition, the applicant shall identify and characterize these differences and provide information demonstrating that the differences do not affect the safety of the proposed drug product.

(iii) *Inactive ingredient changes permitted in drug products intended for parenteral use.* Generally, a drug product intended for parenteral use shall contain the same inactive ingredients and in the same concentration as the reference listed drug identified by the applicant under § 314.94(a)(3). However, an applicant may seek approval of a drug product that differs from the reference listed drug in preservative, buffer, or antioxidant provided that the applicant identifies and characterizes the differences and provides information demonstrating that the differences do not affect the safety of the proposed drug product.

(iv) *Inactive ingredient changes permitted in drug products intended for ophthalmic or otic use.* Generally, a drug product intended for ophthalmic or otic use shall contain the same inactive ingredients and in the same concentration as the reference listed drug identified by the applicant under § 314.94(a)(3). However, an applicant may seek approval of a drug product that differs from the reference listed drug in preservative, buffer, substance to adjust tonicity, or thickening agent provided that the applicant identifies and characterizes the differences and provides information demonstrating that the differences do not affect the safety of the proposed drug product, except that in a product intended for ophthalmic use, an applicant may not change a buffer or substance to adjust tonicity for the purpose of claiming a therapeutic advantage over or difference from the listed drug, e.g., by using a balanced salt solution as a diluent as opposed to an isotonic saline solution, or by making a significant change in the pH or other change that may raise questions of irritability.

(10) *Samples.* The information required under § 314.50(e) (1) and (2)(i). Samples need not be submitted until requested by FDA.

(11) *Other.* The information required under § 314.50(g).

(12) *Patent certification*—(i) *Patents claiming drug, drug product, or method of use.* (A) Except as provided in paragraphs (a)(12)(iv) of this section, a certification with respect to each patent issued by the United States Patent and Trademark Office that, in the opinion of the applicant and to the best of its knowledge, claims the reference listed drug or that claims a use of such listed drug for which the applicant is seeking approval under section 505(j) of the act and for which information is required to be filed under section 505 (b) and (c) of the act and § 314.53. For each such patent, the applicant shall provide the patent number and certify, in its opinion and to the best of its knowledge, one of the following circumstances:

(*1*) That the patent information has not been submitted to FDA. The applicant shall entitle such a certification "Paragraph I Certification;"

(*2*) That the patent has expired. The applicant shall entitle such a certification "Paragraph II Certification;"

(*3*) The date on which the patent will expire. The applicant shall entitle such a certification "Paragraph III Certification;" or

(*4*) That the patent is invalid or will not be infringed by the manufacture, use, or sale of the drug product for which the abbreviated application is submitted. The applicant shall entitle such a certification "Paragraph IV Certification. This certification shall be submitted in the following form:

> I (*name of applicant*), certify that Patent No. _____ (*is invalid or will not be infringed by the manufacture, use, or sale of*) (*name of proposed drug product*) for which this application is submitted.

The certification shall be accompanied by a statement that the applicant will comply with the requirements under § 314.95(a) with respect to providing a notice to each owner of the patent or their representatives and to the holder of the approved application for the listed drug, and with the requirements under § 314.95(c) with respect to the content of the notice.

(B) If the abbreviated new drug application refers to a listed drug that is itself a licensed generic product of a patented drug first approved under section 505(b) of the act, the appropriate patent certification under paragraph (a)(12)(i) of this section with respect to each patent that claims the first-approved patented drug or that claims a use for such drug.

(ii) *No relevant patents.* If, in the opinion of the applicant and to the best of its knowledge, there are no patents described in paragraph (a)(12)(i) of this section, a certification in the following form:

> In the opinion and to the best knowledge of (*name of applicant*), there are no patents that claim the listed drug referred to in this application or that claim a use of the listed drug.

(iii) *Method of use patent.* (A) If patent information is submitted under section 505 (b) or (c) of the act and § 314.53 for a patent claiming a method of using the listed drug, and the labeling for the drug product for which the applicant is seeking approval does not include any indications that are covered by the use patent, a statement explaining that the method of use patent does not claim any of the proposed indications.

(B) If the labeling of the drug product for which the applicant is seeking approval includes an indication that, according to the patent information submitted under section 505 (b) or (c) of the act and § 314.53 or in the opinion of the applicant, is claimed by a use patent, an applicable certification under paragraph (a)(12)(i) of this section.

(iv) *Method of manufacturing patent.* An applicant is not required to make a certification with respect to any patent that claims only a method of manufacturing the listed drug.

(v) *Licensing agreements.* If the abbreviated new drug application is for a drug or method of using a drug claimed by a patent and the applicant has a licensing agreement with the patent owner, a certification under paragraph (a)(12)(i)(A)(*4*) ("Paragraph IV Certification") as to that patent and a statement that it has been granted a patent license. If the patent owner consents to an immediate effective date upon approval of the abbreviated

application, the abbreviated application shall contain a written statement from the patent owner that it has a licensing agreement with the applicant and that it consents to an immediate effective date.

(vi) *Late submission of patent information.* If a patent on the listed drug is issued and the holder of the approved application for the listed drug does not submit the required information on the patent within 30 days of issuance of the patent, an applicant who submitted an abbreviated new drug application for that drug that contained an appropriate patent certification before the submission of the patent information is not required to submit an amended certification. An applicant whose abbreviated new drug application is submitted after a late submission of patent information, or whose pending abbreviated application was previously submitted but did not contain an appropriate patent certification at the time of the patent submission, shall submit a certification under paragraph (a)(12)(i) or a statement under paragraph (a)(12)(iii) of this section as to that patent.

(vii) *Disputed patent information.* If an applicant disputes the accuracy or relevance of patent information submitted to FDA, the applicant may seek a confirmation of the correctness of the patent information in accordance with the procedures under § 314.53(f). Unless the patent information is withdrawn or changed, the applicant shall submit an appropriate certification for each relevant patent.

(viii) *Amended certifications.* A certification submitted under paragraphs (a)(12) (i) through (iii) of this section may be amended at any time before the effective date of the approval of the application. An applicant shall submit an amended certification as an amendment to a pending application or by letter to an approved application. Once an amendment or letter is submitted, the application will no longer be considered to contain the prior certification.

(A) *After finding of infringement.* An applicant who has submitted a certification under paragraph (a)(12)(i)(A)(*4*) of this section and is sued for patent infringement within 45 days of the receipt of notice sent under § 314.95, shall amend the certification if a final judgment in the action against that applicant is entered finding the patent to be infringed. In the amended certification, the applicant shall certify under paragraph (a)(12)(i)(A)(*3*) of this section that the patent will expire on a specific date. Once an amendment or letter for the change has been submitted, the application will no longer be considered to be one containing a certification under paragraph (a)(12)(i)(A)(*4*) of this section.

(B) *After removal of a patent from the list.* If a patent is removed from the list, for any reason other than because the patent has been declared invalid in a lawsuit brought pursuant to a notice under § 314.95, after one or more applicants have submitted certifications under paragraph (a)(12)(i)(A)(*4*) of this section on that patent, any applicant with a pending application or with an approved application with a delayed effective date who has made such a certification shall amend the certification. The applicant shall certify under paragraph (a)(12)(ii) of this section, if applicable, that no patents described in paragraph (a)(12)(i) of this section claim the drug. If other relevant patents claim the drug, the applicant shall instead submit a request to withdraw the certification under paragraph (a)(12)(i)(A)(*4*) of this section. Once an amendment or letter for the change has been submitted, the application will no longer be considered to be one containing a certification under paragraph (a)(12)(i)(A)(*4*) of this section.

(C) *Other amendments.* (*1*) Except as provided in paragraphs (a)(12)(iv) and (viii)(C)(*2*) of this section, an applicant shall amend a submitted certification if, at any time before the effective date of the approval of the application the applicant learns that the submitted certification is no longer accurate.

(*2*) An applicant is not required to amend a submitted certification when information on a patent on the listed drug is submitted after the abbreviated application is approved, whether or not the approval of the abbreviated application is effective.

(b) *Drug products subject to the Drug Efficacy Study Implementation (DESI) review.* (1) If the abbreviated new drug application is for a duplicate of a drug product that is subject to FDA's Drug Efficacy Study Implementation (DESI) review (a review of drug products approved as safe between 1938 and 1962) or other DESI-like review and the drug product evaluated in the review is a listed drug, the applicant shall comply with the provisions of paragraph (a) of this section.

(2) If the abbreviated new drug application is for a duplicate of a drug product that is subject to FDA's DESI review or other DESI-like review and the drug product evaluated in the review is not a listed drug at the time of submission of the abbreviated application, the applicant shall comply with the conditions set forth in the applicable DESI notice or other notice with respect to conditions of use and labeling and with the provisions of paragraph (a) of this section. However, if a drug product has been approved pursuant to a DESI notice and later withdrawn from sale, the applicant shall follow the procedures in § 314.122.

(c) *Abbreviated antibiotic application.* For applications submitted under section 507 of the act, the applicant shall submit a complete archival copy of the abbreviated application that contains the information described under § 314.50(a) (1), (3), (4), and (5), (b), (d) (1) and (3), (e), and (g). The applicant shall state whether the submission is an abbreviated application under § 314.94 or a supplement to an abbreviated application under § 314.97

(d) *Format of an abbreviated application.* (1) The applicant shall submit a complete archival copy of the abbreviated application as required under paragraphs (a) and (c) of this section. FDA will maintain the archival copy during the review of the application to permit individual reviewers to refer to information that is not contained in their particular technical sections of the application, to give other agency personnel access to the application for official business, and to maintain in one place a complete copy of the application. An applicant may submit all or portions of the archival copy of the abbreviated application in any form (e.g., microfiche) that the applicant and FDA agree is acceptable.

(2) For abbreviated new drug applications, the applicant shall submit a review copy of the abbreviated application that contains two separately-bound sections. One section shall contain the information described under paragraphs (a) (3) through (6), (8), (9), and (12) of this section and 1 copy of the analytical methods and descriptive information needed by FDA's laboratories to perform tests on samples of the proposed drug product and to validate the applicant's analytical methods. The other section shall contain the information described under paragraphs (a) (3), (7), and (8) of this section. Each of the sections in the review copy is required to contain a copy of the application form described under § 314.50(a).

(3) For abbreviated antibiotic applications, the applicant shall submit a review copy that contains the technical sections described in § 314.50(d) (1) and (3). Each of the technical sections in the review copy is required to be separately bound with a copy of the application form required under § 314.50(a).

(4) The applicant may obtain from FDA sufficient folders to bind the archival and the review copies of the abbreviated application.

§ 314.95 Notice of certification of invalidity or noninfringement of a patent.

(a) For each patent that claims the listed drug or that claims a use for such listed drug for which the applicant is seeking approval and that the applicant certifies under § 314.94(a)(12) is invalid or will not be infringed, the applicant shall send notice of such certification by registered or certified mail, return receipt requested to each of the following persons:

(1) Each owner of the patent which is the subject of the certification or the representative designated by the owner to receive the notice. The name and address of the patent owner or its representative may be obtained from the United States Patent and Trademark Office; and

(2) The holder of the approved application under section 505(b) of the act for the listed drug that is claimed by the patent and for which the applicant is seeking approval, or, if the application holder does not reside or maintain a place of business within the United States, the application holder's attorney, agent, or other authorized official. The name and address of the application holder or its attorney, agent, or authorized official may be obtained from the Division of Drug Information Resources (HFD-80), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857

(3) This paragraph does not apply to a use patent that claims no uses for which the applicant is seeking approval.

(b) The applicant shall send the notice required by paragraph (a) of this section when it receives from FDA an acknowledgment letter stating that its abbreviated new drug application is sufficiently complete to permit a substantive review. At the same time, the applicant shall amend its abbreviated new drug application to include a statement certifying that the notice has been provided to each person identified under paragraph (a) of this section and that the notice met the content requirements under paragraph (c) of this section.

(c) *Content of a notice.* In the notice, the applicant shall cite section 505(j)(2)(B)(ii) of the act and shall include, but not be limited to, the following information:

(1) A statement that FDA has received an abbreviated new drug application submitted by the applicant containing any required bioavailability or bioequivalence data or information.

(2) The abbreviated application number.

(3) The established name, if any, as defined in section 502(e)(3) of the act, of the proposed drug product.

(4) The active ingredient, strength, and dosage form of the proposed drug product.

(5) The patent number and expiration date, as submitted to the agency or as known to the applicant, of each patent alleged to be invalid or not infringed.

(6) A detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed. The applicant shall include in the detailed statement:

(i) For each claim of a patent alleged not to be infringed, an explanation of why the claim is not infringed.

(ii) For each claim of a patent alleged to be invalid, an explanation of the grounds supporting the allegation, including all statutory bases, affirmative defenses, reasoning, and evidence supporting the allegation, citing any relevant case precedent upon which the allegation is based, providing a copy of any patent or publication relied upon, and indicating that portion of each such patent or publication which is alleged to invalidate such claim and the reasons supporting such allegation.

(iii) For formulation or composition patents, a description of a mechanism through which the applicant agrees to make the formulation or composition of the proposed drug product known to the patent owner or to a designated intermediary who will act as a referee.

(7) If the applicant does not reside or have a place of business in the United States, the name and address of an agent in the United States authorized to accept service of process for the applicant.

(d) *Amendment to abbreviated application.* If an abbreviated application is amended to include the certification described in § 314.94(a)(12)(i)(A)(*4*), the applicant shall send the notice required by paragraph (a) of this section at the same time that the amendment to the abbreviated application is submitted to FDA.

(e) *Documentation of receipt of notice.* The applicant shall amend its abbreviated application to document receipt of the notice required under paragraph (a) of this section by each person provided the notice. The applicant shall include a copy of the return receipt or other similar evidence of the date the notification was received. FDA will accept as adequate documentation of the date of receipt a return receipt or a letter acknowledging receipt by the person provided the notice. An applicant may rely on another form of documentation only if FDA has agreed to such documentation in advance. A copy of the notice itself need not be submitted to the agency.

(f) If the above requirements are met, FDA will presume the notice to be complete and sufficient, and it will count the day following the date of receipt of the notice by the patent owner or its representative or by the approved application holder if the holder is an exclusive patent licensee as the first day of the 45-day period provided for in section 505(j)(4)(B)(iii) of the act. FDA may, if the applicant amends its ANDA with a written statement that a later date should be used, count from such later date.

§ 314.96 Amendments to an unapproved abbreviated application.

(a) *Abbreviated new drug application.* (1) An applicant may amend an abbreviated new drug application that is submitted under § 314.94, but not yet approved, to revise existing information or provide additional information.

(2) Ordinarily, an amendment submitted before the end of the 180-day review period will not extend the review period. If, however, the agency concludes that an amendment contains significant new data requiring additional time for agency review, FDA will extend the review period, but only for the length of time needed to review the submission and for no more than 180 days. The agency will notify the applicant of the length of the extension.

(3) Submission of an amendment to resolve substantial deficiencies in the application as set forth in a not approvable letter issued under § 314.120 will extend the review period for 120 days from the date of receipt by FDA of the amendment. The submission of such an amendment constitutes an agreement by FDA and the applicant under section 505(j)(4)(A) of the act to extend the date by which the agency is required to reach a decision on the abbreviated new drug application.

(b) *Abbreviated antibiotic application.* The applicant shall comply with the provisions of § 314.60.

§ 314.97 Supplements and other changes to an approved abbreviated application.

The applicant shall comply with the requirements of §§ 314.70 and 314.71 regarding the submission of supplemental applications and other changes to an approved abbreviated application.

§ 314.98 Postmarketing reports.

(a) Except as provided in paragraphs (b) and (c) of this section, each applicant having an approved abbreviated antibiotic application under § 314.94 or approved abbreviated new drug application under § 314.94 that is effective under § 314.107 shall comply with the requirements of § 314.80 regarding the reporting of adverse drug experiences.

(b) Except as provided in paragraph (c) of this section, the applicant shall submit one copy of each report required under § 314.80 to the Division of Epidemiology and Surveillance (HFD-730), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857

(c) Periodic reporting of adverse drug experiences under § 314.80(c)(2) is not required if no adverse drug experience reports have been received and no labeling changes have been initiated by the applicant during the reporting interval.

(d) Each applicant shall make the reports required under § 314.81 and sections 505(k) and 507(g) of the act for each of its approved abbreviated applications.

§ 314.99 Other responsibilities of an applicant of an abbreviated application.

(a) An applicant shall comply with the requirements of § 314.65 regarding withdrawal by the applicant of an unapproved abbreviated application and § 314.72 regarding a change in ownership of an abbreviated application.

(b) An applicant may ask FDA to waive under this section any requirement that applies to the applicant under §§ 314.92 through 314.99. The applicant shall comply with the requirements for a waiver under § 314.90.

18. Part 314 is amended by revising the heading for Subpart D, §§ 314.100, 314.101, and 314.102 to read as follows:

Subpart D—FDA Action on Applications and Abbreviated Applications

§ 314.100 Time frames for reviewing applications and abbreviated applications.

(a) Within 180 days of receipt of an application for a new drug under section 505(b) of the act, or of an abbreviated application for a new drug under section 505(j) of the act, or of an application or abbreviated application for an antibiotic drug under section 507 of the act, FDA will review it and send the applicant either an approval letter under § 314.105, an approvable letter under § 314.110, or a not approvable letter under § 314.120. This 180-day period is called the "review clock."

(b) During the review period an applicant may withdraw an application under § 314.65 or an abbreviated application under § 314.99 and later resubmit it. FDA will treat the resubmission as a new application or abbreviated application.

(c) The review clock may be extended by mutual agreement between FDA and an applicant or as provided in §§ 314.60 and 314.96, as the result of a major amendment.

§ 314.101 Filing an application and an abbreviated antibiotic application and receiving an abbreviated new drug application.

(a)(1) Within 60 days after FDA receives an application or abbreviated antibiotic application, the agency will determine whether the application or abbreviated antibiotic application may be filed. The filing of an application or abbreviated antibiotic application means that FDA has made a threshold determination that the application or abbreviated antibiotic application is sufficiently complete to permit a substantive review.

(2) If FDA finds that none of the reasons in paragraphs (d) and (e) of this section for refusing to file the application or abbreviated antibiotic application apply, the agency will file the application or abbreviated antibiotic application and notify the applicant in writing. The date of filing will be the date 60 days after the date FDA received the application or abbreviated antibiotic application. The date of filing begins the 180-day period described in section 505(c) of the act. This 180-day period is called the "filing clock."

(3) If FDA refuses to file the application or abbreviated antibiotic application, the agency will notify the applicant in writing and state the reason under paragraph (d) or (e) of this section for the refusal. If FDA refuses to file the application or abbreviated antibiotic application under paragraph (d) of this section, the applicant may request in writing within 30 days of the date of the agency's notification an informal conference with the agency about whether the agency should file the application or abbreviated antibiotic application. If following the informal conference the applicant requests that FDA file the application or abbreviated antibiotic application (with or without amendments to correct the deficiencies), the agency will file the application or abbreviated antibiotic application over protest under paragraph (a)(2) of this section, notify the applicant in writing, and review it as filed. If the application or abbreviated antibiotic application is filed over protest, the date of filing will be the date 60 days after the date the applicant requested the informal conference. The applicant need not resubmit a copy of an application or abbreviated antibiotic application that is filed over protest. If FDA refuses to file the application or abbreviated antibiotic application under paragraph (e) of this section, the applicant may amend the application or abbreviated antibiotic application and resubmit it and the agency will make a determination under this section whether it may be filed.

(b)(1) An abbreviated new drug application will be reviewed after it is submitted to determine whether the abbreviated application may be received. Receipt of an abbreviated new drug application means that FDA has made a threshold determination that the abbreviated application is sufficiently complete to permit a substantive review.

(2) If FDA finds that none of the reasons in paragraphs (d) and (e) of this section for considering the abbreviated new drug application not to have been received apply, the agency will receive the abbreviated new drug application and notify the applicant in writing.

(3) If FDA considers the abbreviated new drug application not to have been received under paragraphs (d) or (e) of this section, FDA will notify the applicant, ordinarily by telephone. The applicant may then:

(i) Withdraw the abbreviated new drug application pursuant to § 314.99, or

(ii) Amend the abbreviated new drug application to correct the deficiencies, or

(iii) Take no action, in which case FDA will refuse to receive the abbreviated new drug application.

(c) [Reserved]

(d) FDA may refuse to file an application or abbreviated antibiotic application or may not consider an abbreviated new drug application to be received if any of the following applies.

(1) The application or abbreviated application does not contain a completed application form.

(2) The application or abbreviated application is not submitted in the form required under § 314.50 or § 314.94.

(3) The application or abbreviated application is incomplete because it does not on its face contain information required under section 505(b), section 505(j), or section 507 of the act and § 314.50 or § 314.94.

(4) The applicant fails to submit a complete environmental assessment which addresses each of the items

specified in the applicable format under § 25.31 of this chapter or fails to provide sufficient information to establish that the requested action is subject to categorical exclusion under § 25.24 of this chapter.

(5) The application or abbreviated application does not contain an accurate and complete English translation of each part of the application that is not in English.

(6) The application does not contain a statement for each nonclinical laboratory study that it was conducted in compliance with the requirements set forth in Part 58, or, for each study not conducted in compliance with Part 58, a brief statement of the reason for the noncompliance.

(7) The application does not contain a statement for each clinical study that it was conducted in compliance with the institutional review board regulations in Part 56 of this chapter, or was not subject to those regulations, and that it was conducted in compliance with the informed consent regulations in Part 50; or, if the study was subject to but was not conducted in compliance with those regulations, the application does not contain a brief statement of the reason for the noncompliance.

(8) The abbreviated new drug application contains a certification under § 314.94(a)(12)(i)(A)(*4*), but does not contain the results of any required and completed bioequivalence or bioavailability study, or, if appropriate, a request for waiver of such study requirement.

(e) The agency will refuse to file an application or abbreviated antibiotic application or will consider an abbreviated new drug application not to have been received if any of the following applies:

(1) The drug product that is the subject of the submission is already covered by an approved application or abbreviated application and the applicant of the submission is merely a distributor and/or a repackager of the already approved drug product.

(2) The drug product is subject to licensing by FDA under the Public Health Service Act [58 Stat. 632 as amended [42 U.S.C. 201 *et seq.*]] and Subchapter F of Chapter I of Title 21 of the Code of Federal Regulations.

(f)(1) Within 180 days after the date of filing, plus the period of time the review period was extended (if any), FDA will either (i) approve the application or abbreviated antibiotic application or (ii) issue a notice of opportunity for hearing if the applicant asked FDA to provide it an opportunity for a hearing on an application or abbreviated antibiotic application in response to an approvable letter or a not approvable letter.

(2) Within 180 days after the date of receipt, plus the period of time the review clock was extended (if any), FDA will either approve or disapprove the abbreviated new drug application. If FDA disapproves the abbreviated new drug application, FDA will issue a notice of opportunity for hearing if the applicant asked FDA to provide it an opportunity for a hearing on an abbreviated new drug application in response to a not approvable letter.

(3) This paragraph does not apply to applications or abbreviated applications that have been withdrawn from FDA review by the applicant.

§ 314.102 Communications between FDA and applicants.

(a) *General principles.* During the course of reviewing an application or an abbreviated application, FDA shall communicate with applicants about scientific, medical, and procedural issues that arise during the review process. Such communication may take the form of telephone conversations, letters, or meetings, whichever is most appropriate to discuss the particular issue at hand. Communications shall be appropriately documented in the application in accordance with § 10.65. Further details on the procedures for communication between FDA and applicants are contained in a staff manual guide that is publicly available.

(b) *Notification of easily correctable deficiencies.* FDA reviewers shall make every reasonable effort to communicate promptly to applicants easily correctable deficiencies found in an application or an abbreviated application when those deficiencies are discovered, particularly deficiencies concerning chemistry, manufacturing, and controls issues. The agency will also inform applicants promptly of its need for more data or information or for technical changes in the application or the abbreviated application needed to facilitate the agency's review. This early communication is intended to permit applicants to correct such readily identified deficiencies relatively early in the review process and to submit an amendment before the review period has elapsed. Such early communication would not ordinarily apply to major scientific issues, which require consideration of the entire pending application or abbreviated application by agency managers as well as reviewing staff. Instead, major scientific issues will ordinarily be addressed in an action letter.

(c) *Ninety-day conference.* Approximately 90 days after the agency receives the application, FDA will provide applicants with an opportunity to meet with agency reviewing officials. The purpose of the meeting will be to inform applicants of the general progress and status of their applications, and to advise applicants of deficiencies which have been identified by that time and which have not already been communicated. This meeting will be available on applications for all new chemical entities and major new indications of marketed drugs. Such meetings will be held at the applicant's option, and may be held by telephone if mutually agreed upon. Such meetings would not ordinarily be held on abbreviated applications because they are not submitted for new chemical entities or new indications.

(d) *End of review conference.* At the conclusion of FDA's review of an application or an abbreviated application as designated by the issuance of an approvable or not approvable letter, FDA will provide applicants with an opportunity to meet with agency reviewing officials. The purpose of the meeting will be to discuss what further steps need to be taken by the applicant before the application or abbreviated application can be approved. This meeting will be available on all applications or abbreviated applications, with priority given to applications for new chemical entities and major new indications for marketed drugs and for the first duplicates for such drugs. Requests for such meetings shall be directed to the director of the division responsible for reviewing the application or abbreviated application.

(e) *Other meetings.* Other meetings between FDA and applicants may be held, with advance notice, to discuss scientific, medical, and other issues that arise during the review process. Requests for meetings shall be directed to the director of the division responsible for reviewing the application or abbreviated application. FDA will make every attempt to grant requests for meetings that involve important issues and that can be scheduled at mutually convenient times. However, "drop-in" visits (i.e., an unannounced and unscheduled visit by a company representative) are discouraged except for urgent matters, such as to discuss an important new safety issue.

19. Section 314.103 is amended by revising paragraph (a), the first sentence in paragraph (b), and the fourth sentence in paragraph (c)(2), to read as follows:

§ 314.103 Dispute resolution.

(a) *General.* FDA is committed to resolving differences between applicants and FDA reviewing divisions with respect to technical requirements for applications or abbreviated applications as quickly and amicably as possible through the cooperative exchange of information and views.

(b) *Administrative and procedural issues.* When administrative or procedural disputes arise, the applicant should first attempt to resolve the matter with the division responsible for reviewing the application or abbreviated application, beginning with the consumer safety officer assigned to the application or abbreviated application.

(c)

(2) Requests for such meetings shall be directed to the director of the division responsible for reviewing the application or abbreviated application.

20. Part 314 is amended by revising §§ 314.104 and 314.105 to read as follows:

§ 314.104 Drugs with potential for abuse.

The Food and Drug Administration will inform the Drug Enforcement Administration under section 201(f) of the Controlled Substances Act (21 U.S.C. 801) when an application or abbreviated application is submitted for a drug that appears to have an abuse potential.

§ 314.105 Approval of an application and an abbreviated application.

(a) The Food and Drug Administration will approve an application or an abbreviated antibiotic application and send the applicant an approval letter if none of the reasons in § 314.125 for refusing to approve the application or abbreviated antibiotic application apply. The date of the agency's approval letter is the date of approval of the application or abbreviated antibiotic application. When FDA sends an applicant an approval letter for an antibiotic, it will promulgate a regulation under § 314.300 providing for certification of the drug, if necessary. A new drug product or antibiotic approved under this paragraph may not be marketed until an approval letter is issued, except that a new drug product subject to a 505(b)(2) application may not be marketed until approval of the application is effective under § 314.107 Marketing of an antibiotic need not await the promulgation of a regulation under § 314.300.

(b) FDA will approve an application or abbreviated antibiotic application and issue the applicant an approval letter (rather than an approvable letter under § 314.110) on the basis of draft labeling if the only deficiencies in the application or abbreviated antibiotic application concern editorial or similar minor deficiencies in the draft labeling. Such approval will be conditioned upon the applicant incorporating the specified labeling changes exactly as directed, and upon the applicant submitting to FDA a copy of the final printed labeling prior to marketing.

(c) FDA will approve an application after it determines that the drug meets the statutory standards for safety and effectiveness, manufacturing and controls, and labeling, and an abbreviated antibiotic application after it determines that the drug meets the statutory standards for manufacturing and controls, and labeling. While the statutory standards apply to all drugs, the many kinds of drugs that are subject to the statutory standards and the wide range of uses for those drugs demand flexibility in applying the standards. Thus FDA is required to exercise its scientific judgment to determine the kind and quantity of data and information an applicant is required to provide for a particular drug to meet the statutory standards. FDA makes its views on drug products and classes of drugs available through guidelines, recommendations, and other statements of policy.

(d) FDA will approve an abbreviated new drug application and send the applicant an approval letter if none of the reasons in § 314.127 for refusing to approve the abbreviated new drug application apply. The date of the agency's approval letter is the date of approval of the abbreviated new drug application. A new drug product approved under this paragraph may not be introduced or delivered for introduction into interstate commerce until approval of the abbreviated new drug application is effective under § 314.107 Ordinarily, the effective date of approval will be stated in the approval letter.

21. Part 314 is amended by adding §§ 314.107 and 314.108 to read as follows:

§ 314.107 Effective date of approval of a 505(b)(2) application or abbreviated new drug application under section 505(j) of the act.

(a) *General.* A drug product may be introduced or delivered for introduction into interstate commerce when approval of the application or abbreviated application for the drug product becomes effective. Except as provided in this section, approval of an application or abbreviated application for a drug product becomes effective on the date FDA issues an approval letter under § 314.105 for the application or abbreviated application.

(b) *Effect of patent on the listed drug.* If approval of an abbreviated new drug application submitted under section 505(j) of the act or of a 505(b)(2) application is granted, that approval will become effective in accordance with the following:

(1) *Date of approval letter.* Except as provided in paragraph (c) of this section, approval will become effective on the date FDA issues an approval letter under § 314.105 if the applicant certifies under § 314.50(i) or § 314.94(a)(12) that:

(i) There are no relevant patents, or

(ii) The applicant is aware of a relevant patent but the patent information required under section 505 (b) or (c) of the act has not been submitted to FDA, or

(iii) The relevant patent has expired, or

(iv) The relevant patent is invalid or will not be infringed.

(A) The patent owner or its representative or the exclusive patent licensee has not brought suit for patent infringement within 45 days of the receipt of the applicant's notice of certification required under § 314.52 or § 314.95, or

(B) The drug product is covered by a patent licensing agreement and the abbreviated new drug application or 505(b)(2) application includes:

(*1*) A statement that the applicant has been granted a patent license;

(*2*) A statement from the patent owner that it has a licensing agreement with the applicant covering the proposed drug product and consents to an immediate effective date; and

(*3*) The patent owner's name and address.

(2) *Upon patent expiration.* If the applicant certifies under § 314.50(i) or § 314.94(a)(12) that the relevant patent will expire on a specified date, approval will become effective on the specified date.

(3) *Upon disposition of patent litigation.* (i)(A) Except as provided in paragraphs (b)(3) (ii), (iii), and (iv) of this section, if the applicant certifies under § 314.50(i) or § 314.94(a)(12) that the relevant patent is invalid or will not be infringed, and the patent owner or its representative or the exclusive patent licensee brings suit for patent infringement within 45 days of receipt of the notice of certification from the applicant under § 314.52 or § 314.95, approval will be made effective 30 months after the date of the receipt of the notice of certification by the patent

owner or by the exclusive licensee (or their representatives) unless the court has extended or reduced the period because of a failure of either the plaintiff or defendant to cooperate reasonably in expediting the action, or

(B) If the patented drug product qualifies for 5 years of exclusive marketing under § 314.108(b)(2) and the patent owner or its representative or the exclusive patent licensee brings suit for patent infringement during the 1-year period beginning 4 years after the date the patented drug was approved and within 45 days of receipt of the notice of certification, the 30-month period will be extended by an amount of time, if any, that is required for 7½ years to have elapsed from the date of approval of the application for the patented drug product and approval will be made effective at the expiration of the 7½ years.

(ii) If before the expiration of the 30-month period, or 7½ years where applicable, the court issues a final order that the patent is invalid or not infringed, approval will be made effective on the date the court enters judgment,

(iii) If before the expiration of the 30-month period, or 7½ years where applicable, the court issues a final order that the patent has been infringed, approval will be made effective on the date the court determines that the patent will expire or otherwise orders, or

(iv) If before the expiration of the 30-month period, or 7½ years where applicable, the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug product until the court decides the issues of patent validity and infringement, and if the court later decides that the patent is invalid or not infringed, approval will be made effective on the date the court enters final judgment.

(4) *Multiple certifications.* If the applicant has submitted certifications under § 314.50(i) or § 314.94(a)(12) for more than one patent, the date of approval will be calculated for each certification, and the approval will become effective on the last applicable date.

(c) *Subsequent abbreviated new drug application submission.* (1) If an abbreviated new drug application contains a certification that a relevant patent is invalid or will not be infringed and the application is for a generic copy of the same listed drug for which an abbreviated new drug application was previously submitted containing a certification that the same patent was invalid or would not be infringed and the previous applicant has been sued for patent infringement within 45 days of the patent owner's receipt of notice submitted under § 314.95, approval of the subsequent abbreviated new drug application will be made effective no sooner than 180 days from whichever of the following dates is earlier:

(i) The date the first of the previous applicants to submit a substantially complete abbreviated new drug application containing a certification that a patent on the listed drug was invalid or not infringed and to be sued within 45 days of the patent owner's receipt of notice submitted under § 314.95 first commences commercial marketing of its drug product, or

(ii) The date of a decision of the court holding the relevant patent invalid or not infringed.

(2) For purposes of paragraph (c)(1) of this section, an abbreviated new drug application will be considered to have been "previously submitted" with respect to another application for the same listed drug if the date on which the first application was both substantially complete and contained a certification that the patent was invalid or not infringed is earlier than the date on which the second application was both substantially complete and contained the same certification. A "substantially complete" application must contain the results of any required bioequivalence studies, or, if applicable, a request for a waiver of such studies.

(3) For purposes of paragraph (c)(1) of this section, if the "first applicant" described in paragraph (c)(1)(i) of this section has not yet received approval of its abbreviated new drug application, FDA will make the approval of subsequent abbreviated applications immediately effective if FDA concludes that the first applicant is not actively pursuing approval of its abbreviated application.

(4) For purposes of paragraph (c)(1)(i) of this section, the first applicant that makes a certification that one or more patents on a drug is invalid or will not be infringed and that has been sued for patent infringement shall notify FDA of the date that it commences commercial marketing of its drug product. Commercial marketing commences with the first date of introduction or delivery for introduction into interstate commerce outside the control of the manufacturer of a drug product, except for investigational use under 21 CFR Part 312, but does not include transfer of the drug product for reasons other than sale within the control of the manufacturer or application holder. If an applicant does not promptly notify FDA of such date, the effective date of approval shall be deemed to be the date of the commencement of first commercial marketing.

(d) *Delay due to exclusivity.* The agency will also delay the effective date of the approval of an abbreviated new drug application under section 505(j) of the act or a 505(b)(2) application if delay is required by the exclusivity provisions in § 314.108. When the effective date of an application is delayed under both this section and § 314.108, the effective date will be the later of the 2 days specified under this section and § 314.108.

(e)(1) References to actions of "the court" in paragraphs (b) and (c) of this section are to the court that enters final judgment from which no appeal can be or has been taken.

(2) For purposes of establishing the effective date of approval based on a court judgment, the applicant shall submit to the Division of Generic Drugs (HFN-230), within 10 working days of a final judgment, a copy of the entry of judgment.

(f) *Computation of 45-day time clock.* (1) The 45-day clock described in paragraph (b)(3) of this section begins on the day after the date of receipt of the applicant's notice of certification by the patent owner or its representative, or by the approved application holder if the holder is an exclusive patent licensee. When the 45th day falls on Saturday, Sunday, or on a Federal holiday, the 45th day will be the next day that is not a Saturday, Sunday, or a Federal holiday.

(2) If the applicant of the abbreviated new drug application or 505(b)(2) application does not notify FDA in writing before the expiration of the 45-day time period or the completion of the agency's review of the application, whichever occurs later, that a legal action for patent infringement was filed within 45 days of receipt of the notice of certification, approval of the abbreviated new drug application or 505(b)(2) application will be made effective immediately upon expiration of the 45 days or upon completion of the agency's review and approval of the application, whichever is later. The 505(b)(2) applicant or abbreviated new drug applicant shall notify FDA of the filing of any such legal action and shall include in such notification:

(i) The abbreviated new drug application or 505(b)(2) application number.

(ii) The name of the abbreviated new drug application or 505(b)(2) applicant.

(iii) The established name of the drug, if any, strength, and dosage form.

(iv) A certification that action to defend the patent, identified by number, has been filed in an appropriate court on a specified date. The applicant of an abbreviated new drug application shall send the notification to FDA's Division of Generic Drugs (HFD-230). A 505(b)(2) applicant shall send the notification to the appropriate division in the Center for Drug Research and Evaluation reviewing the application.

(3) If the patent owner or approved application holder who is an exclusive patent licensee waives its opportunity to file a legal action for patent infringement within 45 days of receipt of the notice of certification and the patent owner or approved application holder who is an exclusive patent licensee submits to FDA a valid waiver before the 45 days elapses, approval of the abbreviated new drug application or 505(b)(2) application will be made effective upon completion of the agency's review and approval of the application. FDA will only accept a waiver in the following form:

(*Name of patent owner or exclusive patent licensee*) has received notice from (*name of applicant*) under (*section 505(b)(3) or 505(j)(2)(B) of the act*) and does not intend to file an action for patent infringement against (*name of applicant*) concerning the drug (*name of drug*) before (*date on which 45 days elapses*). (*Name of patent owner or exclusive patent licensee*) waives the opportunity provided by (*section 505(c)(3)(C) or 505(j)(4)(B)(iii) of the act*) and does not object if (*name of applicant*)'s (*505(b)(2) or abbreviated new drug application*) for (*name of drug*) is approved with an immediate effective date on or after the date of this letter.

§ 314.108 New drug product exclusivity.

(a) The following definitions of terms apply to this section:

Active moiety" means the molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt (including a salt with hydrogen or coordination bonds) or other noncovalent derivative (such as a complex, chelate, or clathrate) of the molecule, responsible for the physiological or pharmacological action of the drug substance.

Approved under section 505(b)" means an application submitted under section 505(b) and approved on or after October 10, 1962, or an application that was "deemed approved" under section 107(c)(2) of Pub. L. 87-781.

"Clinical investigation" means any experiment other than a bioavailability study in which a drug is administered or dispensed to, or used on human subjects.

"Conducted or sponsored by the applicant" with regard to an investigation means that before or during the investigation, the applicant was named in Form FDA 1571 filed with FDA as the sponsor of the investigational new drug application under which the investigation was conducted, or the applicant or the applicant's predecessor in interest, provided substantial support for the investigation. Ordinarily, substantial support will mean providing 50 percent or more of the cost of conducting the study. A predecessor in interest is an entity, e.g., a corporation, that the applicant has taken over, merged with, or purchased, or from which the applicant has purchased all rights to the drug. Purchase of a clinical investigation itself or the rights to an investigation after it is completed is not sufficient to satisfy this definition.

"Date of approval" means the date on the letter from the Food and Drug Administration (FDA) stating that the new drug application is approved, whether or not final printed labeling or other materials must yet be submitted as long as approval of such labeling or materials is not expressly required.

"Essential to approval" with regard to an investigation means that the application could not be approved by FDA without that investigation, even with a delayed effective date.

"New chemical entity" means a drug that contains no active moiety that has been approved by FDA in any other application submitted under section 505(b) of the act.

"New clinical investigation" means an investigation in humans the results of which have not been relied on by FDA to demonstrate substantial evidence of effectiveness of a previously approved drug product for any indication or of safety for a new patient population and do not duplicate the results of another investigation that was relied on by the agency to demonstrate the effectiveness or safety in a new patient population of a previously approved drug product. For purposes of this section, data from a clinical investigation previously submitted for use in the comprehensive evaluation of the safety of a drug product but not to support the effectiveness of the drug product would be considered new.

(b) *Submission of and effective date of approval of an abbreviated new drug application submitted under section 505(j) of the act or a 505(b)(2) application.* (1) If a drug product that contains a new chemical entity was approved between January 1, 1982, and September 24, 1984, in an application submitted under section 505(b) of the act, the agency will not make effective for a period of 10 years from the date of approval of the first approved new drug application the approval of a 505(b)(2) application or an abbreviated new drug application submitted under section 505(j) of the act for a drug product that contains the same active moiety in the new chemical entity in the first approved application.

(2) If a drug product that contains a new chemical entity was approved after September 24, 1984, in an application submitted under section 505(b) of the act, no person may submit a 505(b)(2) application or abbreviated new drug application under section 505(j) of the act for a drug product that contains the same active moiety as in the new chemical entity for a period of 5 years from the date of approval of the first approved new drug application, except that the 505(b)(2) application or abbreviated application may be submitted after 4 years if it contains a certification of patent invalidity or noninfringement described in § 314.50(i)(1)(i)(*a*)(*4*) or § 314.94(a)(12)(i)(A)(*4*).

(3) The approval of a 505(b)(2) application or abbreviated application described in paragraph (b)(2) of this section will become effective as provided in § 314.107(b) (1) or (2), unless the owner of a patent that claims the drug or the patent owner's representative, or exclusive licensee brings suit for patent infringement against the applicant during the 1-year period beginning 48 months after the date of approval of the new drug application for the new chemical entity and within 45 days after receipt of the notice described at § 314.52 or § 314.95, in which case, approval of the 505(b)(2) application or abbreviated application will be made effective as provided in § 314.107(b)(3).

(4) If an application:

(i) Was submitted under section 505(b) of the act;

(ii) Was approved after September 24, 1984;

(iii) Was for a drug product that contains an active moiety that has been previously approved in another application under section 505(b) of the act; and

(iv) Contained reports of new clinical investigations (other than bioavailability studies) conducted or sponsored by the applicant that were essential to approval of the application, the agency will not make effective for a period of 3 years after the date of approval of the application the approval of: a 505(b)(2) application or an abbreviated new drug application for the conditions of approval of the original application, or an abbreviated new drug application

submitted pursuant to an approved petition under section 505(j)(2)(C) of the act that relies on the information supporting the conditions of approval of an original new drug application.

(5) If a supplemental application:

(i) Was approved after September 24, 1984, and

(ii) Contained reports of new clinical investigations (other than bioavailability studies) that were conducted or sponsored by the applicant that were essential to approval of the supplemental application, the agency will not make effective for a period of 3 years after the date of approval of the supplemental application the approval of a 505(b)(2) application or an abbreviated new drug application for a change, or an abbreviated new drug application submitted pursuant to an approved petition under section 505(j)(2)(C) of the act that relies on the information supporting a change approved in the supplemental new drug application.

22. Part 314 is amended by revising §§ 314.110 and 314.120 to read as follows:

§ 314.110 Approvable letter to the applicant.

(a) In selected circumstances it is useful at the end of the review period for the Food and Drug Administration to indicate to the applicant that the application or abbreviated application is basically approvable providing certain issues are resolved. An approvable letter may be issued in such circumstances. FDA will send the applicant an approvable letter if the application or abbreviated application substantially meets the requirements of this part and the agency believes that it can approve the application or abbreviated application if specific additional information or material is submitted or specific conditions (for example, certain changes in labeling) are agreed to by the applicant. The approvable letter will describe the information or material FDA requires or the conditions the applicant is asked to meet. As a practical matter, the approvable letter will serve in most instances as a mechanism for resolving outstanding issues on drugs that are about to be approved and marketed. For an application or an abbreviated antibiotic application, the applicant shall, within 10 days after the date of the approvable letter:

(1) Amend the application or abbreviated antibiotic application or notify FDA of an intent to file an amendment. The filing of an amendment or notice of intent to file an amendment constitutes an agreement by the applicant to extend the review period for 45 days after the date FDA receives the amendment. The extension is to permit the agency to review the amendment;

(2) Withdraw the application or abbreviated antibiotic application. FDA will consider the applicant's failure to respond within 10 days to an approvable letter to be a request by the applicant to withdraw the application under § 314.65 or the abbreviated antibiotic application under § 314.99. A decision to withdraw an application or abbreviated antibiotic application is without prejudice to a refiling;

(3) For a new drug application, ask the agency to provide the applicant an opportunity for a hearing on the question of whether there are grounds for denying approval of the application under section 505(d) of the act. The applicant shall submit the request to the Division of Regulatory Affairs (HFD-360), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857 Within 60 days of the date of the approvable letter, or within a different time period to which FDA and the applicant agree, the agency will either approve the application under § 314.105 or refuse to approve the application under § 314.125 and give the applicant written notice of an opportunity for a hearing under § 314.200 and section 505(c)(2) of the act on the question of whether there are grounds for denying approval of the application under section 505(d) of the act;

(4) For an antibiotic, file a petition or notify FDA of an intent to file a petition proposing the issuance, amendment, or repeal of a regulation under § 314.300 and section 507(F) of the act; or

(5) Notify FDA that the applicant agrees to an extension of the review period under section 505(c) of the act, so that the applicant can determine whether to respond further under paragraphs (a) (1), (2), (3), or (4) of this section. The applicant's notice is required to state the length of the extension. FDA will honor any reasonable request for such an extension. FDA will consider the applicant's failure to respond further within the extended review period to be a request to withdraw the application under § 314.65 or the abbreviated antibiotic application under § 314.99. A decision to withdraw an application or abbreviated antibiotic application is without prejudice to a refiling.

(b) FDA will send the applicant of an abbreviated new drug application an approvable letter only if the application substantially meets the requirements of this part and the agency believes that it can approve the abbreviated application if minor deficiencies in the draft labeling are corrected and final printed labeling is submitted. The approvable letter will describe the labeling deficiencies and state a time period within which the applicant must respond. Unless the applicant corrects the deficiencies by amendment or submits final printed labeling within the specified time period, FDA will refuse to approve the abbreviated application under § 314.127

§ 314.120 Not approvable letter to the applicant.

(a) The Food and Drug Administration will send the applicant a not approvable letter if the agency believes that the application or abbreviated antibiotic application may not be approved for one of the reasons given in § 314.125 or the abbreviated new drug application may not be approved for one of the reasons given in § 314.127 The not approvable letter will describe the deficiencies in the application or abbreviated application. Except as provided in paragraph (b), within 10 days after the date of the not approvable letter, the applicant shall:

(1) Amend the application or abbreviated application or notify FDA of an intent to file an amendment. The filing of an amendment or a notice of intent to file an amendment constitutes an agreement by the applicant to extend the review period under § 314.60 or § 314.96;

(2) Withdraw the application or abbreviated application. Except as provided in paragraph (b), FDA will consider the applicant's failure to respond within 10 days to a not approvable letter to be a request by the applicant to withdraw the application under § 314.65 or abbreviated application under § 314.99. A decision to withdraw the application or abbreviated application is without prejudice to refiling;

(3) For a new drug application, ask the agency to provide the applicant an opportunity for a hearing on the question of whether there are grounds for denying approval of the application under section 505(d) or section 505(j)(3) of the act. The applicant shall submit the request to the Division of Regulatory Affairs (HFD-360), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857 Within 60 days of the date of the not approvable letter, or within a different time period to which FDA and the applicant agree, the agency will either approve the application or abbreviated application under § 314.105

or refuse to approve the application or abbreviated antibiotic application under § 314.125 or abbreviated new drug application under § 314.127 and give the applicant written notice of an opportunity for a hearing under § 314.200 and section 505(c)(1)(B) or 505(j)(4)(C) of the act on the question of whether there are grounds for denying approval of the application under section 505(d) or 505(j)(3) of the act;

(4) For an antibiotic application, file a petition or notify FDA of an intent to file a petition proposing the issuance, amendment, or repeal of a regulation under § 314.300 and section 507(F) of the act; or

(5) Notify FDA that the applicant agrees to an extension of the review period under section 505(c)(1) or 505(j)(4)(A) of the act, so that the applicant can determine whether to respond further under paragraphs (a) (1), (2), (3), or (4) of this section. The applicant's notice is required to state the length of the extension. FDA will honor any reasonable request for such an extension. FDA will consider the applicant's failure to respond further within the extended review period to be a request to withdraw the application under § 314.65 or abbreviated application under § 314.99. A decision to withdraw an application or abbreviated application is without prejudice to a refiling.

(b) The 10-day time period in this section for responding to a not approvable letter does not apply to abbreviated new drug applications. FDA may consider the applicant's failure to respond within 180 days to a not approvable letter to be a request by the applicant to withdraw the abbreviated new drug application under § 314.99.

23. New § 314.122 is added to Subpart D to read as follows:

§ 314.122 Submitting an application for, or a 505(j)(2)(C) petition that relies on, a listed drug that is no longer marketed.

(a) An abbreviated new drug application that refers to, or a petition under section 505(j)(2)(C) of the act and § 314.93 that relies on, a listed drug that has been voluntarily withdrawn from sale in the United States must be accompanied by a petition seeking a determination whether the listed drug was withdrawn for safety or effectiveness reasons. The petition must be submitted under §§ 10.25(a) and 10.30 of this chapter and must contain all evidence available to the petitioner concerning the reasons for the withdrawal from sale.

(b) When a petition described in paragraph (a) of this section is submitted, the agency will consider the evidence in the petition and any other evidence before the agency, and determine whether the listed drug is withdrawn from sale for safety or effectiveness reasons, in accordance with the procedures in § 314.161.

(c) An abbreviated new drug application described in paragraph (a) of this section will be disapproved, pursuant to § 314.127(k), and a 505(j)(2)(C) petition described in paragraph (a) of this section will be disapproved, pursuant to § 314.93(e)(1)(iv), unless the agency determines that the withdrawal of the listed drug was not for safety or effectiveness reasons.

(d) Certain drug products approved for safety and effectiveness that were no longer marketed on September 24, 1984, are not included in the list. Any person who wishes to obtain marketing approval for such a drug product under an abbreviated new drug application must petition FDA for a determination whether the drug product was withdrawn from the market for safety or effectiveness reasons and request that the list be amended to include the drug product. A person seeking such a determination shall use the petition procedures established in § 10.30 of this chapter. The petitioner shall include in the petition information to show that the drug product was approved for safety and effectiveness and all evidence available to the petitioner concerning the reason that marketing of the drug product ceased.

24. Section 314.125 is amended by revising the section heading, the introductory text of paragraph (a), the introductory text of paragraph (b), paragraphs (b) (7), (9), (10), (12), (14), (15), (16), and by adding new paragraph (b)(17) to read as follows:

§ 314.125 Refusal to approve an application or abbreviated antibiotic application.

(a) The Food and Drug Administration will refuse to approve the application or abbreviated antibiotic application and for a new drug give the applicant written notice of an opportunity for a hearing under § 314.200 on the question of whether there are grounds for denying approval of the application under section 505(d) of the act, or for an antibiotic publish a proposed regulation based on an acceptable petition under § 314.300, if:

(b) FDA may refuse to approve an application or abbreviated antibiotic application for any of the following reasons:

(7) The application or abbreviated antibiotic application contains an untrue statement of a material fact.

(9) The application or abbreviated antibiotic application does not contain bioavailability or bioequivalence data required under Part 320.

(10) A reason given in a letter refusing to file the application or abbreviated antibiotic application under § 314.101(d), if the deficiency is not corrected.

(12) The applicant does not permit a properly authorized officer or employee of the Department of Health and Human Services an adequate opportunity to inspect the facilities, controls, and any records relevant to the application or abbreviated antibiotic application.

(14) The application or abbreviated antibiotic application does not contain an explanation of the omission of a report of any investigation of the drug product sponsored by the applicant, or an explanation of the omission of other information about the drug pertinent to an evaluation of the application or abbreviated antibiotic application that is received or otherwise obtained by the applicant from any source.

(15) A nonclinical laboratory study that is described in the application or abbreviated antibiotic application and that is essential to show that the drug is safe for use under the conditions prescribed, recommended, or suggested in its proposed labeling was not conducted in compliance with the good laboratory practice regulations in Part 58 of this chapter and no reason for the noncompliance is provided or, if it is, the differences between the practices used in conducting the study and the good laboratory practice regulations do not support the validity of the study.

(16) Any clinical investigation involving human subjects described in the application or abbreviated antibiotic application, subject to the institutional review board regulations in Part 56 or informed consent regulations in Part 50 of this chapter, was not conducted in compliance with those regulations such that the rights or safety of human subjects were not adequately protected.

(17) For a new drug, the application failed to contain the patent information required by section 505(b)(1) of the act and § 314.53.

24a. New § 314.127 is added to Subpart D to read as follows:

§ 314.127 Refusal to approve an abbreviated new drug application.

FDA will refuse to approve an abbreviated application for a new drug under section 505(j) of the act for any of the following reasons:

(a) The methods used in, or the facilities and controls used for, the manufacture, processing, and packing of the drug product are inadequate to assure and preserve its identity, strength, quality, and purity;

(b) Information submitted with the abbreviated new drug application is insufficient to show that each of the proposed conditions of use have been previously approved for the listed drug referred to in the application;

(c)(1) If the reference listed drug has only one active ingredient, information submitted with the abbreviated new drug application is insufficient to show that the active ingredient is the same as that of the reference listed drug.

(2) If the reference listed drug has more than one active ingredient, information submitted with the abbreviated new drug application is insufficient to show that the active ingredients are the same as the active ingredients of the reference listed drug, or

(3) If the reference listed drug has more than one active ingredient and if the abbreviated new drug application is for a drug product which has an active ingredient different from the reference listed drug,

(i) Information submitted with the abbreviated new drug application is insufficient to show:

(A) That the other active ingredients are the same as the active ingredients of the reference listed drug, or

(B) That the different active ingredient is an active ingredient of a listed drug or a drug which does not meet the requirements of section 201(p) of the act, or

(ii) No petition to submit an abbreviated application for the drug product with the different active ingredient was approved under § 314.93;

(d)(1) If the abbreviated new drug application is for a drug product whose route of administration, dosage form, or strength purports to be the same as that of the listed drug referred to in the abbreviated new drug application, information submitted in the abbreviated new drug application is insufficient to show that the route of administration, dosage form, or strength is the same as that of the reference listed drug, or

(2) If the abbreviated new drug application is for a drug product whose route of administration, dosage form, or strength is different from that of the listed drug referred to in the application, no petition to submit an abbreviated new drug application for the drug product with the different route of administration, dosage form, or strength was approved under § 314.93.

(e) If the abbreviated new drug application was submitted pursuant to the approval of a petition under § 314.93, the abbreviated new drug application did not contain the information required by FDA with respect to the active ingredient, route of administration, dosage form, or strength that is not the same as that of the reference listed drug;

(f)(1) Information submitted in the abbreviated new drug application is insufficient to show that the drug product is bioequivalent to the listed drug referred to in the abbreviated new drug application or, (2) if the abbreviated new drug application was submitted pursuant to a petition approved under § 314.93, information submitted in the abbreviated new drug application is insufficient to show that the active ingredients of the drug product are of the same pharmacological or therapeutic class as those of the reference listed drug and that the drug product can be expected to have the same therapeutic effect as the reference listed drug when administered to patients for each condition of use approved for the reference listed drug;

(g) Information submitted in the abbreviated new drug application is insufficient to show that the labeling proposed for the drug is the same as the labeling approved for the listed drug referred to in the abbreviated new drug application except for changes required because of differences approved in a petition under § 314.93 or because the drug product and the reference listed drug are produced or distributed by different manufacturers;

(h)(1) Information submitted in the abbreviated new drug application or any other information available to FDA shows that:

(i) The inactive ingredients of the drug product are unsafe for use, as described in paragraph (h)(2) of this section, under the conditions prescribed, recommended, or suggested in the labeling proposed for the drug product, or

(ii) The composition of the drug product is unsafe, as described in paragraph (h)(2) of this section, under the conditions prescribed, recommended, or suggested in the proposed labeling because of the type or quantity of inactive ingredients included or the manner in which the inactive ingredients are included;

(2)(i) FDA will consider the inactive ingredients or composition of a drug product unsafe and refuse to approve an abbreviated new drug application under paragraph (h)(1) of this section if, on the basis of information available to the agency, there is a reasonable basis to conclude that one or more of the inactive ingredients of the proposed drug or its composition raise serious questions of safety. From its experience with reviewing inactive ingredients, and from other information available to it, FDA may identify changes in inactive ingredients or composition that may adversely affect a drug product's safety. The inactive ingredients or composition of a proposed drug product will be considered to raise serious questions of safety if the product incorporates one or more of these changes. Examples of the changes that raise serious questions of safety include:

(A) change in an inactive ingredient so that the product does not comply with an official compendium.

(B) A change in composition to include an inactive ingredient that has not been previously approved in a drug product for human use by the same route of administration.

(C) A change in the composition of a parental drug product to include an inactive ingredient that has not been previously approved in a parental drug product.

(D) A change in composition of a drug product for ophthalmic use to include an inactive ingredient that has not been previously approved in a drug for ophthalmic use.

(E) The use of a controlled release mechanism never before approved for the drug.

(F) A change in composition to include a significantly higher concentration of one or more inactive ingredients than previously used in the drug product.

(G) If the drug product is intended for topical administration, a change in the properties of the vehicle or base that might increase absorption of certain potentially toxic active ingredients thereby affecting the safety of the drug product, or a change in the lipophilic properties of a vehicle or base, e.g., a change from an oleaginous to a water soluble vehicle or base.

(ii) FDA will consider an inactive ingredient in, or the composition of, a drug product intended for parenteral use to be unsafe and will refuse to approve the abbreviated new drug application unless it contains the same inactive ingredients, other than preservatives, buffers, and antioxidants, in the same concentration as the listed drug, and, if it differs from the listed drug in a preservative, buffer, or antioxidant, the application contains sufficient

information to demonstrate that the difference does not affect the safety of the drug product.

(iii) FDA will consider an inactive ingredient in, or the composition of, a drug product intended for ophthalmic or otic use unsafe and will refuse to approve the abbreviated new drug application unless it contains the same inactive ingredients, other than preservatives, buffers, substances to adjust toxicity or thickening agents, in the same concentration as the listed drug, and if it differs from the listed drug in a preservative, buffer, substance to adjust toxicity or thickening agent, the application contains sufficient information to demonstrate that the difference does not affect the safety of the drug product and the labeling does not claim any therapeutic advantage over or difference from the listed drug.

(i) Approval of the listed drug referred to in the abbreviated new drug application has been withdrawn or suspended for grounds described in § 314.150(a) or FDA has published a notice of opportunity for hearing to withdraw approval of the reference listed drug under § 314.150(a);

(j) Approval of the reference listed drug has been withdrawn under § 314.151 or FDA has proposed to withdraw approval of the reference listed drug under § 314.151(a);

(k) FDA has determined that the reference listed drug has been withdrawn from sale for safety or effectiveness reasons under § 314.161, or the reference listed drug has been voluntarily withdrawn from sale and the agency has not determined whether the withdrawal is for safety or effectiveness reasons, or approval of the reference listed drug has been suspended under § 314.153, or the agency has issued an initial decision proposing to suspend the reference listed drug under § 314.153(a)(1);

(l) The abbreviated new drug application does not meet any other requirement under section 505(j)(2)(A) of the act; or

(m) The abbreviated new drug application contains an untrue statement of material fact.

25. Section 314.150 is revised to read as follows:

§ 314.150 Withdrawal of approval of an application or abbreviated application.

(a) The Food and Drug Administration will notify the applicant, and, if appropriate, all other persons who manufacture or distribute identical, related, or similar drug products as defined in §§ 310.6 and 314.151(a) and for a new drug afford an opportunity for a hearing on a proposal to withdraw approval of the application or abbreviated new drug application under section 505(e) of the act and under the procedure in § 314.200, or, for an antibiotic, rescind a certification or release, or amend or repeal a regulation providing for certification under section 507 of the act and under the procedure in § 314.300, if any of the following applies:

(1) The Secretary of Health and Human Services has suspended the approval of the application or abbreviated application for a new drug on a finding that there is an imminent hazard to the public health. FDA will promptly afford the applicant an expedited hearing following summary suspension on a finding of imminent hazard to health.

(2) FDA finds:

(i) That clinical or other experience, tests, or other scientific data show that the drug is unsafe for use under the conditions of use upon the basis of which the application or abbreviated application was approved; or

(ii) That new evidence of clinical experience, not contained in the application or not available to FDA until after the application or abbreviated application was approved, or tests by new methods, or tests by methods not deemed reasonably applicable when the application or abbreviated application was approved, evaluated together with the evidence available when the application or abbreviated application was approved, reveal that the drug is not shown to be safe for use under the conditions of use upon the basis of which the application or abbreviated application was approved; or

(iii) Upon the basis of new information before FDA with respect to the drug, evaluated together with the evidence available when the application or abbreviated application was approved, that there is a lack of substantial evidence from adequate and well-controlled investigations as defined in § 314.126, that the drug will have the effect it is purported or is represented to have under the conditions of use prescribed, recommended, or suggested in its labeling; or

(iv) That the application or abbreviated application contains any untrue statement of a material fact; or

(v) That the patent information prescribed by section 505(c) of the act was not submitted within 30 days after the receipt of written notice from FDA specifying the failure to submit such information.

(b) FDA may notify the applicant, and, if appropriate, all other persons who manufacture or distribute identical, related, or similar drug products as defined in § 310.6, and for a new drug afford an opportunity for a hearing on a proposal to withdraw approval of the application or abbreviated new drug application under section 505(e) of the act and under the procedure in § 314.200, or, for an antibiotic, rescind a certification or release, or amend or repeal a regulation providing for certification under section 507 of the act and the procedure in § 314.300, if the agency finds:

(1) That the applicant has failed to establish a system for maintaining required records, or has repeatedly or deliberately failed to maintain required records or to make required reports under section 505(k) or 507(g) of the act and §§ 314.80, 314.81, or 314.98, or that the applicant has refused to permit access to, or copying or verification of, its records.

(2) That on the basis of new information before FDA, evaluated together with the evidence available when the application or abbreviated application was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of the drug are inadequate to assure and preserve its identity, strength, quality, and purity and were not made adequate within a reasonable time after receipt of written notice from the agency.

(3) That on the basis of new information before FDA, evaluated together with the evidence available when the application or abbreviated application was approved, the labeling of the drug, based on a fair evaluation of all material facts, is false or misleading in any particular; and the labeling was not corrected by the applicant within a reasonable time after receipt of written notice from the agency.

(4) That the applicant has failed to comply with the notice requirements of section 510(j)(2) of the act.

(5) That the applicant has failed to submit bioavailability or bioequivalence data required under Part 320 of this chapter.

(6) The application or abbreviated application does not contain an explanation of the omission of a report of any investigation of the drug product sponsored by the applicant, or an explanation of the omission of other information about the drug pertinent to an evaluation of the application or abbreviated application that is received or otherwise obtained by the applicant from any source.

(7) That any nonclinical laboratory study that is described in the application or abbreviated application and that is essential to show that the drug is safe

for use under the conditions prescribed, recommended, or suggested in its labeling was not conducted in compliance with the good laboratory practice regulations in Part 58 of this chapter and no reason for the noncompliance was provided or, if it was, the differences between the practices used in conducting the study and the good laboratory practice regulations do not support the validity of the study.

(8) Any clinical investigation involving human subjects described in the application or abbreviated application, subject to the institutional review board regulations in Part 56 of this chapter or informed consent regulations in Part 50 of this chapter was not conducted in compliance with those regulations such that the rights or safety of human subjects were not adequately protected.

(c) FDA will withdraw approval of an application or abbreviated application if the applicant requests its withdrawal because the drug subject to the application or abbreviated application is no longer being marketed, provided none of the conditions listed in paragraphs (a) and (b) of this section apply to the drug. FDA will consider a written request for withdrawal under this paragraph to be a waiver of an opportunity for hearing otherwise provided for in this section. Withdrawal of approval of an application or abbreviated application under this paragraph is without prejudice to refiling.

(d) FDA may notify an applicant that it believes a potential problem associated with a drug is sufficiently serious that the drug should be removed from the market and may ask the applicant to waive the opportunity for hearing otherwise provided for under this section, to permit FDA to withdraw approval of the application or abbreviated application for the product, and to remove voluntarily the product from the market. If the applicant agrees, the agency will not make a finding under paragraph (b) of this section, but will withdraw approval of the application or abbreviated application in a notice published in the **Federal Register** that contains a brief summary of the agency's and the applicant's views of the reasons for withdrawal.

26. New § 314.151 is added to Subpart D to read as follows:

§ 314.151 Withdrawal of approval of an abbreviated new drug application pursuant to section 505(j)(5) of the act.

(a) Approval of an abbreviated new drug application approved under § 314.105(d) may be withdrawn when the agency withdraws approval, under § 314.150(a) or under this section, of the approved drug referred to in the abbreviated new drug application. If the agency proposes to withdraw approval of a listed drug under § 314.150(a), the holder of an approved application for the listed drug has a right to notice and opportunity for hearing. The published notice of opportunity for hearing will identify all drug products approved under § 314.105(d) whose applications are subject to withdrawal under this section if the listed drug is withdrawn, and will propose to withdraw such drugs. Holders of approved applications for the identified drug products will be provided notice and an opportunity to respond to the proposed withdrawal of their applications as described in paragraphs (b) and (c) of this section.

(b)(1) The published notice of opportunity for hearing on the withdrawal of the listed drug will serve as notice to holders of identified abbreviated new drug applications of the grounds for the proposed withdrawal.

(2) Holders of applications for drug products identified in the notice of opportunity for hearing may submit written comments on the notice of opportunity for hearing issued on the proposed withdrawal of the listed drug. If an abbreviated new drug application holder submits comments on the notice of opportunity for hearing and a hearing is granted, the abbreviated new drug application holder may participate in the hearing as a nonparty participant as provided for in § 12.89 of this chapter.

(3) Except as provided in paragraphs (c) and (d) of this section, the approval of an abbreviated new drug application for a drug product identified in the notice of opportunity for hearing on the withdrawal of a listed drug will be withdrawn when the agency has completed the withdrawal of approval of the listed drug.

(c)(1) If the holder of an application for a drug identified in the notice of opportunity for hearing has submitted timely comments but does not have an opportunity to participate in a hearing because a hearing is not requested or is settled, the submitted comments will be considered by the agency, which will issue an initial decision. The initial decision will respond to the comments, and contain the agency's decision whether there are grounds to withdraw approval of the listed drug and of the abbreviated new drug applications on which timely comments were submitted. The initial decision will be sent to each abbreviated new drug application holder that has submitted comments.

(2) Abbreviated new drug application holders to whom the initial decision was sent, may, within 30 days of the issuance of the initial decision submit written objections.

(3) The agency may, at its discretion, hold a limited oral hearing to resolve dispositive factual issues that cannot be resolved on the basis of written submissions.

(4) If there are no timely objections to the initial decision, it will become final at the expiration of 30 days.

(5) If timely objections are submitted, they will be reviewed and responded to in a final decision.

(6) The written comments received, the initial decision, the evidence relied on in the comments and in the initial decision, the objections to the initial decision, and, if a limited oral hearing has been held, the transcript of that hearing and any documents submitted therein, shall form the record upon which the agency shall make a final decision.

(7) Except as provided in paragraph (d) of this section, any abbreviated new drug application whose holder submitted comments on the notice of opportunity for hearing shall be withdrawn upon the issuance of a final decision concluding that the listed drug should be withdrawn for grounds as described in § 314.150(a). The final decision shall be in writing and shall constitute final agency action, reviewable in a judicial proceeding.

(8) Documents in the record will be publicly available in accordance with § 10.20(j) of this chapter. Documents available for examination or copying will be placed on public display in the office of the Dockets Management Branch promptly upon receipt in that office.

(d) If the agency determines, based upon information submitted by the holder of an abbreviated new drug application, that the grounds for withdrawal of the listed drug are not applicable to a drug identified in the notice of opportunity for hearing, the final decision will state that the approval of the abbreviated new drug application for such drug is not withdrawn.

27. Section 314.152 is revised to read as follows:

§ 314.152 Notice of withdrawal of approval of an application or abbreviated application for a new drug.

If the Food and Drug Administration withdraws approval of an application or abbreviated application for a new drug, FDA will publish a notice in the **Federal Register** announcing the withdrawal of

approval. If the application or abbreviated application was withdrawn for grounds described in § 314.150(a) or § 314.151, the notice will announce the removal of the drug from the list of approved drugs published pursuant to section 505(j)(6) of the act and shall satisfy the requirement of § 314.162(b).

28. New § 314.153 is added to Subpart D to read as follows:

§ 314.153 Suspension of approval of an abbreviated new drug application.

(a) The approval of an abbreviated new drug application approved pursuant to § 314.105(d) shall be suspended for the period stated when:

(1) The Secretary, pursuant to the imminent hazard authority of section 505(e) of the act or the authority of this paragraph, suspends approval of a listed drug referred to in the abbreviated new drug application, for the period of the suspension;

(2) The agency, in the notice described in paragraph (b) of this section, or in any subsequent written notice given an abbreviated new drug application holder by the agency, concludes that the risk of continued marketing and use of the drug is inappropriate, pending completion of proceedings to withdraw or suspend approval under § 314.151 or paragraph (b) of this section; or

(3) The agency, pursuant to the procedures set forth in paragraph (b) of this section, issues a final decision stating his determination that the abbreviated application is suspended because the listed drug on which the approval of the abbreviated new drug application depends has been withdrawn from sale for reasons of safety or effectiveness or has been suspended under paragraph (b) of this section. The suspension will take effect on the date stated in the decision and will remain in effect until the agency determines that the marketing of the drug has resumed or that the withdrawal is not for safety or effectiveness reasons.

(b) *Procedures for suspension of abbreviated new drug applications when a listed drug is voluntarily withdrawn for safety or effectiveness reasons.* (1) If a listed drug is voluntarily withdrawn from sale, and the agency determines that the withdrawal from sale was for reasons of safety or effectiveness, the agency will send each holder of an approved abbreviated new drug application that is subject to suspension as a result of the determination a copy of the agency's initial decision setting forth the reasons for the determination. The initial decision will also be placed on file with the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, Rockville, MD 20857

(2) Each abbreviated new drug application holder will have 30 days from the issuance of the initial decision to present, in writing, comments and information bearing on the initial decision. If no comments or information are received, the initial decision will become final at the expiration of 30 days.

(3) Comments and information received within 30 days of the issuance of the initial decision will be considered by the agency and responded to in a final decision.

(4) The agency may, in its discretion, hold a limited oral hearing to resolve dispositive factual issues that cannot be resolved on the basis of written submissions.

(5) If the final decision affirms the agency's initial decision that the listed drug was withdrawn for reasons of safety or effectiveness, the decision will be published in the **Federal Register** in compliance with § 314.152, and will, except as provided in paragraph (b)(6) of this section, suspend approval of all abbreviated new drug applications identified pursuant to paragraph (b)(1) of this section and remove from the list the listed drug and any drug whose approval was suspended pursuant to this paragraph. The notice will satisfy the requirement of § 314.162(b). The agency's final decision and copies of materials on which it relies will also be filed with the Dockets Management Branch (address in paragraph (b)(1) of this section).

(6) If the agency determines in its final decision that the listed drug was withdrawn for reasons of safety or effectiveness but, based upon information submitted by the holder of an abbreviated new drug application, also determines that the reasons for the withdrawal of the listed drug are not relevant to the safety and effectiveness of the drug subject to such abbreviated new drug application, the final decision will state that the approval of such abbreviated new drug application is not suspended.

(7) Documents in the record will be publicly available in accordance with § 10.20(j) of this chapter. Documents available for examination or copying will be placed on public display in the Dockets Management Branch (address in paragraph (b)(1) of this section) promptly upon receipt in that office.

29. Section 314.160 is revised to read as follows:

§ 314.160 Approval of an application or abbreviated application for which approval was previously refused, suspended, or withdrawn.

Upon the Food and Drug Administration's own initiative or upon request of an applicant, FDA may, on the basis of new data, approve an application or abbreviated application which it had previously refused, suspended, or withdrawn approval. FDA will publish a notice in the **Federal Register** announcing the approval.

30. New §§ 314.161 and 314.162 are added to Subpart D to read as follows:

§ 314.161 Determination of reasons for voluntary withdrawal of a listed drug.

(a) A determination whether a listed drug that has been voluntarily withdrawn from sale was withdrawn for safety or effectiveness reasons may be made by the agency at any time after the drug has been voluntarily withdrawn from sale, but must be made:

(1) Prior to approving an abbreviated new drug application that refers to the listed drug;

(2) Whenever a listed drug is voluntarily withdrawn from sale and abbreviated new drug applications that referred to the listed drug have been approved; and

(3) When a person petitions for such a determination under §§ 10.25(a) and 10.30 of this chapter.

(b) Any person may petition under §§ 10.25(a) and 10.30 of this chapter for a determination whether a listed drug has been voluntarily withdrawn for safety or effectiveness reasons. Any such petition must contain all evidence available to the petitioner concerning the reason that the drug is withdrawn from sale.

(c) If the agency determines that a listed drug is withdrawn from sale for safety or effectiveness reasons, the agency will, except as provided in paragraph (d) of this section, publish a notice of the determination in the **Federal Register.**

(d) If the agency determines under paragraph (a) of this section that a listed drug is withdrawn from sale for safety or effectiveness reasons and there are approved abbreviated new drug applications that are subject to suspension under section 505(j)(5) of the act, FDA will initiate a proceeding in accordance with § 314.153(b).

(e) A drug that the agency determines is withdrawn for safety or effectiveness reasons will be removed from the list, pursuant to § 314.162. The drug may be relisted if the agency has evidence that marketing of the drug has resumed or that the withdrawal is not for safety or

effectiveness reasons. A determination that the drug is not withdrawn for safety or effectiveness reasons may be made at any time after its removal from the list, upon the agency's initiative or upon the submission of a petition pursuant to §§ 10.25(a) and 10.30 of this chapter. If the agency determines that the drug is not withdrawn for safety or effectiveness reasons, the agency shall publish a notice of this determination in the **Federal Register**. The notice will also announce that the drug is relisted, pursuant to § 314.162(c). The notice will also serve to reinstate approval of all suspended abbreviated new drug applications that referred to the listed drug.

§ 314.162 Removal of a drug product from the list.

(a) FDA will remove a previously approved new drug product from the list for the period stated when:

(1) The agency withdraws or suspends approval of a new drug application or an abbreviated new drug application pursuant to § 314.150(a) or § 314.151 or pursuant to the imminent hazard authority of section 505(e) of the act, for the same period as the withdrawal or suspension of the application; or

(2) The agency, in accordance with the procedures in § 314.153(b) or § 314.161, issues a final decision stating that the listed drug was withdrawn from sale for safety or effectiveness reasons, or suspended pursuant to § 314.153(b), until the agency, determines that the withdrawal from the market has ceased or is not for safety or effectiveness reasons.

(b) FDA will publish a notice announcing the removal of a drug from the list in the **Federal Register**.

(c) At the end of the period specified in paragraph (a) (1) or (2) of this section, FDA will relist a drug that has been removed from the list. The agency will publish a notice announcing the relisting of the drug in the **Federal Register**.

31. Section 314.200 is amended by revising the introductory text of paragraph (a), paragraphs (b) (1) and (2), the last sentence in paragraph (c)(1), and paragraph (c)(3), and the first sentence in paragraph (g)(1) to read as follows:

§ 314.200 Notice of opportunity for hearing; notice of participation and request for hearing; grant or denial of hearing.

(a) *Notice of opportunity for hearing.* The Director of the Center for Drug Evaluation and Research, Food and Drug Administration, will give the applicant, and all other persons who manufacture or distribute identical, related, or similar drug products as defined in § 310.6 of this chapter, notice and an opportunity for a hearing on the Center's proposal to refuse to approve an application or abbreviated application or to withdraw the approval of an application or abbreviated application pursuant to section 505(e) of the act. The notice will state the reasons for the action and the proposed grounds for the order.

(b)

(1) To any person who has submitted an application or abbreviated application, by delivering the notice in person or by sending it by registered or certified mail to the last address shown in the application or abbreviated application.

(2) To any person who has not submitted an application or abbreviated application but who is subject to the notice under § 310.6 of this chapter, by publication of the notice in the **Federal Register**.

(c)(1) *Notice of participation and request for a hearing, and submission of studies and comments.* The applicant, or other person, may incorporate by reference the raw data underlying a study if the data were previously submitted to FDA as part of an application, abbreviated application or other report.

(3) Any other interested person who is not subject to the notice of opportunity for a hearing may also submit comments on the proposal to withdraw approval of the application or abbreviated application. The comments are requested to be submitted within the time and under the conditions specified in this section.

(g)

(1) Where a specific notice of opportunity for hearing (as defined in paragraph (a)(1) of this section) is used, the Commissioner will enter summary judgment against a person who requests a hearing, making findings and conclusions, denying a hearing, if it conclusively appears from the face of the data, information, and factual analyses in the request for the hearing that there is no genuine and substantial issue of fact which precludes the refusal to approve the application or abbreviated application or the withdrawal of approval of the application or abbreviated application; for example, no adequate and well-controlled clinical investigations meeting each of the precise elements of § 314.126 and, for a combination drug product, § 300.50 of this chapter, showing effectiveness have been identified.

32. Section 314.430 is amended by revising the section heading, paragraphs (a), (b), (c), and (d), the introductory text of paragraph (e), paragraphs (f) (5) and (6), and the introductory text of paragraph (g), to read as follows:

§ 314.430 Availability for public disclosure of data and information in an application or abbreviated application.

(a) The Food and Drug Administration will determine the public availability of any part of an application or abbreviated application under this section and Part 20 of this chapter. For purposes of this section, the application or abbreviated application includes all data and information submitted with or incorporated by reference in the application or abbreviated application, including investigational new drug applications, drug master files under § 314.420, supplements submitted under § 314.70 or § 314.97 reports under § 314.80 or § 314.98, and other submissions. For purposes of this section, safety and effectiveness data include all studies and tests of a drug on animals and humans and all studies and tests of the drug for identity, stability, purity, potency, and bioavailability.

(b) FDA will not publicly disclose the existence of an application or abbreviated application before an approvable letter is sent to the applicant under § 314.110, unless the existence of the application or abbreviated application has been previously publicly disclosed or acknowledged. The Center for Drug Evaluation and Research will maintain and make available for public disclosure a list of applications or abbreviated applications for which the agency has sent an approvable letter to the applicant.

(c) If the existence of an unapproved application or abbreviated application has not been publicly disclosed or acknowledged, no data or information in the application or abbreviated application is available for public disclosure.

(d) If the existence of an application or abbreviated application has been publicly disclosed or acknowledged before the agency sends an approval letter to the applicant, no data or information contained in the application or abbreviated application is available for public disclosure before the agency sends an approval letter, but the Commissioner may, in his or her discretion, disclose a summary of selected portions of the safety and effectiveness data that are appropriate

for public consideration of a specific pending issue, for example, for consideration of an open session of an FDA advisory committee.

(e) After FDA sends an approval letter to the applicant, the following data and information in the application or abbreviated application are immediately available for public disclosure, unless the applicant shows that extraordinary circumstances exist. A list of approved applications and abbreviated applications, entitled "Approved Drug Products with Therapeutic Equivalence Evaluations, is available from the Government Printing Office, Washington DC 20402. The list is updated monthly.

(f)

(5) For applications submitted under section 505(b) of the act, the effective date of the approval of the first abbreviated application submitted under section 505(j) of the act which refers to such drug, or the date on which the approval of an abbreviated application under section 505(j) which refers to such drug could be made effective if such an abbreviated application had been submitted.

(6) For applications or abbreviated applications submitted under sections 505(j), 506, and 507 of the act, when FDA sends an approval letter to the applicant.

(g) The following data and information in an application or abbreviated application are not available for public disclosure unless they have been previously disclosed to the public as set forth in § 20.81 of this chapter or they relate to a product or ingredient that has been abandoned and they do not represent a trade secret or confidential commercial or financial information under § 20.61 of this chapter:

33. Section 314.440 is amended by revising the section heading and paragraph (a), introductory text, and paragraphs (a) (1) and (2) to read as follows:

§ 314.440 Addresses for applications and abbreviated applications.

(a) Applicants shall send applications, abbreviated applications, and other correspondence relating to matters covered by this part, except for products listed in paragraph (b) of this section, to the Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857 and directed to the appropriate office identified below:

(1) An application under § 314.50 or § 314.54 submitted for filing should be directed to the Central Document Room, Center for Drug Evaluation and Research, Park Bldg., Rm. 214, 12420 Parklawn Dr., Rockville, MD 20852. Applicants may obtain folders for binding applications from that office. After FDA has filed the application, the agency will inform the applicant which division is responsible for the application. Amendments, supplements, resubmissions, requests for waivers, and other correspondence about an application that has been filed should be directed to the appropriate division.

(2) An abbreviated application under § 314.94, and amendments, supplements, resubmissions, and other correspondence about an abbreviated application should be directed to the Division of Generic Drugs (HFD-230). Applicants may obtain folders for binding abbreviated applications from that office.

PART 320—BIOAVAILABILITY AND BIOEQUIVALENCE REQUIREMENTS

34. Part 320 is amended by revising the table of contents, by adding an authority citation to follow the table of contents, and by removing the authority citations following § 320.1 and the authority citations following the headings for Subparts B and C to read as follows:

PART 320—BIOAVAILABILITY AND BIOEQUIVALENCE REQUIREMENTS

Subpart A—General Provisions

Sec.
320.1 Definitions.

Subpart B—Procedures for Determining the Bioavailability or Bioequivalence of Drug Products

320.21 Requirements for submission of in vivo bioavailability and bioequivalence data.
320.22 Criteria for waiver of evidence of in vivo bioavailability or bioequivalence.
320.23 Basis for demonstrating bioavailability or bioequivalence.
320.24 Types of evidence to establish bioavailability or bioequivalence.
320.25 Guidelines for the conduct of an in vivo bioavailability study.
320.26 Guidelines on the design of a single-dose in vivo bioavailability study.
320.27 Guidelines on the design of a multiple-dose in vivo bioavailability study.
320.28 Correlation of bioavailability with an acute pharmacological effect or clinical evidence.
320.29 Analytical methods for an in vivo bioavailability study.
320.30 Inquiries regarding bioavailability and bioequivalence requirements and review of protocols by the Food and Drug Administration.
320.31 Applicability of requirements regarding an "Investigational New Drug Application"
320.32 Criteria and evidence to assess actual or potential bioequivalence problems.
320.33 Requirements for batch testing and certification by the Food and Drug Administration.
320.34 Requirements for in vitro testing of each batch.
320.35 Requirements for maintenance of records of bioequivalence testing.

Authority: Secs. 201(p), 501, 502, 505, 701(a) (21 U.S.C. 321(p), 351, 352, 355, 371(a)).

§ 320.1 [Amended]

35. Section 320.1 is amended by revising paragraphs (a) and (e), and by removing paragraph (f) to read as follows:

329 § 320.1 Definitions.

(a) "Bioavailability" means the rate and extent to which the active ingredient or active moiety is absorbed from a drug product and becomes available at the site of action. For drug products that are not intended to be absorbed into the bloodstream, bioavailability may be assessed by measurements intended to reflect the rate and extent to which the active ingredient or active moiety becomes available at the site of action.

(e) "Bioequivalence" means the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study. Where there is an intentional difference in rate (e.g., in certain controlled release dosage forms), certain pharmaceutical equivalents or alternatives may be considered bioequivalent if there is no significant difference in the extent to which the active ingredient or moiety from each product becomes available at the site of drug action. This applies only if the difference in the rate at which the active ingredient or moiety becomes available at the site of drug action is reflected in the proposed labeling, is not essential to the attainment of effective body drug concentrations on chronic use, and is considered medically insignificant for the drug.

36. Part 320 is amended by revising the heading for Subpart B, §§ 320.21, 320.22, 320.23, 320.24, 320.30, and 320.31, and by removing the heading for Subpart C to read as follows:

Subpart B—Procedures for Determining the Bioavailability or Bioequivalence of Drug Products

§ 320.21 Requirements for submission of in vivo bioavailability and bioequivalence data.

(a) Any person submitting a full new drug application to the Food and Drug Administration (FDA) shall include in the application either:

(1) Evidence demonstrating the in vivo bioavailability of the drug product that is the subject of the application; or

(2) Information to permit FDA to waive the submission of evidence demonstrating in vivo bioavailability.

(b) Any person submitting an abbreviated new drug application to FDA shall include in the application either:

(1) Evidence demonstrating that the drug product that is the subject of the abbreviated new drug application is bioequivalent to the reference listed drug (defined in § 314.3(b)); or,

(2) Information to show that the drug product is bioequivalent to the reference listed drug which would permit FDA to waive the submission of evidence demonstrating bioequivalence as provided in paragraph (f) of this section.

(c) Any person submitting a supplemental application to FDA shall include in the supplemental application the evidence or information set forth in paragraph (a) and (b) of this section if the supplemental application proposes any of the following changes:

(1) A change in the manufacturing process, including a change in product formulation or dosage strength, beyond the variations provided for in the approved application.

(2) A change in the labeling to provide for a new indication for use of the drug product, if clinical studies are required to support the new indication for use.

(3) A change in the labeling to provide for a new dosage regimen or for an additional dosage regimen for a special patient population, e.g., infants, if clinical studies are required to support the new or additional dosage regimen.

(d) FDA may approve a full new drug application, or a supplemental application proposing any of the changes set forth in paragraph (c) of this section, that does not contain evidence of in vivo bioavailability or information to permit waiver of the requirement for in vivo bioavailability data, if all of the following conditions are met:

(1) The application was under review by FDA on July 7 1977

(2) The application is otherwise approvable.

(3) The applicant agrees to submit, within the time specified by FDA, either:

(i) Evidence demonstrating the in vivo bioavailability of the drug product that is the subject of the application; or,

(ii) Information to permit FDA to waive demonstration of in vivo bioavailability.

(e) Evidence demonstrating the in vivo bioavailability and bioequivalence of a drug product shall be obtained using one of the approaches for determining bioavailability set forth in § 320.24.

(f) Information to permit FDA to waive the submission of evidence demonstrating in vivo bioavailability or bioequivalence shall meet the criteria set forth in § 320.22.

(g) Any person holding an approved full or abbreviated new drug application shall submit to FDA a supplemental application containing new evidence demonstrating the in vivo bioavailability or bioequivalence of the drug product that is the subject of the application if notified by FDA that:

(1) There are data demonstrating that the dosage regimen in the labeling is based on incorrect assumptions or facts regarding the pharmacokinetics of the drug product and that following this dosage regimen could potentially result in subtherapeutic or toxic levels; or,

(2) There are data demonstrating significant intra-batch and batch-to-batch variability, e.g., plus or minus 25 percent, in the bioavailability of the drug product.

(h) The requirements of this section regarding the submission of evidence demonstrating in vivo bioavailability and bioequivalence apply only to a full or abbreviated new drug application or a supplemental application for a finished dosage formulation.

§ 320.22 Criteria for waiver of evidence of in vivo bioavailability or bioequivalence.

(a) Any person submitting a full or abbreviated new drug application, or a supplemental application proposing any of the changes set forth in § 320.21(c), may request the Food and Drug Administration (FDA) to waive the requirement for the submission of evidence demonstrating the in vivo bioavailability or bioequivalence of the drug product that is the subject of the application. An applicant shall submit a request for waiver with the application. Except as provided in paragraph (g) of this section, FDA shall waive the requirement for the submission of evidence of in vivo bioavailability or bioequivalence if the drug product meets any of the provisions of paragraphs (b), (c), (d), or (e) of this section.

(b) For certain drug products the in vivo bioavailability or bioequivalence of the drug product may be self-evident. FDA shall waive the requirement for the submission of evidence obtained in vivo demonstrating the bioavailability or bioequivalence of these drug products. A drug product's in vivo bioavailability or bioequivalence is considered self-evident if the product meets one of the following criteria:

(1) The drug product:

(i) Is a solution intended solely for intravenous administration, and

(ii) Contains the same active and inactive ingredients in the same concentration as a drug product that is the subject of an approved full new drug application.

(2) The drug product:

(i) Is administered by inhalation as a gas, e.g., a medicinal or an inhalation anesthetic, and

(ii) Contains an active drug ingredient in the same dosage form as a drug product that is the subject of an approved full new drug application.

(3) The drug product:

(i) Is an oral solution, elixir, syrup, tincture, or similar other solubilized form,

(ii) Contains an active drug ingredient in the same concentration and dosage form as a drug product that is the subject of an approved full new drug application, and

(iii) Contains no inactive ingredient that may significantly affect absorption of the active drug ingredient or active moiety.

(c) FDA shall waive the requirement for the submission of evidence demonstrating the in vivo bioavailability of a parenteral drug product that is determined to be effective for at least one indication in a Drug Efficacy Study Implementation notice or that, upon submission of evidence, is shown to be identical in both active and inactive ingredient formulation to that drug as currently approved in a new drug application, if the drug product is not one of the following:

(1) A drug in suspension form.

(2) Phenytoin sodium powder for injection.

(d) FDA shall waive the requirement for the submission of evidence demonstrating the in vivo bioavailability of a solid oral dosage form (other than an enteric coated or controlled release dosage form) of a drug product determined to be effective for at least one indication in a Drug Efficacy Study Implementation notice or which is identical, related, or similar to such a drug product under § 310.6 of this chapter unless FDA has evaluated the drug product under the criteria set forth in § 320.32, included the drug product in the Approved Drug Products with Therapeutic Equivalence Evaluations

List, and rated the drug product as having a known or potential bioequivalence problem. A drug product so rated reflects a determination by FDA that an in vivo bioequivalence study is required.

(e) For certain drug products bioavailability or bioequivalence may be demonstrated by evidence obtained in vitro in lieu of in vivo data. FDA shall waive the requirement for the submission of evidence obtained in vivo demonstrating the bioavailability of the drug product if the drug product meets one of the following criteria:

(1) [Reserved]

(2) The drug product is in the same dosage form, but in a different strength, and is proportionally similar in its active and inactive ingredients to another drug product for which the same manufacturer has obtained approval and the following conditions are met:

(i) The bioavailability of this other drug product has been demonstrated,

(ii) Both drug products meet an appropriate in vitro test approved by FDA, and

(iii) The applicant submits evidence showing that both drug products are proportionally similar in their active and inactive ingredients.

(3) The drug product is, on the basis of scientific evidence submitted in the application, shown to meet an in vitro test that has been correlated with in vivo data.

(4) The drug product is a reformulated product that is identical, except for a different color, flavor, or preservative that could not affect the bioavailability of the reformulated product, to another drug product for which the same manufacturer has obtained approval and the following conditions are met:

(i) The bioavailability of the other product has been demonstrated, and

(ii) Both drug products meet an appropriate in vitro test approved by FDA.

(f) FDA, for good cause, may waive a requirement for the submission of evidence of in vivo bioavailability if waiver is compatible with the protection of the public health. For full new drug applications, FDA may defer a requirement for the submission of evidence of in vivo bioavailability if deferral is compatible with the protection of the public health.

(g) FDA, for good cause, may require evidence of in vivo bioavailability or bioequivalence for any drug product if the agency determines that any difference between the drug product and a listed drug may affect the bioavailability or bioequivalence of the drug product.

§ 320.23 Basis for demonstrating in vivo bioavailability or bioequivalence.

(a)(1) The in vivo bioavailability of a drug product is demonstrated if the product's rate and extent of absorption, as determined by comparison of measured 338 parameters, e.g., concentration of the active drug ingredient in the blood, urinary excretion rates, or pharmacological effects, do not indicate a significant difference from the reference material's rate and extent of absorption. For drug products that are not intended to be absorbed into the bloodstream, bioavailability may be assessed by measurements intended to reflect the rate and extent to which the active ingredient or active moiety becomes available at the site of action.

(2) Statistical techniques used shall be of sufficient sensitivity to detect differences in rate and extent of absorption that are not attributable to subject variability.

(3) A drug product that differs from the reference material in its rate of absorption, but not in its extent of absorption, may be considered to be bioavailable if the difference in the rate of absorption is intentional, is appropriately reflected in the labeling, is not essential to the attainment of effective body drug concentrations on chronic use, and is considered medically insignificant for the drug product.

(b) Two drug products will be considered bioequivalent drug products if they are pharmaceutical equivalents or pharmaceutical alternatives whose rate and extent of absorption do not show a significant difference when administered at the same molar dose of the active moiety under similar experimental conditions, either single dose or multiple dose. Some pharmaceutical equivalents or pharmaceutical alternatives may be equivalent in the extent of their absorption but not in their rate of absorption and yet may be considered bioequivalent because such differences in the rate of absorption are intentional and are reflected in the labeling, are not essential to the attainment of effective body drug concentrations on chronic use, and are considered medically insignificant for the particular drug product studied.

§ 320.24 Types of evidence to establish bioavailability or bioequivalence.

(a) Bioavailability or bioequivalence may be determined by several in vivo and in vitro methods. FDA may require in vivo or in vitro testing, or both, to establish the bioavailability of a drug product or the bioequivalence of specific drug products. Information on bioequivalence requirements for specific products is included in the current edition of FDA's publication Approved Drug Products with Therapeutic Equivalence Evaluations and any current supplement to the publication. The selection of the method used to meet an in vivo or in vitro testing requirement depends upon the purpose of the study, the analytical methods available, and the nature of the drug product. Applicants shall conduct bioavailability and bioequivalence testing using the most accurate, sensitive, and reproducible approach available among those set forth in paragraph (b) of this section. The method used must be capable of demonstrating bioavailability or bioequivalence, as appropriate, for the product being tested.

(b) The following in vivo and in vitro approaches, in descending order of accuracy, sensitivity, and reproducibility are acceptable for determining the bioavailability or bioequivalence of a drug product.

(1)(i) An in vivo test in humans in which the concentration of the active ingredient or active moiety and its active metabolites, in whole blood, plasma, serum, or other appropriate biological fluid is measured as a function of time. This approach is particularly applicable to dosage forms intended to deliver the active moiety to the bloodstream for systemic distribution within the body; or

(ii) An in vitro test that has been correlated with and is predictive of human in vivo bioavailability data; or

(iii) An in vivo test in animals that has been correlated with and is predictive of human bioavailability data.

(2) An in vivo test in humans in which the urinary excretion of the active moiety and its active metabolites are measured as a function of time. The intervals at which measurements are taken should ordinarily be as short as possible so that the measure of the rate of elimination is as accurate as possible. Depending on the nature of the drug product, this approach may be applicable to the category of dosage forms described in paragraph (b)(1)(i) of this section. This method is not appropriate where urinary excretion is not a significant mechanism of elimination.

(3) An in vivo test in humans in which an appropriate acute pharmacological effect of the active moiety and its active metabolites are measured as a function of time if such effect can be measured with sufficient accuracy, sensitivity, and reproducibility. This approach is applicable to the category of dosage

forms described in paragraph (b)(1)(i) of this section only when appropriate methods are not available for measurement of the concentration of the active moiety and its active metabolites in biological fluids or excretory products but a method is available for the measurement of an appropriate acute pharmacological effect. This approach may be particularly applicable to dosage forms that are not intended to deliver the active moiety to the bloodstream for systemic distribution.

(4) Well-controlled clinical trials in humans that establish the safety and effectiveness of the drug product, for purposes of establishing bioavailability or, appropriately designed comparative clinical trials, for purposes of demonstrating bioequivalence. This approach is the least accurate, sensitive, and reproducible of the general approaches for determining bioavailability or bioequivalence. For dosage forms intended to deliver the active moiety to the bloodstream for systemic distribution, this approach may be considered acceptable only when analytical methods cannot be developed to permit use of one of the approaches outlined in paragraphs (b)(1)(i) and (2) of this section, when the approaches described in paragraphs (b)(1) (ii) and (iii) and (b)(3) are not available. This approach may also be considered sufficiently accurate for determining the bioavailability or bioequivalence of dosage forms intended to deliver the active moiety locally, e.g., topical preparations for the skin, eye, and mucous membranes; oral dosage forms not intended to be absorbed, e.g., an antacid or radiopaque medium; and bronchodilators administered by inhalation if the onset and duration of pharmacological activity are defined.

(5) Any other approach deemed adequate to establish bioavailability or bioequivalence by the Food and Drug Administration (FDA).

(c) FDA may, notwithstanding prior requirements for establishing bioavailability or bioequivalence, require in vivo testing in humans of a product at any time if the agency has evidence that the product:

(1) May not produce therapeutic effects comparable to a pharmaceutical equivalent or alternative with which it is intended to be used interchangeably;

(2) May not be bioequivalent to a pharmaceutical equivalent or alternative with which it is intended to be used interchangeably; or

(3) Has greater than anticipated potential toxicity related to pharmacokinetic or other characteristics.

§ 320.30 Inquiries regarding bioavailability and bioequivalence requirements and review of protocols by the Food and Drug Administration.

(a) The Commissioner of Food and Drugs strongly recommends that, to avoid the conduct of an improper study and unnecessary human research, any person planning to conduct a bioavailability or bioequivalence study submit the proposed protocol for the study to the Food and Drug Administration (FDA) for review prior to the initiation of the study.

(b) FDA may review a proposed protocol for a bioavailability or bioequivalence study and will offer advice with respect to whether the following conditions are met:

(1) The design of the proposed bioavailability or bioequivalence study is appropriate.

(2) The reference material to be used in the bioavailability or bioequivalence study is appropriate.

(3) The proposed chemical and statistical analytical methods are adequate.

(c)(1) General inquiries relating to in vivo bioavailability requirements and methodology shall be submitted to the Food and Drug Administration, Center for Drug Evaluation and Research, Division of Biopharmaceutics (HFD-420), 5600 Fishers Lane, Rockville, MD 20857

(2) General inquiries relating to bioequivalence requirements and methodology shall be submitted to the Food and Drug Administration, Center for Drug Evaluation and Research, Division of Bioequivalence (HFD-250), 5600 Fishers Lane, Rockville, MD 20857

§ 320.31 Applicability of requirements regarding an "Investigational New Drug Application.

(a) Any person planning to conduct an in vivo bioavailability or bioequivalence study in humans shall submit an "Investigational New Drug Application (IND) if:

(1) The test product contains a new chemical entity as defined in § 314.108(a) of this chapter; or

(2) The study involves a radioactively labeled drug product; or

(3) The study involves a cytotoxic drug product.

(b) Any person planning to conduct a bioavailability study in humans using a drug product that contains an already approved non-new chemical entity shall submit an IND if the study is one of the following:

(1) A single-dose study in normal subjects or patients where either the single or total daily dose exceeds that specified in the labeling of the drug product that is the subject of an approved new drug application or abbreviated new drug application.

(2) A multiple-dose study in normal subjects or patients where either the single or total daily dose exceeds that specified in the labeling of the drug product that is the subject of an approved new drug application or abbreviated new drug application.

(3) A multiple-dose study on a controlled release product on which no single-dose study has been completed.

(c) The provisions of Part 312 of this chapter are applicable to any bioavailability or bioequivalence study conducted under an "Investigational New Drug Application.

(d) [Reserved]

(e) [Reserved]

(f) An in vivo bioavailability or bioequivalence study in humans shall be conducted in compliance with the requirements for institutional review set forth in Part 56 of this chapter, and informed consent set forth in Part 50 of this chapter, regardless of whether the study is conducted under an "Investigational New Drug Application.

§ 320.50 [Removed]

37 Section 320.50 *Purpose* is removed.

§ 320.51 [Removed]

38. Section 320.51 *Procedures for establishing or amending a bioequivalence requirement* is removed.

§ 320.52 [Redesignated as § 320.32]

39. Part 320 is amended by redesignating § 320.52 as § 320.32 in Subpart B, and by revising the section heading and the introductory paragraph to read as follows:

§ 320.32 Criteria and evidence to assess actual or potential bioequivalence problems.

The Commissioner shall consider the following factors, when supported by well-documented evidence, to identify specific pharmaceutical equivalents and pharmaceutical alternatives that are not or may not be bioequivalent drug products:

§ 320.53 [Removed]

40. Section 320.53 *Types of bioequivalence requirements* is removed.

§ 320.54 [Removed]

41. Section 320.54 *Contents of a petition to establish a bioequivalence requirement* is removed.

§§ 320.55 and 320.56 [Redesignated as §§ 320.33 and 320.34]

42. Part 320 is amended by redesignating § 320.55 *Requirements for batch testing and certification by the Food and Drug Administration* and § 320.56 *Requirements for in vitro testing of each batch* as §§ 320.33 and 320.34 in Subpart B, respectively.

§ 320.57 [Removed]

43. Section 320.57 *Requirements for the conduct of in vivo bioequivalence testing in humans* is removed.

§ 320.58 [Removed]

44. Section 320.58 *Requirements for marketing a drug product subject to a bioequivalence requirement* is removed.

§ 320.59 [Removed]

45. Section 320.59 *Bioequivalence requirements based on data voluntarily submitted* is removed.

§ 320.60 [Removed]

46. Section 320.60 *Bioequivalence requirements for a drug product subject to an old drug monograph* is removed.

§ 320.61 [Removed]

47 Section 320.61 *Requirements for in vivo testing of a drug product not meeting an in vitro bioequivalence standard* is removed.

§ 320.62 [Redesignated]

48. Part 320 is amended by redesignating § 320.62 *Requirements for maintenance of records of bioequivalance testing* as § 320.35 in Subpart B.

Dated: March 2, 1989.

Frank E. Young,

Commissioner of Food and Drugs.

[FR Doc. 89-16024 Filed 7-7-89; 8:45 am]

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Part III

Pension Benefit Guaranty Corporation

29 CFR Part 2610
Payment of Premiums; Final Rule

PENSION BENEFIT GUARANTY CORPORATION

29 CFR Part 2610

RIN 1212-AA53

Payment of Premiums

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Final rule.

SUMMARY: This final rule revises the Pension Benefit Guaranty Corporation s interim regulation on Payment of Premiums, 29 CFR Part 2610. The PBGC published the interim regulation expeditiously, on June 30, 1988, in order to provide necessary guidance for 1988 premium payments. Thereafter, on October 5, 1988, the PBGC issued a notice of proposed rulemaking that addressed certain issues not covered in the interim rule and that afforded the public the opportunity to comment on the entire premium regulation. The effect of this final regulation is to replace the interim rule, effective for premium payment years beginning on or after January 1, 1989.

EFFECTIVE DATE: July 10, 1989.

FOR FURTHER INFORMATION CONTACT: Harold J. Ashner, Senior Counsel, Office of the General Counsel (Code 22500), Pension Benefit Guaranty Corporation, 2020 K Street, NW Washington, DC 20006; telephone 202-778-8823 (202-778-8059 for TTY and TDD). These are not toll-free numbers.

SUPPLEMENTARY INFORMATION:

Background

The Omnibus Budget Reconciliation Act of 1987 Pub.L. 100-203, ("OBRA '87") includes the Pension Protection Act, which amends section 4006 of the Employee Retirement Income Security Act of 1974, as amended, ("ERISA") to establish a two-part premium structure for single-employer plans, *i.e.*, a flat rate per capita assessment and a variable rate assessment based on a plan's unfunded vested benefits, effective for plan years beginning on or after January 1, 1988. In order to reflect and to implement these changes, the Pension Benefit Guaranty Corporation (the "PBGC") on June 30, 1988, issued an interim rule revising its regulation on Payment of Premiums at 29 CFR Part 2610 (53 FR 24906). Because of the urgent need to provide plans with the rules for computing and paying premiums for 1988 plan years, the PBGC determined that it would be impracticable and contrary to the public interest to provide for notice of and public comment on that regulation prior to issuance.

On October 5, 1988, the PBGC issued a notice of proposed rulemaking that largely restated the interim rule, in order to solicit public comment (53 FR 39200). The proposed rulemaking also included a number of proposed amendments to the interim rule and addressed a number of issues that the PBGC had not previously addressed. Twenty comments were submitted on the proposed rule, with most of the comments coming from actuarial consulting firms. The PBGC has reviewed these comments and has made a number of changes in the regulation in response to them. The PBGC has also made other changes in the regulation on its own initiative, many of them in response to questions asked by plan professionals preparing their 1988 premium filings.

Statutory and Regulatory Framework

The statutory provisions governing the variable rate premium are discussed in some detail in the preamble to the interim regulation and are only briefly summarized here. Under section 9331 of OBRA '87 (amending ERISA section 4006), the single-employer plan premium for plan years beginning on or after January 1, 1988, is composed of a flat rate per capita assessment (as under prior law) and a new variable rate assessment that is based on the value of a plan's unfunded vested benefits and is also determined on a per participant basis (section 4006(a)(3)(A) and (a)(3)(E)). The flat rate assessment is $16 per participant.

ERISA section 4006(a)(3)(E) provides the basic formula for computing the variable rate assessment for each participant: $6 for each $1,000 (or fraction thereof) of a plan's "unfunded vested benefits" (determined as of the last day of the preceding plan year) with that product divided by the number of participants in the plan as of the last day of the preceding plan year. The variable rate assessment is subject to a statutory ceiling (ERISA section 4006(a)(3)(E)(iv)(I)) of $34 per participant, resulting in a maximum per participant premium of $50. This $34 statutory ceiling is subject to reduction based on the contribution history of the plan.

The formula for computing the variable rate assessment for each participant is based, in large part, on the determination of the plan's "unfunded vested benefits. This term is defined in the statute (ERISA section 4006(a)(3)(E)(iii)) as the amount that would be the plan's "unfunded current liability" (within the meaning of ERISA section 302(d)(8)(A)) as of the close of the preceding plan year, subject to two qualifications: (1) Only vested benefits are taken into account in the calculation (ERISA section 4006(a)(3)(E)(iii)(I)); and (2) The interest rate used in valuing vested benefits must equal 80% of the annual yield on 30-year Treasury securities for the month preceding the month in which the plan year begins (ERISA section 4006(a)(3)(E)(iii)(II)).

The PBGC's proposed rule, like the interim rule, provided two methods for determining the amount of a plan's unfunded vested benefits. Under the "general rule" (§ 2610.23(a)), an enrolled actuary must determine the amount of the plan's unfunded vested benefits as of the last day of the plan year preceding the premium payment year based on the plan's provisions and population as of that date, and must certify that the determination was made in a manner consistent with generally accepted actuarial principles and practices. Under the "alternative calculation method" (§ 2610.23(c)), which is subject to certain restrictions for large plans (*i.e.*, those with 500 or more participants), the plan administrator must calculate the amount of the plan's unfunded vested benefits based on certain data from the plan's Form 5500, Schedule B, for the plan year preceding the premium payment year, using formulae specified in the regulation. Finally, both the interim rule and the proposed rule provide a number of exemptions and special rules (§ 2610.24) regarding the variable rate portion of the premium.

General Comments

While most of the comments addressed particular sections of the proposed regulation, some addressed more general matters. These general comments are discussed first.

Two commenters objected to the increase in the flat rate assessment to $16. The new premium structure was designed to generate enough revenue to eliminate the PBGC's deficit over a reasonable period of time and to pay future claims and expenses as they are incurred. The introduction of a premium charge based on plan underfunding permits a fairer allocation of cost among plans based on their funding levels. However, it would not have been possible to generate all the additional revenue needed from a charge on underfunded plans without overburdening these plans and, in many cases, the companies maintaining them. The combination of flat rate and variable rate charges enacted by the Congress reflects a careful balancing of concerns for equity and affordability. Finally, the PBGC points out that the

increase in the flat rate assessment is required by statute and is thus outside the scope of the PBGC's rulemaking authority.

Three commenters objected to the imposition of a variable rate assessment on plans that, while underfunded for premium purposes, are overfunded for funding purposes. The reason that this may occur is that the statutory interest rate used for premium purposes is different from the rate or rates used for funding purposes. The statute does not exempt plans at the full funding limit from the variable rate premium requirements, and the PBGC does not have the authority to create such an exemption by regulation.

Five commenters expressed concern about the administrative burden and the related costs imposed on plans as a result of the variable rate premium requirements. The comments focused particularly on the burdens for small plans (*i.e.*, those with fewer than 100 participants). (One of these commenters argued, erroneously, that the premium requirements are burdensome for small plans in that actuarial certification is required; in fact, under the alternative calculation method, such certification is required only for plans with more than 500 participants (§ 2610.23(d)).) Two of the commenters suggested that small plans be exempted from the variable rate premium. The PBGC has no authority under the law to exempt small plans from the new premium requirements, and thus has not adopted this suggestion.

Nevertheless, the PBGC shares the concerns expressed by the commenters. The new statutory rules obviously add complexity to the premium payment process and, as a result, some level of increased burden and cost is unavoidable. The PBGC has attempted in the premium regulation to keep these burdens and costs to a minimum. Thus, for example, the interim and proposed regulations permit plans to use data collected for other purposes as the starting point for determining unfunded vested benefits under the general rule; provide plans with the option of using a simplified alternative calculation method; include a number of exemptions and special rules to simplify or, in some cases, to eliminate calculation requirements; and establish a later due date for the variable rate portion of the premium. Moreover, this final regulation contains additional simplifications not included in the interim or proposed regulations. The PBGC will continue to explore ways in which it may further reduce the burdens and costs imposed on premium payers in a manner consistent with the pertinent statutory requirements.

The premium regulation requires enrolled actuaries to make a number of determinations in a manner consistent with generally accepted actuarial principles and practices. One commenter requested that the PBGC elaborate on the scope of the actuary's responsibility under the regulation, the penalties the actuary could face, and the recourse available to the actuary in connection with any such penalty.

The responsibility of the actuary, simply put, is to comply with the premium regulation in a manner consistent with generally accepted actuarial principles and practices. The PBGC, of course, does not establish these principles and practices. If the PBGC has reason to believe that an actuary has not met this responsibility and premiums are underpaid as a result, the PBGC may bring appropriate legal action against an actuary. In addition, the PBGC may refer a matter involving apparent misfeasance by an actuary to an appropriate authority, such as the Joint Board for the Enrollment of Actuaries. The penalties that might be imposed in this event, and the recourse available to the actuary, are matters that fall outside the jurisdiction of the PBGC.

The same commenter requested that the PBGC provide specific guidelines regarding the degree of error in a premium filing that would be material enough to require an amended filing, and asked to whom the enrolled actuary should report any such error and how the error should be reported. Another commenter asked whether an amended premium filing is required if the plan would not owe a variable rate amount under both the original and the amended filing. An enrolled actuary who determines that a premium filing is erroneous is required to report the error to the plan administrator, and the plan administrator is required to correct the error through an amended premium filing with the PBGC. These steps must be followed anytime the enrolled actuary or the plan administrator determines that any of the data reported on the premium payment forms or any of the underlying data were incorrect. Of course, in cases where the error resulted in an underpayment of the premium, the PBGC would assess interest and, unless waived, penalties.

Another commenter proposed that plan administrators submit the plan's Schedule B to the PBGC as part of the plan's premium filing, and that the PBGC compute the plan's premium obligation based on the data on the Schedule B. The PBGC does not have the staff to do this and, thus, has not adopted the proposal.

In the proposed rule, the PBGC solicited public comment on the frequency with which it should update the interest rates in Appendix B. One commenter addressed this issue, expressing a preference that the PBGC continue updating Appendix B on a monthly basis so as to facilitate the ability of actuaries to calculate a plan's premium obligation as part of a plan valuation prepared early in the plan year.

After careful consideration of this matter, the PBGC has concluded that the best approach is to consolidate the publication of both sets of interest rates under the premium regulation on a quarterly basis, to publish these rates on the same date as the various other Title IV rates are published, and to continue the monthly distribution of PBGC rates to plan professionals through the PBGC's "Technical Updates. As an example, the PBGC will publish on October 13, 1989, (because the normal publication date, the 15th, is a Sunday) the Appendix A late payment interest rate applicable to the October to December quarter and the Appendix B valuation interest rates for August, September and October. (The PBGC notes that under this system, it would publish the Appendix A rate every quarter, even when there is no change from the prior quarter. This change is made in response to complaints from practitioners that they have difficulty keeping track of the Appendix A rate under the current system in which a new rate is published only when there is a rate change.)

The valuation interest rates collected in Appendix B change monthly, and a given rate applies with respect to all premium payment years beginning during that month. Thus, for a calendar year plan, the January interest rate is used to value vested benefits for the variable rate portion of the premium due on September 15. Because few plan professionals do plan valuations at the very beginning of a plan year, the PBGC does not believe that a one or two month delay in its publication of the interest rates in the **Federal Register** will be an inconvenience. Those actuaries that are doing a valuation within the first two months of a plan year can obtain the rates by subscribing to the PBGC's monthly "Technical Updates" (for which the PBGC has a mailing list of some 4,000 plan professionals) or by checking the pertinent Federal Reserve Board publications, Statistical Release G.13 and H.15.

Finally, one commenter requested that the PBGC specify which changes in the premium regulation are effective only for 1989 and later premium payment years. In order to provide the clearest possible guidance for the public, the PBGC has indicated in the final regulation which provisions apply for which premium payment years. Unless otherwise indicated, Subpart A of the final regulation (covering both single-employer and multiemployer plans) is effective for all premium payment years; Subpart B (covering single-employer plans only) is effective for post-1987 premium payment years; and Subpart C is effective for all premium payment years for multiemployer plans and for pre-1988 premium payment years for single-employer plans.

Section 2610.2—Definitions

One commenter suggested a change in the definition of active participant (§ 2610.2(a)(2)) to permit plans not to count as participants for premium purposes certain non-vested individuals that leave employment. The PBGC has received numerous inquiries about the same subject since the Retirement Equity Act of 1984 ("REA") established certain rights for non-vested individuals who had left employment. The specific suggestion in the comment was to exclude non-vested employees who had either incurred a one-year break-in-service (or had a one-year severance from service in a plan using elapsed time vesting rules), or who had quit or been discharged. The PBGC is generally sympathetic to the commenter's position, but believes that nonvested individuals should not be dropped from the premium count as soon as they separate from employment, regardless of the reason for separation. The final regulation, like the proposed and interim regulations, excludes from the definition of participant for premium purposes individuals who have had a break in service the greater of one year or the break-in-service period specified in the plan. For example, in a plan with a one-year or shorter break-in-service period, a nonvested individual would be counted as a participant for premium purposes if he or she left covered employment less than a year before the participant count date but would not be counted if he or she left a year or more before the participant count date. The PBGC does not believe that counting the former individual as a participant creates an undue premium burden.

On a related issue, the PBGC notes that under REA, a nonvested participant who has a break in service retains credit for the pre-break service if the number of consecutive one-year breaks is equal to or less than the greater of five years or the aggregate pre-break service. Apparently after REA, some plans were amended to redefine a break-in-service period as five years instead of one year. However, a plan with a break-in-service period longer than one year may be amended prospectively to provide for five consecutive one-year break-in-service periods and still meet the REA requirements. This amendment may reduce the number of individuals that must be counted as participants for premium purposes and thus provide the premium relief sought by the commenter.

Finally, the PBGC notes that the instructions to the PBGC Form 1 have been misleading on this point, in that the instructions have stated that the participant count reported on the Form 1 should usually be the same as the Form 5500 participant count for the plan year preceding the premium payment year. This probably would not be true for a plan that has a five-year or 60-month break-in-service period. Accordingly, the 1989 Form 1 instructions will be clarified on this point and will provide that the Form 5500 participant count may be used as a safe harbor for premium computation purposes.

Section 2610.3—Forms

One commenter suggested that the PBGC publish its annual premium Payment Package (which contains the Form 1-ES, Form 1 and Schedule A, along with instructions) in proposed form each year so as to give the public an opportunity to comment on it. While agency forms are not typically published as proposals for public comment, as are regulations, there is an existing procedure for the public to comment on agency forms prior to their issuance. This procedure is established under the Paperwork Reduction Act of 1980, as amended, and is administered by the Office of Management and Budget ("OMB"). *See* 5 CFR Part 1320.

Any time an agency wants to issue a new or revised form, that form must first be approved by OMB. (Every approved form carries an OMB number in the upper right-hand corner.) In addition, forms that do not change must nevertheless be re-approved by OMB every three years. When an agency submits a form to OMB for approval, it must publish concurrently a notice in the **Federal Register** advising the public that it has requested approval of the form, stating where copies of the form can be obtained and how interested persons may submit comments on the form. This review period normally runs 60 days. The PBGC Form 1, Form 1-ES and Schedule A go through this procedure, and the PBGC welcomes public comment on the forms.

One commenter suggested that the PBGC adopt a "substitute forms" program like that of the Internal Revenue Service (the "IRS"), so that plan professionals can input data into their computers and run the data off directly onto suitable forms that could be filed with the PBGC. While the PBGC does not presently have staff resources adequate to review and to approve substitute forms, as is done under the IRS program, it will permit the use of re-typed or other facsimile forms. However, any such forms must present the same information items, with each in the same location, as on the PBGC forms. A form that does not satisfy this condition may be treated as not having been filed and returned to the submitter.

Section 2610.4—Mailing Address

One commenter requested that the PBGC publish a street address for premium filings, in addition to the Post Office Box address it now publishes, so that mail delivery services other than the U.S. Postal Service may compete for delivery of premium filings. The PBGC agrees and has amended § 2610.4 to include a street address.

Section 2610.11—Recordkeeping Requirements; PBGC Audits

Section 2610.11 of the proposed regulation required plan administrators to retain "all plan records that are necessary to support or to validate premium payments. One commenter suggested that the PBGC instead require only that plan administrators retain documentation needed to support adjustments made to entries reported (or to be reported) on the Schedule B, since the documentation needed to support the Schedule B must already be retained under section 107 of ERISA. The PBGC has not adopted this suggestion. The PBGC's recordkeeping requirement is needed to enable the PBGC to monitor and to enforce compliance with the premium regulation and, as such, it is properly included in the premium regulation. Because this recordkeeping requirement is, as the commenter states, largely duplicative of the recordkeeping requirements of section 107 of ERISA, it should not impose any significant additional burden on plan administrators.

Section 2610.22(a)(3)—Cap on Variable Rate Amount

One commenter objected to the proposed rule in § 2610.22(a)(3)(iii) establishing the qualifications for the cap reduction when the sponsor

maintains at least one defined contribution plan and at least one defined benefit plan. The comment asserted that, as written, the rule would require that contributions to the defined benefit plan had equalled the Code section 404(a)(7)(A) limit in order for the plans to qualify for the cap reduction, determined without regard to participant coverage of the plans. The comment objected to this result.

The PBGC notes that the rule as proposed referenced Code section 404(a)(7)(A), which, by its own terms, applies only in situations where a plan sponsor maintains both defined contribution and defined benefit plans and some employees are participants in both. (The final regulation has been revised to reflect explicitly this common-participation requirement.) In all other situations (*e.g.*, both defined contribution and defined benefit plans but with separate participant groups, or multiple defined benefit plans covering overlapping groups of participants but no defined contribution plans), the general maximum deductibility rules in Code section 404 (a)(1)–(a)(3) apply, as does the usual rule under the premium regulation that all plans maintained by the same sponsor (or controlled group) are treated separately. Thus, if a sponsor maintained several defined benefit plans but no defined contribution plans, the determination of whether the cap reduction applied would be made in a plan-by-plan basis, comparing the contributions to each against the maximum deductible limit for each during the five base period years. This rule is unchanged even if the plans cover some of the same participants.

The PBGC has also revised § 2610.22(a)(3)(iii) to clarify that it applies only when the plan did not receive the maximum deductible amount determined without regard to the Code section 404(a)(7)(A) limitation. Thus, a covered defined benefit plan does not lose the benefit of the cap reduction merely because the contributing sponsor reduced contributions to another covered defined benefit plan below the Code section 404(a)(1) limitation in order to meet the Code section 404(a)(7)(A) limitation.

A commenter requested that the PBGC provide for carryover of contributions where a contributing sponsor credits a contribution to the plan's funding standard account for a particular plan year, but does not reflect the contribution for deduction purposes until the contributing sponsor's next taxable year. The statutory provisions governing the cap reduction measure the contribution history of the plan with respect to plan years rather than taxable years. The taxable year in which the contribution is reflected for deduction purposes is not relevant, and there is thus no need to provide for carryover rules.

The PBGC stated in the preamble to the proposed rule that it was considering whether the cap reduction should apply in the case of a plan maintained by a nonprofit entity and, if so, how to determine whether a contribution during the base period equalled the maximum deductible amount. One commenter addressed these issues, arguing that, since nonprofit entities get the maximum tax deduction with a contribution of zero dollars, they should get the benefit of the cap reduction even if they made no contribution during a base period year. The PBGC does not believe that this approach is consistent with the underlying purpose of the cap reduction, *i.e.*, to provide relief in the case of plan sponsors that attempted to improve the plan's funding level by making the maximum deductible contribution, and therefore has not adopted it.

The PBGC believes that a plan maintained by a nonprofit entity should get the benefit of the cap reduction on the same basis as for-profit entities, *i.e.*, when the nonprofit entity made contributions in amounts that would have been the maximum deductible contribution under Code section 404 if the contributing sponsor were a for-profit entity. This approach furthers the purposes of the cap reduction by providing relief in the case of all plan sponsors that made comparable attempts to improve the plan's funding level, irrespective of the tax status of the sponsor. Accordingly, beginning with the 1989 premium payment year, a plan maintained by a nonprofit entity is entitled to the cap reduction with respect to a base period year if an enrolled actuary certifies that the amounts contributed to the plan for that year were at least equal to the amount that would have been the maximum deductible contribution if the contributing sponsor of the plan was a for-profit entity.

A question has been raised in connection with a 1988 premium filing as to whether and under what circumstances the cap reduction applies in the case of plans that have received funding waivers. The IRS permits the contributing sponsor of such a plan to deduct (subject to the full funding limit) contributions sufficient to create a credit balance in the funding standard account (as of the end of the plan year) equal to the total of the outstanding balances of all waived funding deficiencies. Accordingly, if the credit balance in the plan's funding standard account (as of the end of the plan year) for a base period year is less than this total, the plan did not receive the maximum deductible contribution and thus is not entitled to the benefit of the cap reduction with respect to that base period year.

One commenter requested that the PBGC establish rules providing for the pass-through of the cap reduction in the case of mergers and spinoffs. Such rules would have to be complex in order to deal properly with all transfers of plan liabilities. The PBGC does not believe that the addition of this complexity to the premium regulation is warranted, particularly since the cap reduction is only a transitional, and thus temporary, part of the premium structure.

Section 2610.22(d)—Special refund rule for certain short plan years

The PBGC stated in the preamble to the proposed rule that it had decided not to promulgate the lengthy and complicated rules that would be needed to eliminate so-called "duplicate premiums" in connection with certain mergers, consolidations and spinoffs. Two commenters requested that the PBGC issue such rules. For the reasons stated in the proposed rule preamble, the PBGC is not doing so at this time. However, the PBGC will continue to consider whether to issue these rules at a future time.

The PBGC did propose a special refund rule for short plan years resulting from events other than multiple plan transactions (§ 2610.22(d)). This special rule, covering short initial plan years, changes in plan years and short final plan years, is effective beginning with the 1989 premium payment year. (However, as noted in the preamble to the proposed rule (53 FR 39205), the special refund rule applicable to a change in plan years is a codification of the PBGC's existing practice with regard to pre-1989 premium payment years.) One commenter requested that the PBGC extend the special refund rule to apply to the 1988 premium payment year. The retroactive application of this rule would create significant administrative burdens for the PBGC. In addition, the PBGC sees no reason in this case to depart from the general principle of prospective rulemaking. Accordingly, the PBGC has decided not to change the effective date of this special rule.

Finally, one commenter suggested that the refund for a plan's final short plan

year be determined by treating the plan year as ending (in the case of a standard termination) at the expiration of the period within which the PBGC may issue a notice of noncompliance under ERISA section 4041(b)(2)(C). The statute does not permit this. Under ERISA section 4007(a), premiums continue to accrue until the plan's assets are distributed pursuant to the termination procedure, or until a trustee is appointed pursuant to ERISA section 4042, whichever is earlier. Accordingly, the PBGC has not adopted this suggestion.

Section 2610.23(a)—General rule

The PBGC stated in the preamble to the proposed rule that it is left to the enrolled actuary to decide, in a manner consistent with generally accepted actuarial principles and practices, whether to perform a separate valuation for premium purposes or to rely on an existing valuation. One commenter objected to the PBGC's reference in this context to generally accepted actuarial principles and practices, arguing that the actuary's decision to rely on an existing valuation may be based on the unavailability of the data needed to perform a new valuation, rather than on generally accepted actuarial principles and practices. The concept of generally accepted actuarial principles and practices necessarily encompasses practical considerations such as the availability of needed data and, therefore, is adequate to define the actuary's responsibility in the context cited.

One commenter requested guidance regarding the adjustments an actuary would have to make to an earlier valuation (*e.g.*, a valuation performed as of the first day of the prior plan year) so as to reflect the plan's population on the statutory date for determining unfunded vested benefits (*i.e.*, the last day of the prior plan year). As the PBGC stated in the preamble to the interim rule, the actuary may determine the plan's population either on the basis of an actual census or a representative sample of the plan's population. It is up to the enrolled actuary to determine, in a manner consistent with generally accepted actuarial principles and practices, what data to collect, and what sampling technique to use, in connection with any such sample.

The same commenter stated that the requirement that the actuary determine the plan's population as of the last day of the prior plan year is burdensome in the case of a plan for which the valuation is done as of a date other than the first or last day of the plan year. The commenter recommended that the actuary be permitted in such a case to base the determination of the plan's unfunded vested benefits on the plan's population as of any date in the prior plan year. The PBGC has not adopted this recommendation. Under the statute, a plan's unfunded vested benefits must be determined as of the last day of the prior plan year, irrespective of the date as of which the plan valuation is performed. Moreover, the problem does not appear to be a significant one. In this connection, the PBGC points out that relatively few plans have a valuation date other than the first or last day of the plan year; that the actuary for such a plan may, as noted above, rely on a representative sample rather than on an actual census; and that the plan may avoid the problem altogether by using the alternative calculation method.

The PBGC has made a change in the general rule regarding premium valuations that are done as of the first day of the premium payment year. Under the proposed rule, the actuary was required to base such a valuation on the assumptions and methods used for funding purposes for the prior plan year. The PBGC has revised the final rule (§ 2610.23(a)(1)) to provide that when the actuary is using a valuation as of the first day of the premium payment year, that valuation must be based on the assumptions and methods used for funding purposes for the premium payment year. However, the PBGC reminds enrolled actuaries that if the premium valuation results are materially different than what would have been determined as of the last day of the prior plan year, the enrolled actuary is required to make adjustments so as to reflect appropriately the values as of the last day of the prior plan year (except where the unadjusted valuation would result in greater unfunded vested benefits) (§ 2610.23(a)(2)).

Finally, the PBGC reminds plan professionals that the various adjustments and modifications required or permitted under the general rule (and under the alternative calculation method) in determining a plan's unfunded vested benefits apply only for premium calculation purposes and are not applicable to the determination of current liability under section 302 of ERISA and section 412 of the Code.

Section 2610.23(b)(1)—Vested Benefits Amount

One commenter requested that the PBGC clarify the assumptions to be used in determining the vested portion of current liability for premium purposes, or at least give interim guidance that may be used pending clarification by the IRS. The PBGC is unable to provide the requested guidance, because only the IRS has authority to prescribe the assumptions to be used in determining current liability. The PBGC has discussed this issue with the IRS, and the IRS is not yet ready to issue guidance on this matter.

Another commenter suggested that the PBGC require that the interest rate used in valuing vested benefits for premium purposes be the same for all plan years beginning in a given calendar year. The statute does not permit this. Under ERISA section 4006(a)(3)(E)(iii)(II), the required interest rate is tied to the month, rather than the calendar year, in which the plan year begins. Accordingly, the PBGC has not adopted this suggestion.

Finally, under the proposed regulation, both the general rule (§ 2610.23(b)(1)) and the alternative calculation method (§ 2610.23(c)) provided that vested benefits need not be adjusted to reflect the statutory interest rate if the rate (or rates) used under the plan to determine vested benefits was (or were all) lower than the statutory rate. A commenter suggested that the PBGC substitute "not greater than" for "lower than" so that a plan would have the benefit of the interest rate adjustment exemption even though one of the plan rates used to value vested benefits equalled the statutory rate. The PBGC agrees and has made the requested change both in the general rule and in the alternative calculation method.

In addition, the PBGC has made a minor revision in § 2610.23(b)(1) to delete the ambiguous reference to the interest rate used "in the plan's funding valuation, because for 1988 and later plan years, many plans will use a valuation interest rate determined under Code section 412(c)(3) for some purposes and the statutory rate prescribed under section 412(b)(5) for determining current liability. Therefore, § 2610.23(b)(1) is revised to refer to the interest rate used for determining current liability.

Section 2610.23(b)(2)—Actuarial Value of Assets

One commenter objected to the proposed rule's exclusion of contributions "for the premium payment year from the actuarial value of assets, pointing out that employer contributions enhance benefit security regardless of the plan year for which they are made. Initially, the PBGC notes that contributions for the premium payment year would rarely be part of a plan's assets as of the statutory date for determining unfunded vested benefits, *i.e.*, the last day of the prior plan year. Moreover, even in those few cases in

which an employer has made advance contributions for the premium payment year, the PBGC believes that it would be inappropriate to count those contributions as part of the plan s assets for premium purposes.

The determination of unfunded vested benefits serves as a snapshot of the plan s funding status as of the end of the plan year preceding the premium payment year. Changes in plan liabilities relating to the premium payment year are not taken into account, whether they result from benefit accruals, benefit payouts, a change in actuarial assumptions or methods, a plan amendment or other causes. Similarly, any increase or decrease in asset values during the premium payment year is irrelevant, regardless of the cause. The PBGC believes that the inclusion of contributions for the premium payment year in the plan's asset values, without also taking into account the various other changes to asset and benefit values relating to the premium payment year, would distort the determination of the plan's unfunded vested benefits.

The same commenter requested guidance regarding how to determine whether a particular contribution is "for a plan year preceding the premium payment year. The plan year for which a contribution is made is the plan year for which the contribution is credited to the funding standard account as "the amount considered contributed by the employer to or under the plan for the plan year" pursuant to section 412(b)(2)(A) of the Code and section 302(b)(2)(A) of ERISA. If this designation has been ambiguous in the past, it should no longer be so, now that contributions must be paid quarterly. Beginning with contributions for the 1989 plan year, contributing sponsors will have to designate the plan year for which a contribution is to be credited so as to distinguish the quarterly contributions required during the plan year from the final contribution(s) made for the previous plan year.

The same commenter also requested that the PBGC eliminate the requirement that contributions paid during the premium payment year be discounted with interest to the last day of the prior plan year, arguing that such discounting is not required for funding purposes and therefore should not be required for premium purposes. Code section 412(c)(10)(A) provides for an eight and one-half month "grace period" for contributions, thereby eliminating the need for discounting of contributions made during that period. However, the funding rules recognize that the contribution was made after the last day of the plan year by treating the "lost" earnings on that contribution as an experience loss that is amortized over future plan years. No such mechanism exists for premium purposes. Thus, the only way to recognize, for premium purposes, the date on which the contribution is made is to discount the contribution on a current basis.

The proposed rule specifies that the interest rate used to discount contributions is the plan asset valuation rate under the general rule (§ 2610.23(b)(2)) and the statutory rate under the alternative calculation method (§ 2610.23(c)(3)). Two commenters argued that the statutory rate should also be used to discount contributions under the general rule. The PBGC disagrees.

Under the general rule, all asset values must be determined in accordance with the plan s assumptions and methods used to value assets for funding purposes. It would be inconsistent with this requirement to discount the value of certain assets (i.e., contributions received after the last day of the plan year preceding the premium payment year) at a different interest rate. Under the alternative calculation method, in the interest of simplicity, contributions are discounted back to the first day of the plan year preceding the premium payment year at the same rate used to bring forward the value of the plan s unfunded vested benefits determined as of that date, i.e., the statutory 2ate. Thus, the discounting rules in the regulation ensure that the value of plan assets is adjusted in a manner appropriate to the method used for determining a plan's unfunded vested benefits.

Two commenters raised a number of questions concerning the requirement to discount contributions on a daily compound basis. (The proposed rule required daily compounding both under the general rule and the alternative calculation method.) The PBGC has modified this rule in the final regulation. With respect to the general rule, a plan must discount contributions at the plan asset valuation rate and in accordance with the plan's discounting rules. Thus, if a plan normally discounts asset values with interest compounded monthly, it is required to discount contributions at the plan's interest rate compounded monthly. This is consistent with the overall approach under the general rule of requiring plans to determine unfunded vested benefits using the same methods and assumptions that are used for funding purposes. This rule applies for 1988 and later premium payment years.

With respect to the alternative calculation method, the PBGC has determined that daily compounding of interest in the discounting calculation may be unduly burdensome for some plans. Accordingly, under the final rule, contributions are to be discounted at the statutory interest rate, with interest generally compounded annually. However, for any partial years within the discounting period, a plan may, at its discretion, use simple interest. This rule applies for premium payment years beginning on or after January 1, 1989. (For 1988 premium payment years, plans using the alternative calculation method were required simply to discount contributions at the statutory interest rate. Therefore, for 1988 premiums, any reasonable method of discounting is acceptable.)

Finally, the PBGC has made a change on its own initiative with respect to the adjustment for contributions in the case of a plan with fewer than 500 participants. Under the final regulation, such a plan is not required, under either the general rule or the alternative calculation method, to add to the value of plan assets contributions for plan years preceding the premium payment year. This will eliminate one more calculation, for all but the largest plans, in cases where the calculation would not affect the premium obligation because, *e.g.*, the plan is fully funded without the addition of contributions. This new rule applies for premium payment years beginning on or after January 1, 1989.

Section 2610.23(c)—Alternative Method for Calculating Unfunded Vested Benefits

Proposed § 2610.23(c) exempted plans from the interest rate adjustment requirement if the plan administrator certifies that the "plan's interest rate (or rates) used to determine the values in lines 6d(i) and 6d(ii) of the Schedule B was (or were all) lower than" the statutory rate. The PBGC has substituted "not greater than" for "lower" in this provision, for the same reasons noted above in the discussion of § 2610.23(b)(2). In addition, one commenter stated that the use of the term, "plan's interest rate, is confusing in that either the plan rate or the disclosure rate may be used to determine the values in line 6d of the Schedule B. (Whether the plan rate or the disclosure rate is used, it must, pursuant to the instructions for the 1988 Schedule B, be within 10% of the weighted average of the 30-year

Treasury bond rate as published by the IRS.) The PBGC agrees, and has therefore deleted the word, "plan s.

One commenter raised a question as to whether contributions made during the plan year preceding the premium payment year, but not included in the asset values reported on the Schedule B for that prior plan year, are to be included in the asset value under the alternative calculation method. Section 2610.23(c)(4) states that the asset values reported on the Schedule B (normally line 8b) are to be adjusted in accordance with the provisions governing asset values under the general rule (§ 2610.23(b)(2)), subject to the exception relating to discounting of contributions. Thus, as under the general rule, contributions for any plan year prior to the premium payment year are to be included (or may be included, for plans with fewer than 500 participants) in the asset value if paid by the earlier of the due date or payment date for the variable rate portion of the premium. This is so irrespective of whether the contribution is included in the asset values reported on the Schedule B.

The PBGC proposed the use under the alternative calculation method of a surrogate for calculating a plan's accruals during the plan year preceding the premium payment year (proposed § 2610.23(c)(1)). That surrogate was 7% of the value reported in line 6d(ii) of the Schedule B for vested benefits of active and deferred vested participants. The PBGC received one comment on this surrogate. That commenter objected to the surrogate on the basis that it would overstate benefit values for a plan with a low percentage of active participants. The commenter suggested that plans be permitted, as an alternative to the 7% surrogate, to use the value of the prior plan year's accruals as calculated for purposes of determining the "150% of current liability" full funding limit (Code section 412(c)(7)(A)(i)(I)). The PBGC has not adopted this suggestion because the calculation is not required to be reported on the Schedule B.

The PBGC has decided to include the 7% surrogate in the final regulation. Except for the above comment, the PBGC received no comments that objected to the use of the 7% surrogate or that suggested an alternative approach. While this surrogate will not be a precise measure of the prior plan year's accruals for each plan, the use of a surrogate that would be more reflective of each plan's population and benefit structure would involve substantial complications and would thus defeat the primary goal of keeping the alternative calculation method relatively simple. Those plans that believe they are disadvantaged by the use of the 7% surrogate are free to use the general rule.

The PBGC received numerous inquiries from plan administrators in connection with 1988 premium filings, regarding the computations required for the mathematical term, $.94^{(RIR-BIR)}$ in the alternative calculation method's interest rate adjustment formula. The PBGC recognizes that persons other than actuaries may have difficulty with this term, because it will generally contain an exponent that is fractional, negative or both. In order to simplify this computation, the PBGC has developed tables (§ 2610.23(c)(3)) that convert this term to a "substitution factor, expressed as a decimal fraction carried out to four decimal places. Thus, the user need only select the appropriate factor from the tables (based on the difference between the statutory interest rate and the interest rate used to determine the values on the Schedule B) and substitute that factor for the term, $.94^{(RIR-BIR)}$ in the interest rate adjustment formula.

The PBGC has rounded all substitution factors up or down, as appropriate, whichever produces the higher value of vested benefits. The impact of this rounding, however, is minimal for any given plan; at most, it would lead to an increase in the value of vested benefits of just under 1%. The use of this table is optional, and is effective beginning with the 1989 premium payment year.

The PBGC has received a number of inquiries from plan administrators attempting to complete 1988 premium filings for plans that have terminated, or that are in the process of doing so. These inquiries fall into two categories. First, in the case of standard terminations with proposed termination dates falling on or before the statutory date for determining unfunded vested benefits, plan administrators have argued that the PBGC should not impose any variable rate premium because the plan must provide funding for all benefits in order to satisfy the requirements for a standard termination. Second, in the case of distress and involuntary terminations in which the plan does not have a Schedule B for the plan year preceding the premium payment year, plan administrators have expressed concern that, because of the unavailability of the Schedule B needed for the alternative calculation method, they must incur the expense of a general rule determination.

The PBGC believes these concerns are valid and has, therefore, made two changes in the final premium regulation in response to these inquiries. First, a new variable rate exemption (§ 2610.24(a)(4)) exempts a plan from the variable rate portion of the premium if the plan is terminating in a standard termination with a proposed termination date during a plan year preceding the premium payment year. This exemption is conditional, subject to the plan's actually closing out in a standard termination. If the plan does not complete the standard termination and, thus, becomes an ongoing plan again, the unpaid variable rate portion(s) of the premium(s) will be due and payable with interest and, unless waived by the PBGC, penalties. In addition, the PBGC is adopting a new special rule (§ 2610.24(c)) applicable to plans undergoing distress or involuntary terminations with termination dates during a plan year preceding the premium payment year. These plans may use the Schedule B filed for the plan year in which the termination date fell, or, if the Schedule B for that plan year is not filed, the Schedule B for the preceding plan year, as the basis for the alternative calculation method. Both of these new rules are effective beginning with the 1989 premium payment year.

Finally, one commenter suggested that the PBGC not make reference in the premium regulation to specific line numbers on the Schedule B, since these line numbers may change and thus require a corresponding change in the premium regulation. The PBGC recognizes that the referenced line numbers may change, but has nonetheless decided to use specific line numbers in the premium regulation in the interest of ease of reference for premium payers.

Section 2610.23(d)—Restrictions on Alternative Calculation Method for Large Plans

One commenter requested guidance on how to perform the alternative calculation method in the case of a plan into which another plan has merged. If the merged plan has 500 or more participants, the merger (except if *de minimis*) must be recognized as a "significant event" requiring an appropriate adjustment by an enrolled actuary to the value of unfunded vested benefits. As is the case with all significant events, the enrolled actuary must make this adjustment in a manner consistent with generally accepted actuarial principles and practices. Thus, the various assumptions and formulae in the alternative calculation method may not be used as a "safe harbor in making this adjustment.

One commenter argued that two of the proposed significant events—§ 2610.23(d)(4) (dealing with certain shutdowns) and § 2610.23(d)(5) (dealing with certain early retirement windows)—are not automatically significant and thus should be deleted, with the result that they would be reflected only in the catch-all significant event in § 2610.23(d)(7). The PBGC recognizes that these two significant events will not result in all cases in a material increase in the value of unfunded vested benefits. Nonetheless, the PBGC believes that these events are of sufficient importance to require in all cases that an actuary determine their impact for premium purposes. Accordingly, the PBGC has retained these significant events in the final regulation.

Another commenter suggested that the PBGC delete the catch-all significant event in § 2610.23(d)(7) because it is too nebulous. While the PBGC has attempted to specify those significant events that are most likely to result in a material increase in the value of unfunded vested benefits, it is impossible to predict all such events. The PBGC finds that it is, therefore, necessary to retain § 2610.23(d)(7).

Section 2610.24—Variable Rate Exemptions and Special Rules

Two commenters objected to the PBGC's elimination of the "$5 rule" under the interim regulation for plans with fewer than 100 participants that had not reported the Schedule B data needed to use the alternative calculation method for the 1988 premium payment year. As the PBGC noted in the preamble to the proposed rule, the $5 rule was a temporary measure that is no longer necessary beginning with the 1989 premium payment year, because all plans, regardless of size, are now required to report on the Schedule B the data needed to use the alternative calculation method. The PBGC does not believe that the alternative calculation method is so burdensome for small plans as to justify retention of the $5 rule.

One commenter expressed concern that the PBGC not eliminate the $5 rule before the IRS finalizes the related change to Schedule B reporting requirements. While the Schedule B change was not yet final when the PBGC proposed the deletion of the $5 rule, it is in effect now.

Another commenter suggested that the PBGC impose certain restrictions on the use of the actuarial certification option (§ 2610.24(a)(1)) and on the use of the special rule permitting the enrolled actuary to report the value of accrued benefits in lieu of the value of vested benefits if the value of plan assets exceeds the value of accrued benefits (§ 2610.24(b)). Under the suggested restrictions, these options would be available only to plans using interest rates that do not exceed the statutory rate by a specified percentage, with that percentage linked to the plan's funding level. The PBGC does not believe that such restrictions are necessary. Under the regulation, the enrolled actuary may select these options only when the pertinent regulatory criteria are met, irrespective of the plan's interest rate or funding level. The PBGC expects to be able to monitor and to ensure compliance with these requirements through appropriate audits.

Section 2610.25—Filing Requirement

Four commenters requested that the filing deadline for the variable rate portion of the premium (which is September 15, 1989, for calendar year plans paying 1989 premiums) be changed to conform to the filing deadline for the prior plan year's Schedule B (which is generally September 15, 1989, for calendar year plans filing their 1988 Schedule B's, with extensions available to October 15, 1989). The PBGC has not adopted this suggestion.

Prior to enactment of the Pension Protection Act, PBGC premiums were due by the last day of the second month following the close of the prior plan year for large plans and by the last day of the seventh month following the close of the prior plan year for all other plans. With the enactment of the variable rate premium, however, it was apparent that the due date, at least for large plans, would have to be deferred. When the PBGC began to develop the new premium regulation and decided to give plans the option to use the Schedule B data as the basis for the premium calculation, it also decided to defer the premium due date for plans with fewer than 500 participants in order to approximate more closely the filing schedule for Form 5500.

However, in deciding to defer the premium due date, the PBGC also had to give close consideration to the impact this decision would have on its revenues. At a time when a major increase in premium rates was needed in order to preserve the solvency of the single-employer insurance system, the PBGC had to be very cautious in implementing rules that would have a negative impact on premium revenues. For this reason, the PBGC dismissed the idea of allowing plans to pay their premiums (or the variable rate portion of the premium in the case of large plans) at whatever filing deadline they had for the Form 5500. (Such a rule would also have created significant administrative burdens for the PBGC, because it would never know in advance what premium due date plans would be using. Plan administrators, too, would be disadvantaged by this uncertainty.)

The PBGC instead settled on a due date of the fifteenth day of the eighth calendar month following the month in which the premium payment year began (September 15 for calendar year plans). This date was chosen in recognition of the fact that many corporations routinely obtain the automatic extension of the due date for corporate tax returns, from March 15 to September 15 for calendar year tax years, and for corporate plan sponsors this automatically moves the Form 5500 due date to September 15.

While September 15 is, thus, the Form 5500 due date for a great number of premium payers, the PBGC recognizes that a significant number of plans do extend their Form 5500 due date to October 15. Nevertheless, the Schedule B data needed for the alternative calculation method ought to be, and generally is, available by the September 15 premium deadline. Under the alternative calculation method, it is not necessary that the Schedule B be filed before the PBGC Form 1 is completed and filed. Premium calculations can be based on the Schedule B data that is expected to be reported.

While an amended premium filing is required if that data, as ultimately reported on the Schedule B, is different, interest and penalties may be assessed only if the premium paid by the filing deadline is less than that required.

A number of plan professionals have asked the PBGC whether it is necessary for a plan to distribute excess assets in order for the premium obligation to cease accruing. Under section 4007(a) of ERISA and § 2610.25(e) of the proposed rule, the obligation to pay premiums continues through the plan year in which all plan assets are distributed pursuant to a plan's termination or in which a trustee is appointed under section 4042 of ERISA, whichever occurs first. For purposes of this rule, a plan's assets are considered distributed pursuant to a termination procedure upon the distribution of all assets that must be allocated to Priority Categories 1 through 6 of ERISA section 4044(a), irrespective of whether there are any assets to be allocated and distributed under ERISA section 4044(d).

Finally, the PBGC has had difficulty in securing voluntary compliance with premium requirements in a number of

cases involving terminating plans. Plan professionals involved in such cases are reminded that failure to pay premiums in accordance with these requirements may lead to a number of adverse consequences, including the addition of penalties and interest to the amount of the premium and the initiation of a lawsuit by the PBGC against any or all of the plan administrator, the contributing sponsor, and members of the contributing sponsor's controlled group. In addition, ERISA section 4003(e)(5) provides that, "[i]n any action brought under [Title IV of ERISA], whether to collect premiums, penalties and interest under section 4007 or for any other purpose, the court may award to the [PBGC] all or a portion of the costs of litigation incurred by the [PBGC] in connection with such action. The PBGC intends to pursue these remedies, as appropriate, in order to ensure compliance with the premium regulation.

E.O. 12291 and the Regulatory Flexibility Act

The PBGC has determined that this rule is a "major rule" within the meaning of Executive Order 12291, February 17 1981 (46 FR 13193) because the single-employer plan premium increase implemented in this regulation will have an annual effect on the economy of more than $100 million. In accordance with E.O. 12291, the PBGC has prepared a Regulatory Impact Analysis. Interested persons may obtain copies of the Regulatory Impact Analysis from the PBGC's Communications and Public Affairs Department (Code 38000), 2020 K Street, NW Washington, DC 20006.

Under section 605(b) of the Regulatory Flexibility Act, the PBGC certifies that these rules will not have a significant economic impact on a substantial number of small entities. The purpose and effect of this regulation is to provide rules for calculating the premium owed under ERISA section 4006. The costs attendant thereto for small pension plans (those with fewer than 100 participants) will not be significant, since virtually all such plans will either use the simplified calculation method or will be exempt from performing the calculation.

List of Subjects in 29 CFR Part 2610

Employee benefit plans, Penalties, Pension insurance, Pensions, Reporting and recordkeeping requirements.

In consideration of the foregoing, Part 2610 of Chapter XXVI of Title 29, Code of Federal Regulations, is revised as follows:

PART 2610—PAYMENT OF PREMIUMS

Subpart A—General Provisions

Sec.
2610.1 Purpose and scope.
2610.2 Definitions.
2610.3 Forms.
2610.4 Mailing address.
2610.5 Date of filing.
2610.6 Computation of time.
2610.7 Late payment interest charges.
2610.8 Late payment penalty charges.
2610.9 Coverage for guaranteed basic benefits.
2610.10 Special rule for certain mergers and spinoffs.
2610.11 Recordkeeping requirements; PBGC audits.

Subpart B—Single-Employer Premiums for Post-1987 Plan Years

2610.21 Purpose and scope.
2610.22 Premium rate.
2610.23 Determination of unfunded vested benefits.
2610.24 Variable rate exemptions and special rules.
2610.25 Filing requirement.
2610.26 Liability for premiums.

Subpart C—Single-Employer Premiums for Pre-1988 Plan Years; Multiemployer Premiums

2610.31 Purpose and scope.
2610.32 Single-employer premium rates.
2610.33 Multiemployer premium rates.
2610.34 Filing requirement.

Appendix A to Part 2610—Late Payment Interest Charges

Appendix B to Part 2610—Interest Rates For Valuing Vested Benefits

Authority: 29 U.S.C. 1302(b)(3), 1306, 1307 as amended by sec. 9331, Pub.L. 100-203, 101 Stat. 1330.

Subpart A—General Provisions

§ 2610.1 Purpose and scope.

(a) *Purpose.* The purpose of this part is to provide rules for computing and procedures for paying the premiums imposed by sections 4006 and 4007 of the Employee Retirement Income Security Act of 1974, as amended. Subpart A contains the rules that apply both to single-employer and multiemployer plans with respect to all plan years. These general rules cover such matters as the definitions of terms under this part, procedural requirements, and late payment interest and penalty charges. Subpart B contains the premium rates and due dates and computational rules for single-employer plans under the variable rate premium structure enacted as part of the Pension Protection Act. These rules apply to single-employer plans for plan years beginning on or after January 1, 1988 (except as otherwise specifically noted). Subpart C contains the premium rates and due dates for single-employer plans with respect to all prior plan years and for multiemployer plans with respect to all plan years.

(b) *Scope.* This part applies to all plans that are covered by Title IV of the Act pursuant to section 4021 of the Act.

§ 2610.2 Definitions.

For purposes of this part:

Act" means the Employee Retirement Income Security Act of 1974, as amended.

"Code" means the Internal Revenue Code of 1986, as amended.

"Multiemployer plan" means a plan defined in section 4001(a)(3) of the Act.

"New plan" means a plan that became effective within the premium payment year and includes a plan resulting from a consolidation or spinoff. A plan that meets this definition is considered to be a new plan for purposes of this part even if the plan constitutes a successor plan within the meaning of section 4021(a) of the Act.

"Newly covered plan" means a plan that is not a new plan and that was not covered by Title IV of the Act pursuant to section 4021 of the Act immediately prior to the premium payment year.

"Participant" means any individual who is included in one of the categories below:

(a) *Active.*

(1) Any individual who is currently in employment covered by the plan and who is earning or retaining credited service under the plan. This category includes any individual who is considered covered under the plan for purposes of meeting the minimum coverage requirements, but because of offset or other provisions (including integration with Social Security benefits), the individual does not have any accrued benefits.

(2) Any non-vested individual who is not currently in employment covered by the plan but who is earning or retaining credited service under the plan. This category does not include a non-vested former employee who has incurred a break in service the greater of one year or the break in service period specified in the plan.

(b) *Inactive*—(1) *Inactive receiving benefits.* Any individual who is retired or separated from employment covered by the plan and who is receiving benefits under the plan. This category does not include an individual to whom an insurer has made an irrevocable commitment to pay all the benefits to which the individual is entitled under the plan.

(2) *Inactive entitled to future benefits.* Any individual who is retired or separated from employment covered by the plan and who is entitled to begin receiving benefits under the plan in the future. This category does not include an individual to whom an insurer has made an irrevocable commitment to pay all the benefits to which the individual is entitled under the plan.

(c) *Deceased.* Any deceased individual who has one or more beneficiaries who are receiving or entitled to receive benefits under the plan. This category does not include an individual if an insurer has made an irrevocable commitment to pay all the benefits to which the beneficiaries of that individual are entitled under the plan. *Provided that,* for plan years beginning before September 2, 1975, a retiree or former employee for whom a fully paid-up immediate or deferred annuity has been purchased shall be treated as a "participant" if such individual retains a legal claim against the plan for benefits or if the plan retains a participating interest in the annuity policy.

"PBGC" means the Pension Benefit Guaranty Corporation.

"Plan year" means the calendar, policy or fiscal year on which the records of the plan are kept.

"Premium payment year" means the plan year for which the premium is being paid.

"Short plan year" means a plan year that is less than twelve full months.

§ 2610.3 Forms.

The estimation, declaration, reconciliation and payment of premiums shall be made using the forms prescribed by and in accordance with the instructions in the PBGC Annual Premium Payment Package.

§ 2610.4 Mailing address.

Plan administrators shall mail all forms required to be filed under this part and all payments for premiums, interest and penalties required to be made under this part to: Pension Benefit Guaranty Corporation, P.O. Box 105655, Atlanta, GA 30348-5655 or, if hand-delivered, to Retail Lockbox Processing Center, 1740 Phoenix Parkway, PBGC Lockbox 105655, College Park, GA 30349.

§ 2610.5 Date of filing.

(a) Any form required to be filed under the provisions of this part and any payment required to be made under the provisions of this part shall be deemed to have been filed or made on the date on which it is mailed.

(b) A form or payment shall be presumed to have been mailed on the date on which it is postmarked by the United States Postal Service, or three days prior to the date on which it is received by the PBGC if it does not contain a legible United States Postal Service postmark.

§ 2610.6 Computation of time.

In computing any period of time prescribed by this part, the day of the act, event, or default from which the designated period of time begins to run is not counted. The last day of the period so computed shall be included, unless it is a Saturday, Sunday, or federal holiday, in which event the period runs until the end of the next day that is not a Saturday, Sunday, or federal holiday. For purposes of computing late payment interest charges under § 2610.7 and late payment penalty charges under § 2610.8, a Saturday, Sunday or federal holiday referred to in the previous sentence shall be included.

§ 2610.7 Late payment interest charges.

(a) If any premium payment due under this part is not paid by the due date prescribed for such payment by § 2610.25 or § 2610.34, as applicable, an interest charge will accrue on the unpaid amount at the rate imposed under section 6601(a) of the Code for the period from the date payment is due to the date payment is made. Late payment interest charges accrue as simple interest before January 1, 1983, and thereafter are compounded daily. (The interest rates for specified time periods are set forth in Appendix A to this part.)

(b) When PBGC issues a bill for premium payments necessary to reconcile the premiums paid with the actual premium due, interest will be accrued on the unpaid premium until the date of the bill if paid no later than 30 days after the date of such bill. If the bill is not paid within the 30-day period following the date of such bill, interest will continue to accrue throughout such 30-day period and thereafter, until the date paid.

(c) PBGC bills for interest assessed under this section will be deemed paid when due if paid no later than 30 days after the date of such bills. Otherwise, interest will accrue in accordance with paragraph (a) of this section on the amount of the bill from the date of the bill until the date of payment.

§ 2610.8 Late payment penalty charges.

(a) *Penalty charge.* If any premium payment due under this part is not paid by the due date prescribed for such payment by § 2610.25 or 2610.34, as applicable, the PBGC will, unless a waiver is granted pursuant to paragraph (b) of this section, assess a late payment charge on the unpaid premium at the rate provided in paragraph (a)(1), (a)(2), or (a)(3) of this section, as applicable.

(1) If the due date for the premium is prior to October 2, 1975, the late payment charge shall be at the rate specified in the following table:

Days late from due date	Late payment charge (percent)
1 to 60	0
61 to 90	25
91 to 120	50
121 to 180	75
More than 180	1000

(2) If the due date for the premium is on or after October 2, 1975, and before July 31, 1984, the late payment charge shall be at the rate specified in the following table:

Days late from due date	Late payment charge (percent)
1 to 30	5
31 to 60	10
61 to 90	20
91 to 120	40
121 to 150	60
151 to 180	80
More than 180	100

(3) If the due date for the premium is on or after July 31, 1984, the late payment charge (not to exceed 100% of the unpaid premium) shall be equal to the greater of—

(i) 5% per month (or fraction thereof) of the unpaid premiums; or

(ii) $25.

(b) *Waiver of penalty charge.* The late payment penalty charge will be waived, in whole or in part—

(1) With respect to any premium payment made within 60 days after the due date prescribed for such payment in § 2610.25 or § 2610.34, as applicable, if, before such due date, the PBGC grants a waiver upon a showing of substantial hardship arising from the timely payment of the premium and a showing that the premium will be paid within such 60-day period;

(2) If the PBGC grants a waiver based on any other demonstration of good cause;

(3) If the PBGC, on its own motion, waives the application of paragraph (a) of this section;

(4) With respect to any premium payment (excluding any variable rate portion of the premium under § 2610.22(a)(2)), if a plan that is required to make a reconciliation filing described in § 2610.25(b)(2)(iii) or § 2610.34(b)—

(i) Paid at least 90 percent of the flat rate portion of the premium due for the

premium payment year by the due date specified in § 2610.25(b)(2)(i) or § 2610.34(b); or

(ii) Paid by the due date specified in § 2610.25(b)(2)(i) or § 2610.34(b) an amount equal to the premium that would be due for the premium payment year, computed using the flat per capita premium rate for the premium payment year and the participant count upon which the prior year's premium was based; and

(iii) Pays 100 percent of the premium due for the premium payment year under § 2610.22 (excluding any variable rate portion of the premium under § 2610.22(a)(2)), § 2610.32, or § 2610.33, as applicable, on or before the due date for the reconciliation filing under § 2610.25(b)(2)(iii) or § 2610.34(b), as applicable; or

(5) With respect to any PBGC bills for the premium payment necessary to reconcile the premium paid with the actual premium due, if such bills are paid no later than 30 days after the date of such bills.

§ 2610.9 Coverage for guaranteed basic benefits.

(a) The failure by a plan administrator to pay the premiums due under this part will not result in that plan's loss of coverage for basic benefits guaranteed under sections 4022(a) or 4022A(a) of the Act.

(b) The payment of the premiums imposed by this part will not result in coverage for basic benefits guaranteed under sections 4022(a) or 4022A(a) of the Act for plans not covered under Title IV of the Act pursuant to section 4021 of the Act.

§ 2610.10 Special rule for certain mergers and spinoffs.

(a) With respect to a plan described in paragraph (b) of this section that is paying its premium for a premium payment year beginning on or after January 1, 1988, all references in §§ 2610.22, 2610.23, 2610.24 and 2610.33, as applicable, to the last day of the plan year preceding the premium payment year shall be deemed to refer to the first day of the premium payment year.

(b) A plan is described in this paragraph if—

(1) The plan engages in a merger or spinoff that is not *de minimis* pursuant to the regulations under section 414(1) of the Code (in the case of single-employer plans) or pursuant to Part 2672 of this chapter (in the case of multiemployer plans), as applicable;

(2) The merger or spinoff is effective on the first day of the plan's premium payment year; and

(3) The plan is the transferee plan in the case of a merger or the transferor plan in the case of a spinoff.

§ 2610.11 Recordkeeping requirements; PBGC audits.

(a) *Retention of records to support premium payments.* With respect to plan years beginning on or after January 1, 1988, all plan records, including calculations and other data prepared by an enrolled actuary or, for a plan described in section 412(i) of the Code, by the insurer from which the insurance contracts are purchased, that are necessary to support or to validate premium payments under this part shall be retained by the plan administrator for a period of six years after the premium due date. Records that must be retained pursuant to this paragraph include, but are not limited to, records that establish the number of plan participants, that reconcile the calculation of the plan's unfunded vested benefits with the actuarial valuation upon which the calculation was based, and, for plans that assert entitlement to the reduction in the cap on the variable rate portion of the premium, that demonstrate the methods and assumptions used by the plan during the base period with respect to calculating its maximum deductible contribution pursuant to section 404 of the Code. Records retained pursuant to this paragraph shall be made available to the PBGC upon request for inspection and photocopying.

(b) *PBGC audit.* Premium payments under this part are subject to audit by the PBGC. If, upon audit, the PBGC determines that a premium due under this part was underpaid, the late payment interest charges under § 2610.7 and the late payment penalty charges under § 2610.8 shall apply to the unpaid balance from the premium due date to the date of payment. In determining the premium due—

(1) If, in the judgment of the PBGC, the plan's records fail to establish the number of plan participants with respect to whom premiums were required for any premium payment year, the PBGC may rely on data it obtains from other sources (including the Internal Revenue Ser6ice and the Department of Labor) for presumptively establishing the number of plan participants for premium computation purposes; and

(2) If, in the judgment of the PBGC, the plan's records fail to establish that the 0lan's unfunded vested benefits were of the amount reported by the plan for the premium payment year, the variable rate portion of the premium owed by the plan with respect to that premium payment may be deemed to be the maximum $34 per participant charge, pursuant to § 2610.22(a)(3).

(Approved by the Office of Management and Budget under control no. 1212-0009.)

Subpart B—Single-Employer Premiums for Post-1987 Plan Years

§ 2610.21 Purpose and scope.

This subpart provides rules for computing and procedures for paying premiums for single-employer plans with respect to plan years beginning, generally, on or after January 1, 1988. Certain provisions, as specifically noted, apply to plan years beginning on or after January 1, 1989.

§ 2610.22 Premium rate.

(a) *General rule.* For plan years beginning on or after January 1, 1988, the premium paid by a single-employer plan for basic benefits guaranteed under section 4022(a) of the Act shall equal the sum of the amounts in paragraphs (a)(1) and (a)(2) of this section (subject to the limitation in paragraph (a)(3) of this section), multiplied by the number of participants in the plan on the last day of the plan year preceding the premium payment year.

(1) *Flat rate amount.* The amount under this paragraph is $16.

(2) *Variable rate amount.* Except for plans covered by an exemption or special rule pursuant to § 2610.24, the amount under this paragraph is $6 for each $1,000 (or fraction thereof) of a plan's unfunded vested benefits, as determined under § 2610.23, with that product divided by the number of participants in the plan on the last day of the plan year preceding the premium payment year. The resulting amount shall be rounded to the nearest cent, with a fraction of one-half cent or more rounded up and a fraction of less than one-half cent rounded down.

(3) *Cap on variable rate amount.* Except as modified by the next sentence, in no event shall the variable rate amount determined under paragraph (a)(2) of this section exceed $34 per participant. For each of the five consecutive premium payment years commencing with the first premium payment year beginning on or after January 1, 1988, the $34 maximum shall be reduced by the product of $3 multiplied by the number of plan years during the last five plan years commencing before January 1, 1988, with respect to which the contributing sponsor or contributing sponsors made contributions to the plan in an amount not less than the maximum amount allowable as a deduction under section 404 of the Code, as determined in

accordance with paragraphs (a)(3)(i) through (a)(3)(v) of this section. The rules in paragraphs (a)(3)(ii), (a)(3)(iii) and (a)(3)(v) apply with respect to plan years beginning on or after January 1, 1989.

(i) *Determination of maximum deductible contribution.* The determination of whether contributions were in an amount not less than the maximum amount allowable as a deduction under section 404 of the Code shall be based on the methods of computing the maximum deductible contribution under section 404, including actuarial assumptions and funding methods, used by the plan and the contributing sponsor or contributing sponsors (provided such assumptions and methods met the requirements for reasonableness under section 412 of the Code) with respect to each of the last five plan years commencing before January 1, 1988.

(ii) *Special rule for rounding of de minimis amounts.* Any contribution that is rounded down to no less than the next lower multiple of one hundred dollars (in the case of maximum deductible amounts up to one hundred thousand dollars) or to no less than the next lower multiple of one thousand dollars (in the case of maximum deductible amounts above one hundred thousand dollars) shall be deemed for purposes of this paragraph to be in an amount not less that the maximum deductible amount.

(iii) *Determination of maximum deductible contribution for sponsors maintaining defined benefit and defined contribution plans.* For purposes of this paragraph, if a contributing sponsor is subject to the limitation on deductions described in section 404(a)(7)(A) of the Code (relating to total deductions in connection with one or more defined contribution plans and one or more defined benefit plans with common participants in each) and if the contributing sponsor or contributing sponsors made contributions to the plan with respect to which the premium is being determined in an amount less than the maximum deductible amount (determined without regard to the Code section 404(a)(7)(A) limitation), amounts contributed to a defined contribution plan (or plans), or to a defined benefit plan (or plans) not covered by Title IV of the Act pursuant to section 4021 of the Act, shall be disregarded in determining whether the amounts contributed equalled the maximum deductible contribution under section 404 of the Code. If the contributing sponsor maintains more than one defined benefit plan covered by Title IV of the Act pursuant to section 4021 of the Act, the determination shall be made by aggregating the amounts contributed to all such plans and comparing that total to the section 404(a)(7)(A) limitation.

(iv) *Determination of maximum deductible contribution in certain cases when plan year and taxable year do not coincide.* If a contributing sponsor determined the maximum deductible contribution for a taxable year by using a weighted average of the maximum deductible contributions for the plan years falling within the taxable year pursuant to 26 CFR 1.404(a)–14(c)(3), the determination under this paragraph of whether the contribution for a plan year was the maximum deductible amount shall be made by aggregating all contributions for the plan year, irrespective of the taxable year in which they were applied. If this total is less than the maximum deductible amount under Code section 404 (without applying the limitation in Code section 404(a)(7)(A)) determined on the basis of the plan year, the contribution shall be treated as being the maximum deductible amount under this paragraph only if the portion of the contribution applied in each taxable year in which the plan year fell equalled the maximum deductible amount (with respect to that plan year) for that taxable year under the limitation in section 404(a)(7)(A).

(v) *Special rule for nonprofit entities.* A plan maintained by a nonprofit entity shall be deemed, for purposes of paragraph (a)(3) of this section, to have received the maximum deductible amount for a plan year if an enrolled actuary certifies that the contributions made to the plan for that plan year were in an amount not less than the maximum amount that would have been allowable as a deduction under section 404 of the Code, as determined under paragraphs (a)(3)(i) through (a)(3)(iv) of this section, if the contributing sponsor(s) of the plan was a (were) for-profit entity(ies).

(b) *Special computation date for new and newly covered plans.* For purposes of this section, the number of plan participants for purposes of computing the premium owed with respect to a new plan or a newly covered plan (as defined in § 2610.2) shall be determined as of the first day of the premium payment year or, if later, the date on which the plan became effective for benefit accruals for future service, and all references in paragraph (a) of this section to the last day of the plan year preceding the premium payment year shall be deemed to refer to such day or date.

(c) *Plans that change plan years.* A plan that changes its plan year shall pay the premium prescribed by this section for the short plan year.

(d) *Special refund rule for certain short plan years.* A plan described in this paragraph is entitled to a refund for a short plan year that begins on or after January 1, 1989. The plan must pay the full premium due and request a refund from the PBGC. The amount of the refund will be determined by prorating the premium for the short plan year by the number of months (treating a part of a month as a month) in the short plan year. A plan is described in this paragraph if—

(1) The plan is a new or newly covered plan that becomes effective for premium purposes on a date other than the first day of its first plan year;

(2) The plan adopts an amendment changing its plan year, resulting in a short plan year;

(3) The plan's assets are distributed pursuant to the plan's termination, in which case the short plan year for purposes of computing the amount of the refund under this paragraph shall be deemed to end on the later of the asset distribution date or the date 30 days prior to the date the PBGC receives the plan's post-distribution certification; or

(4) A trustee of the plan is appointed pursuant to section 4042 of the Act, in which case the short plan year for purposes of computing the amount of the refund under this paragraph shall be deemed to end on the date of appointment.

§ 2610.23 Determination of unfunded vested benefits.

(a) *General rule.* Except as permitted by paragraph (c) of this section or as provided in the exemptions and special rules under § 2610.24, the amount of a plan's unfunded vested benefits (as defined in paragraph (b) of this section) shall be determined as of the last day of the plan year preceding the premium payment year, based on the plan provisions and the plan's population as of that date. The determination shall be made in accordance with paragraph (a)(1) (for premium payment years beginning in 1988) or (a)(2) (for premium payment years beginning on or after January 1, 1989), and shall be certified to in accordance with paragraph (a)(3).

(1) *Determination for 1988 premium payment years.* The determination of vested benefits shall be based on a plan valuation that meets the requirements imposed by section 302(c)(9) of the Act and section 412(c)(9) of the Code, and that was performed as of the first day of the premium payment year or that was the most recent valuation performed (by on or before the date the variable rate

portion of the premium for the premium payment year is due under § 2610.25) for a plan year within the three plan years immediately preceding the premium payment year. If a significant event described in paragraph (d) of this section or other event that has a material impact on the value of vested benefits occurred between the date of the plan valuation and the last day of the plan year preceding the premium payment year, the value of vested benefits shall be determined using assumptions that reflect the occurrence of such significant event. If the plan valuation on which the determination of vested benefits is based was performed as of the first day of the premium payment year, the amount of the plan's vested benefits as of such date shall be deemed to equal the amount of the plan's vested benefits as of the last day of the plan year preceding the premium payment year unless the plan's enrolled actuary determines that there is a material difference between such amounts.

(2) *Determination for post-1988 premium payment years.* The unfunded vested benefits shall be determined using the same actuarial assumptions and methods used by the plan for purposes of determining the minimum funding contribution under section 302 of the Act and section 412 of the Code for the plan year preceding the premium payment year (or, in the case of a new or newly covered plan, for the premium payment year), except to the extent that other actuarial assumptions are specifically prescribed by this section or are necessary to reflect the occurrence of a significant event described in paragraph (d) of this section between the date of the funding valuation and the last day of the plan year preceding the premium payment year. (If the plan does a valuation as of the last day of the plan year preceding the premium payment year, no separate adjustment for significant events is needed.) Under this rule, the determination of the unfunded vested benefits may be based on a plan valuation done as of the first day of the premium payment year, provided that—

(i) The actuarial assumptions and methods used are those used by the plan for purposes of determining the minimum funding contribution under section 302 of the Act and section 412 of the Code for the premium payment year, except to the extent that other actuarial assumptions are specifically prescribed by this section or are required to make the adjustment described in paragraph (a)(2)(ii) of this section; and

(ii) If an enrolled actuary determines that there is a material difference between the values determined under the valuation and the values that would have been determined as of the last day of the preceding plan year, the valuation results are adjusted to reflect appropriately the values as of the last day of the preceding plan year. (This adjustment need not be made if the unadjusted valuation would result in greater unfunded vested benefits.)

(3) In the case of any plan that determines the amount of its unfunded vested benefits under the general rule described in this paragraph, an enrolled actuary must certify, in accordance with the Premium Payment Package, that the determination was made in a manner consistent with generally accepted actuarial principles and practices.

(b) *Unfunded vested benefits.* The amount of a plan's unfunded vested benefits under this section shall be the excess of the plan's vested benefits amount (determined under paragraph (b)(1) of this section) over the actuarial value of the plan's assets (determined under paragraph (b)(2) of this section).

(1) *Vested benefits amount.* A plan's vested benefits amount under this section shall be the plan's current liability (within the meaning of section 302(d)(7) of the Act) determined by taking into account only vested benefits and by using an interest rate equal to 80% of the annual yield for 30-year Treasury constant maturities, as reported in Federal Reserve Statistical Release G.13 and H.15, for the calendar month preceding the calendar month in which the premium payment year begins. (Appendix B to this part sets forth the required intereat rates.) For premium payment years beginning on or after January 1, 1989, if the interest rate (or rates) used by the plan to determine current liability was (or were all) not greater than the required interest rate, the vested benefits need not be revalued if an enrolled actuary certifies that the interest rate (or interest rates) used was (or were all) not greater than the required interest rate.

(2) *Actuarial value of assets.* The actuarial value of a plan's assets under this section shall be determined in accordance with section 302(c)(2) of the Act, except that the value is not reduced by a credit balance in the funding standard account. Contributions owed for any plan year preceding the premium payment year shall be included for premium payment years beginning during 1988 and, for premium payment years beginning on or after January 1, 1989, shall be included for plans with 500 or more participants and may be included for any other plan. However, contributions may be included only to the extent such contributions have been paid into the plan on or before the earlier of the due date for payment of the variable rate portion of the premium under § 2610.25 or the date that portion is paid. Contributions included that are paid after the last day of the plan year preceding the premium payment year shall be discounted at the plan asset valuation rate (on a simple or compound basis in accordance with the plan's discounting rules) to such last day to reflect the date(s) of payment. Contributions for the premium payment year may not be included for any plan.

(c) *Alternative method for calculating unfunded vested benefits.* In lieu of determining the amount of the plan's unfunded vested benefits pursuant to paragraph (a) of this section, a plan administrator may calculate the amount of a plan's unfunded vested benefits under this paragraph using the plan's Form 5500, Schedule B, for the plan year preceding the premium payment year. Pursuant to this paragraph, unfunded vested benefits shall be determined from the entries in lines 6d(i), 6d(ii) and, usually, 8b of the plan's Schedule B. The value of the vested benefits shall be adjusted in accordance with paragraph (c)(1) of this section (for premium payment years beginning on or after January 1, 1989) to reflect accruals during the plan year preceding the premium payment year and with paragraph (c)(2) of this section to reflect the interest rate prescribed in paragraph (b)(1) of this section, and the value of the assets shall be adjusted in accordanoe with paragraph (c)(4) of this section. (For premium payment years beginning on or after January 1, 1989, if the plan administrator certifies that the interest rate (or rates) used to determine the values in lines 6d(i) and 6d(ii) of the Schedule B was (or were all) not greater than the interest rate prescribed in paragraph (b)(1) of this section, the interest rate adjustment prescribed in paragraph (c)(2) of this section is not required.) The resulting unfunded vested benefits amount shall be adjusted in accordance with paragraph (c)(5) of this section to reflect the passage of time from the date of the Schedule B data to the last day of the plan year preceding the premium payment year.

(1) *Vested benefits adjustment for accruals.* For premium payment years beginning on or after January 1, 1989, the value of vested benefits entered in line 6d(ii) shall be adjusted to reflect the increase in vested benefits attributable to accruals during the plan year preceding the premium payment year by multiplying that value by 1.07

(2) *Vested benefits interest rate adjustment.* The value of vested benefits as entered on the Schedule B shall be adjusted in accordance with the following formula (except as provided in paragraph (c)(3) of this section) to reflect the interest rate prescribed in paragraph (b)(1) of this section:

$$VB_{adj} = VB_{6d(i)} \times .94^{(RIB-BIR)} + VB_{6d(ii)} \times .94^{(RIB-BIR)} \times \{(100+BIA)/(100+(RIR))\}^{(ARA-50)}, \text{ where—}$$

(i) VB_{adj} is the adjusted vested benefits amount (as of the first day of the plan year preceding the premium payment year) under the alternative calculation method;

(ii) $VB_{6d(i)}$ is the amount entered in line 6d(i) of the Schedule B;

(iii) $VB_{6(ii)}$ is the amount entered in line 6d(ii) of the Schedule B, multiplied, for premium payment years beginning on or after January 1, 1989, by 1.07 in accordance with paragraph (c)(1) of this section;

(iv) RIR is the required interest rate set forth in Appendix B to this part;

(v) BIR is the interest rate entered on line 12c (post-retirement) of the Schedule B that was used to determine the entry on line 6d(i) of the Schedule B;

(vi) BIA is the interest rate entered on line 12c (pre-retirement) of the Schedule B that was used to determine the entry in line 6d(ii) of the Schedule B: and

(vii) ARA is the assumed retirement age entered on line 12d of the Schedule B that was used to determine the entries on lines 6d(i) and 6d(ii) of the Schedule B.

(3) *Optional use of substitution factors in interest rate adjustment formula.* The substitution factor set forth in Table A (when RIR is equal to or greater than BIR rounded to the nearest hundredth) or Table B (when BIR rounded to the nearest hundredth is greater than RIR) below may be used in lieu of the term, $.94^{(RIR-BIR)}$ in the formula prescribed by paragraph (c)(2) of this section:

TABLE A

If RIR minus BIR (rounded to nearest hundredth) is:		The substitution factor is—
At least	But less than	
0.00	0.10	1.0000
0.10	0.20	0.9938
0.20	0.30	0.9877
0.30	0.40	0.9816
0.40	0.50	0.9756
0.50	0.60	0.9695
0.60	0.70	0.9636
0.70	0.80	0.9576
0.80	0.90	0.9517
0.90	1.00	0.9458
1.00	1.10	0.9400
1.10	1.20	0.9342
1.20	1.30	0.9284
1.30	1.40	0.9227
1.40	1.50	0.9170
1.50	1.60	0.9114
1.60	1.70	0.9057
1.70	1.80	0.9002
1.80	1.90	0.8946
1.90	2.00	0.8891

TABLE A—Continued

If RIR minus BIR (rounded to nearest hundredth) is:		The substitution factor is—
At least	But less than	
2.00	2.10	0.8836
2.10	2.20	0.8781
2.20	2.30	0.8727
2.30	2.40	0.8673
2.40	2.50	0.8620
2.50	2.60	0.8567
2.60	2.70	0.8514
2.70	2.80	0.8461
2.80	2.90	0.8409
2.90	3.00	0.8357
3.00	3.10	0.8306
3.10	3.20	0.8255
3.20	3.30	0.8204
3.30	3.40	0.8153
3.40	3.50	0.8103
3.50	3.60	0.8053
3.60	3.70	0.8003
3.70	3.80	0.7954
3.80	3.90	0.7905
3.90	4.00	0.7856
4.00	4.10	0.7807
4.10	4.20	0.7759
4.20	4.30	0.7711
4.30	4.40	0.7664
4.40	4.50	0.7617
4.50	4.60	0.7570
4.60	4.70	0.7523
4.70	4.80	0.7477
4:80	4.90	0.7430
4.90	5.00	0.7385
5.00	5.10	0.7339
5.10	5.20	0.7294
5.20	5.30	0.7249
5.30	5.40	0.7204
5.40	5.50	0.7160
5.50	5.60	0.7115
5.60	5.70	0.7072
5.70	5.80	0.7028
5.80	5.90	0.6985
5.90	6.00	0.6942

TABLE B

If BIR (rounded to nearest hundredth) minus RIR is:		The substitution factor is—
At least	But less than	
0.01	0.10	1.0062
0.10	0.20	1.0125
0.20	0.30	1.0187
0.30	0.40	1.0251
0.40	0.50	1.0314
0.50	0.60	1.0378
0.60	0.70	1.0443
0.70	0.80	1.0507
0.80	0.90	1.0573
0.90	1.00	1.0638
1.00	1.10	1.0704
1.10	1.20	1.0771
1.20	1.30	1.0838
1.30	1.40	1.0905
1.40	1.50	1.0973
1.50	1.60	1.1041
1.6?	1.70	1.1109
1.70	1.80	1.1178
1.80	1.90	1.1248
1.90	2.00	1.1317
2.00	2.10	1.1388
2.10	2.20	1.1458
2.20	2.30	1.1529
2.30	2.40	1.1601
2.40	2.50	1.1673

TABLE B—Continued

If BIR (rounded to nearest hundredth) minus RIR is:		The substitution factor is—
At least	But less than	
2.50	2.60	1.1745
2.60	2.70	1.1818
2.70	2.80	1.1892
2.80	2.90	1.1965
2.90	3.00	1.2040
3.00	3.10	1.2114
3.10	3.20	1.2190
3.20	3.30	1.2265
3.30	3.40	1.2341
3.40	3.50	1.2418
3.50	3.60	1.2495
3.60	3.70	1.2573
3.70	3.80	1.2651
3.80	3.90	1.2729
3.90	4.00	1.2808
4.00	4.10	1.2888
4.10	4.20	1.2968
4.20	4.30	1.3048
4.30	4.40	1.3129
4.40	4.50	1.3211
4.50	4.60	1.3293
4.60	4.70	1.3375
4.70	4.80	1.3458
4.80	4.90	1.3542
4.90	5.00	1.3626
5.00	5.10	1.3710
5.10	5.20	1.3795
5.20	5.30	1.3881
5.30	5.40	1.3967
5.40	5.50	1.4054
5.50	5.60	1.4141
5.60	5.70	1.4229
5.70	5.80	1.4317
5.80	5.90	1.4406
5.90	6.00	1.4495

(4) *Adjusted value of plan assets.* The value of plan assets shall be the amount reported on line 8b of the Schedule B, unless that amount was determined as of a date other than the first day of the plan year preceding the premium payment year. In that event, the value of plan assets shall be the amount entered in line 6c of the Schedule B. The value of assets reported on line 8b (or 6c) of the Schedule B shall be adjusted in accordance with paragraph (b)(2) of this section, except that the amount of all contributions that are included in the value of assets and that were made after the first day of the plan year preceding the premium payment year shall be discounted to such first day at the interest rate listed in Appendix B of this part for the premium payment year, using any reasonable discounting method for premium payment years beginning during 1988, and for all subsequent plan years, compounded annually except that simple interest may be used for any partial years.

(5) *Adjustment for passage of time.* The amount of the plan s unfunded vested benefits shall be adjusted to reflect the passage of time between the date of the Schedule B data (the first

day of the plan year preceding the premium payment year) and the last day of the plan year preceding the premium payment year in accordance with the following formula:

$$UVB_{adj} = (VB_{adj} - A_{adj}) \times (1 + RIR/100)^{Y}.$$

where—

(i) UVB_{adj} is the amount of the plan's adjusted unfunded vested benefits;

(ii) VB_{adj} is the value of the adjusted vested benefits calculated in accordance with paragraphs (c)(1) and (c)(2) of this section;

(iii) A_{adj} is the adjusted asset amount calculated in accordance with paragraph (c)(3) of this section;

(iv) RIR is the required interest rate set forth in Appendix B to this part; and

(v) Y is deemed to be equal to 1 (unless the plan year preceding the premium payment year is a short plan year, in which case Y is the number of years between the first day and the last day of the short plan year, expressed as a decimal fraction of 1.0 with two digits to the right of the decimal point).

(d) *Restrictions on alternative calculation method for large plans.* A plan with 500 or more participants as of the last day of the plan year preceding the premium payment year may use the alternative calculation method described in paragraph (c) of this section only if no significant event, as described in this paragraph, has occurred between the first day and the last day of the plan year preceding the premium payment year and an enrolled actuary so certifies in accordance with the Premium Payment Package. If a significant event has occurred between those dates, the alternative method may be used only if an enrolled actuary makes an appropriate adjustment to the value of unfunded vested benefits to reflect the occurrence of the significant event and certifies to that fact in accordance with the Premium Payment Package. Significant events described in this paragraph are—

(1) An increase in the plan's actuarial costs (consisting of the plan's normal cost under section 412(b)(2)(A) of the Code, amortization charges under section 412(b)(2)(B) of the Code, and amortization credits under section 412(b)(3)(B) of the Code) attributable to a plan amendment, unless the cost increase attributable to the amendment is less than 5% of the actuarial costs determined without regard to the amendment;

(2) The extension of coverage under the plan to a new group of employees resulting in an increase of 5% or more in the plan's liability for accrued benefits;

(3) A plan merger, consolidation or spinoff that is not *de minimis* pursuant to the regulations under section 414(1) of the Code;

(4) The shutdown of any facility, plant, store, etc., that creates immediate eligibility for benefits that would not otherwise be immediately payable for participants separating from service;

(5) The offer by the plan for a temporary period to permit participants to retire at benefit levels greater than that to which they would otherwise be entitled;

(6) A cost-of-living increase for retirees resulting in an increase of 5% or more in the plan's liability for accrued benefits;

(7) For premium payment years beginning on or after January 1, 1989, any other event or trend that results in a material increase in the value of unfunded vested benefits; and

(8) For premium payment years beginning in 1988, an increase in the average age of plan participants by more than two years.

(e) *Special calculation date for new and newly covered plans.* For purposes of this section, the determination or calculation of a plan's unfunded vested benefits with respect to a new plan or a newly covered plan (as defined in § 2610.2) shall be made as of the first day of the premium payment year or, if later, the date on which the plan became effective for benefit accruals for future service, and all references in paragraphs (a) through (d) of this section to the last day of the plan year preceding the premium payment year shall be deemed to refer to such day or date.

§ 2610.24 Variable rate exemptions and special rules.

(a) *Exemptions.* A plan described in paragraphs (a)(1), (a)(2), (a)(3), or (a)(4) of this section is not required to determine its unfunded vested benefits under § 2610.23 and does not owe a variable rate amount under § 2610.22(a)(2).

(1) *Certain fully funded plans.* With respect to premium payment years beginning on or after January 1, 1989, a plan is described in this paragraph if the plan had fewer than 500 participants on the last day of the plan year preceding the premium payment year, and an enrolled actuary certifies in accordance with the Premium Payment Package that, as of that date, the plan had no unfunded vested benefits (valued at the interest rate prescribed in § 2610.23(b)(1)).

(2) *Plans without vested benefit liabilities.* A plan is described in this paragraph if it did not have any participants with vested benefits as of the last day of the plan year preceding the premium payment year, and the plan administrator so certifies in accordance with the Premium Payment Package.

(3) *Section 412(i) plans.* A plan is described in this paragraph if the plan was a plan described in section 412(i) of the Code and the regulations thereunder at all times during the plan year preceding the premium payment year and the plan administrator so certifies, in accordance with the Premium Payment Package. If the plan is a new plan or a newly covered plan (as defined in § 2610.2), the certification under this paragraph shall be made as of the due date for the premium under § 2610.25(d) and shall certify to the plan's status at all times during the premium payment year through such due date.

(4) *Plans terminating in standard terminations.* The exemption for a plan described in this paragraph applies with respect to premium payment years beginning on or after January 1, 1989, and is conditioned upon the plan's making a final distribution of assets in a standard termination. If a plan is ultimately unable to do so, the exemption is revoked and all variable rate amounts not paid pursuant to this exemption are due retroactive to the applicable due date(s). A plan is described in this paragraph if—

(i) The plan administrator has issued notices of intent to terminate the plan in a standard termination in accordance with section 4041(a)(2) of the Act; and

(ii) The proposed termination date set forth in the notice of intent to terminate is on or before the last day of the plan year preceding the premium payment year.

(b) *Special rule for determining vested benefits for certain large plans.* For premium payment years beginning on or after January 1, 1989, with respect to a plan that had 500 or more participants on the last day of the plan year preceding the premium payment year, if an enrolled actuary determines pursuant to § 2610.23(a) that the actuarial value of plan assets equals or exceeds the value of all benefits accrued under the plan (valued at the interest rate prescribed in § 2610.23(b)(1)), the enrolled actuary need not determine the value of the plan's vested benefits, and may instead report in the Premium Payment Package the value of the accrued benefits.

(c) *Special rule for determining unfunded vested benefits for plans terminating in distress or involuntary terminations.* With respect to premium payment years beginning on or after January 1, 1989, a plan described in this paragraph may determine its unfunded vested benefits by using the special alternative calculation method set forth in this paragraph. A plan is described in this paragraph if it has issued notices of intent to terminate in a distress termination in accordance with section

4041(a)(2) of the Act with a proposed termination date on or before the last day of the plan year preceding the premium payment year, or if the PBGC has instituted proceedings to terminate the plan in accordance with section 4042 of the Act and has sought a termination date on or before the last day of the plan year preceding the premium payment year. Pursuant to this paragraph, a plan shall determine its unfunded vested benefits in accordance with the alternative calculation method in § 2610.23(c), except that—

(2) the calculation shall be based on the Form 5500, Schedule B, for the plan year which includes (in the case of a distress termination) the proposed termination date or (in the case of an involuntary termination) the termination date sought by the PBGC, or, if no Schedule B is filed for that plan year, on the Schedule B for the immediately preceding plan year;

(2) All references in § 2610.23(c) and § 2610.23(d) to the first day of the plan year preceding the premium payment year shall be deemed to refer to the first day of the plan year for which the Schedule B was filed;

(3) The value of vested benefits entered in line 6d(ii) of the Schedule B shall be adjusted (in lieu of the adjustment required by § 2610.23(c)(1)) by multiplying that value by the sum of 1 plus the product of .07 and the number of years (rounded to the nearest hundredth of a year) between the date of the Schedule B data and (in the case of a distress termination) the proposed termination date or (in the case of an involuntary termination) the termination date sought by the PBGC, and

(4) The exponent, "Y in the time adjustment formula of § 2610.23(c)(5) shall be deemed to equal the number of years (rounded to the nearest hundredth of a year) between the date of the Schedule B data and the last day of the plan year preceding the premium payment year.

(d) *New and newly covered plans.* In the case of a new plan or a newly covered plan, all references in paragraphs (a), (b), (e) or (f) of this section to the last day of the plan year preceding the premium payment year shall be deemed to refer to the first day of the premium payment year or, if later, the date on which the plan became effective for benefit accruals for future service.

(e) *Small plan exemption for 1988 premium payment years.* For premium payment years beginning in 1988, a plan described in this paragraph is not required to determine its unfunded vested benefits under § 2610.23 and does not owe a variable rate amount under § 2610.22(a)(2). A plan is described in this paragraph if—

(1) The plan had fewer than 100 participants on the last day of the plan year preceding the premium payment year;

(2) The plan is not eligible to use the alternative method for determining unfunded vested benefits under § 2610.23 because the plan does not have a Form 5500, Schedule B, meeting the requirements of that section; and

(3) The plan's enrolled actuary certifies, in accordance with the Premium Payment Package, that the plan had no unfunded vested benefits as of the last day of the plan year preceding the premium payment year.

(f) *Small plan $5 rule for 1988 premium payment years.* For premium payment years beginning in 1988, the plan administrator of a plan that meets the requirements of paragraphs (e)(1) and (e)(2) of this section may elect to pay, in lieu of the amount described in § 2610.22(a)(2), an amount of $5 per participant, resulting in a total premium under § 2610.22 of $21 per participant. In this event, the variable rate amount owed for such plan for the premium payment year pursuant to § 2610.22(a) shall be deemed to be $5 per participant, and the plan administrator is not required to determine the plan's unfunded vested benefits under § 2610.23.

§ 2610.25 Filing requirement.

(a) *General rule.* The plan administrator of each plan shall file the form or forms prescribed by this part and any premium payments due, in accordance with the instructions in the Premium Payment Package. The premium forms and payments shall be filed no later than the applicable due date specified in paragraph (b) or, for new plans or newly covered plans, paragraph (d) of this section.

(b) *Due dates.* For plan years beginning on or after January 1, 1988, the due date for small plans is prescribed in paragraph (b)(1) of this section and the due dates for large plans are prescribed in paragraph (b)(2) of this section.

(1) *Plans with fewer than 500 participants.* If the plan has fewer than 500 participants, as determined under paragraph (c) of this section, the due date is the fifteenth day of the eighth full calendar month following the month in which the plan year began.

(2) *Plans with 500 or more participants.* If the plan has 500 or more participants, as determined under paragraph (c) of this section—

(i) The due date for the flat rate portion of the premium required by § 2610.22(a)(1) is the last day of the second full calendar month following the close of the plan year preceding the premium payment year; and

(ii) The due date for the variable rate portion of the premium required by § 2610.22(a)(2) is the fifteenth day of the eighth full calendar month following the month in which the premium payment year begins.

(iii) If the number of plan participants on the last day of the plan year preceding the premium payment year is not known by the date specified in paragraph (b)(2)(i) of this section, a reconciliation filing (on the form prescribed by this part) and any required premium payment or request for refund shall be made by the date specified in paragraph (b)(2)(ii) of this section.

(3) *Plans that change plan years.* For any plan that changes its plan year, the premium form or forms and payment or payments for the short plan year shall be filed by the applicable due date or dates specified in paragraphs (b)(1), (b)(2), or (d) of this section. For the plan year that follows a short plan year, the due date or dates for the premium forms and payments shall be, with respect to each such due date, the later of—

(i) The applicable due date or dates specified in paragraphs (b)(1) or (b)(2) of this section; or

(ii) 30 days after the date on which the amendment changing the plan year was adopted.

(c) *Participant count rule for purposes of determining filing due dates.* For purposes of determining under paragraph (b) of this section whether a plan has fewer than 500 participants, or 500 or more participants, the plan administrator shall use the number of participants for whom premiums were payable for the plan year preceding the premium payment year.

(d) *Due dates for new and newly covered plans.* Notwithstanding the provisions of paragraph (b) of this section, the premium form and payment for both the flat rate portion and the variable rate portion of the premium for the first plan year of coverage of any new plan or newly covered plan (as defined in § 2610.2) shall be filed on or before the latest of—

(1) The fifteenth day of the eighth full calendar month following the month in which the plan year began or, if later, in which the plan became effective for benefit accruals for future service;

(2) 90 days after the date of the plan's adoption; or

(3) 90 days after the date on which the plan became covered by Title IV of the Act pursuant to section 4021 of the Act.

(e) *Continuing obligation to file.* The obligation to file the form or forms prescribed by this part and to pay any premiums due continues through the plan year in which all plan assets are distributed pursuant to a plan's termination or in which a trustee is appointed under section 4042 of the Act, whichever occurs earlier. The entire premium computed under this subpart is due, irrespective of whether the plan is entitled to a refund for a short plan year pursuant to § 2610.22(d).

(f) *Improper filings.* Any form not filed in accordance with this part, not filed in accordance with the instructions in the Premium Payment Package, not accompanied by the required premium payment, or otherwise incomplete, may, in the discretion of the PBGC, be returned with any payment accompanying the form to the plan administrator, and such payment shall be treated as not having been made. If on the form or forms filed with the PBGC, any of the items necessary to establish the correct variable rate premium owed by the plan are omitted, the variable rate portion of the premium owed by the plan with respect to that premium payment may be deemed to be the maximum $34 per participant charge, pursuant to § 2610.22(a)(3).

§ 2610.26 Liability for premiums.

(a) The designation under this subpart of the plan administrator as the person required to file the applicable forms and to submit the premium payment is a procedural requirement only and does not alter the liability for premium payments imposed by section 4007 of the Act. Pursuant to section 4007(e) of the Act, both the plan administrator and the plan's contributing sponsor are liable for premium payments, and, if the contributing sponsor is a member of a controlled group, each member of the controlled group is jointly and severally liable for the required premiums. Any entity that is liable for required premiums is also liable for any interest and penalties assessed with respect to such premiums.

(b) For any plan year in which a plan administrator issues (pursuant to section 4041(a)(2) of the Act) notices of intent to terminate in a distress termination under section 4041(c) of the Act or the PBGC initiates a termination proceeding under section 4042 of the Act, and for each plan year thereafter, the obligation to pay the premiums (and any interest or penalties thereon) imposed by the Act and this Part shall be an obligation solely of the contributing sponsor and the members of its controlled group, if any.

Subpart C—Single-Employer Premiums for Pre-1988 Plan Years; Multiemployer Premiums

§ 2610.31 Purpose and scope.

This subpart provides rules for calculating and procedures for paying premiums for single-employer plans with respect to plan years beginning before 1988, and for multiemployer plans with respect to all plan years.

§ 2610.32 Single-employer premium rates.

(a) For plans other than multiemployer plans, the premium rate for basic benefits guaranteed under section 4022(a) of the Act is as follows:

(1) For plan years beginning before September 2, 1976: one dollar for each individual who is a participant in the plan at any time during the plan year;

(2) For plan years beginning on or after September 2, 1976, up to and including plan years beginning on December 31, 1977: one dollar for each individual who is a participant in the plan on the last day of the preceding plan year:

(3) For plan years beginning on or after January 1, 1978, up to and including plan years beginning on December 31, 1985: two dollars sixty cents for each individual who is a participant in the plan on the last day of the preceding plan year;

(4) For plan years beginning on or after January 1, 1986, up to and including plan years beginning on December 31, 1987: eight dollars fifty cents for each individual who is a participant in the plan on the last day of the preceding plan year.

(b) *Newly covered plans.* For any plan not previously covered by section 4021 of the Act, the plan administrator shall pay the applicable premium under paragraph (a) of this section for each individual who is a participant in the plan on the date the plan becomes covered by section 4021(a) of the Act.

(c) *Changes in plan years.* For the first full plan year beginning after a plan changes its plan year, the plan administrator shall pay the applicable premium under paragraph (a) of this section for each individual who is a participant in the plan on the last day of the short plan year.

§ 2610.33 Multiemployer premium rates.

(a) For multiemployer plans, the premium rate for basic benefits guaranteed under section 4022A(a) is as follows:

(1) For plan years beginning after September 26, 1980, multiemployer plans shall pay premiums at the rate set forth in the following table for each individual who is a participant in such plan on the last day of the plan year preceding the premium payment year.

For premium payment years	Rate
After Sept. 26, 1980, and before Sept. 27, 1984	$1.40
After Sept. 26, 1984, and before Sept. 27, 1986	1.80
After Sept. 26, 1986, and before Sept. 27, 1988	2.20
After Sept. 26, 1988	2.60

(2) For the plan year in which September 26, 1980, falls (the "enactment year"), multiemployer plans shall pay a premium for each individual who is a participant in the plan on the last day of the preceding plan year at the rate set forth in the following table:

For premium payment years beginning in	Rate
September 1979	$.50
October 1979	.54
November 1979	.58
December 1979	.62
January 1980	.67
February 1980	.71
March 1980	.75
April 1980	.79
May 1980	.83
June 1980	.88
July 1980	.92
August 1980	.96
September 1980 (on or before Sept. 26)	1.00

(b) *New and newly covered plans.* For any new plan or newly covered plan (as defined in § 2610.2), the plan administrator shall pay the applicable premium under paragraph (a) of this section for each individual who is a participant in the plan on—

(1) The date the plan becomes covered by section 4021(a) of the Act, if the premium payment year begins before January 1, 1988; or

(2) The first day of the premium payment year or, if later, the date on which the plan became effective for benefit accruals for future service, if the premium payment year begins on or after January 1, 1988.

(c) *Changes in plan years.* For the first full plan year beginning after a plan changes its plan year, the plan administrator shall pay the applicable premium under paragraph (a) of this section for each individual who is a participant in the plan on the last day of the short plan year.

(d) *Special refund rule for certain short plan years.* A plan described in this paragraph is entitled to a refund for a short plan year that begins on or after January 1, 1989. The plan must pay the full premium due and request a refund from the PBGC. The amount of the refund will be determined by prorating

the premium for the short plan year by the number of months (treating a part of a month as a month) in the short plan year. A plan is described in this paragraph if—

(1) The plan is a new or newly covered plan that becomes effective for premium purposes on a date other than the first day of its first plan year;

(2) The plan adopts an amendment changing its plan year, resulting in a short plan year; or

(3) The plan's assets are distributed pursuant to the plan's termination, in which case the short plan year for purposes of computing the amount of the refund under this paragraph shall be deemed to end on the asset distribution date.

§ 2610.34 Filing requirement.

(a) The plan administrator of each covered plan shall file the form prescribed by this part and any premium payments due, in accordance with the premium declaration instructions accompanying the form. Due dates for new or newly covered plans and plans with short plan years are in paragraphs (a)(8) and (a)(9) of this section. For other plans, the premium form and payments shall be filed no later than the date specified in the applicable paragraph (a)(1) through (a)(7)(ii) as follows:

(1) For plan years beginning before and in progress on September 2, 1974: October 2, 1974;

(2) For plan years beginning on or after September 2, 1974, up to and including plan years beginning on December 31, 1977· 30 days after the beginning of the plan year;

(3) For plan years beginning on or after January 1, 1978, up to and including plan years beginning on December 31, 1980: seven months after the close of the prior plan year;

(4) For plan years beginning on or after January 1, 1981, up to and including plan years beginning on December 31, 1984: the last day of the seventh month following the close of the prior plan year;

(5) For plan years beginning on or after January 1, 1985, up to and including plan years beginning on December 31, 1985:

(i) If the plan has fewer than 10,000 participants for the plan year, as determined under paragraph (a)(10) of this section, the last day of the seventh month following the close of the prior plan year; or

(ii) If the plan has 10,000 or more participants for the plan year, as determined under paragraph (a)(10) of this section, the last day of the second full month following March 29, 1985 or, if later, the last day of the second month following the close of the prior plan year; and

(6) For plan years beginning on or after January 1, 1986, up to and including plan years beginning on December 31, 1987·

(i) If the plan has fewer than 500 participants for the plan year, as determined under paragraph (a)(10) of this section, the last day of the seventh month following the close of the prior plan year; or

(ii) If the plan has 500 or more participants for the plan year, as determined under paragraph (a)(10) of this section, the last day of the second month following the close of the prior plan year.

(7) For plan years of multiemployer plans beginning on or after January 1, 1988—

(i) If the plan has fewer than 500 participants for the plan year, as determined under paragraph (a)(10) of this section, the fifteenth day of the eighth full calendar month following the month in which the premium payment year begins; or

(ii) If the plan has 500 or more participants for the plan year, as determined under paragraph (a)(10) of this section, the last day of the second month following the close of the prior plan year.

(8) Notwithstanding the provisions of paragraphs (a)(1) through (a)(7) of this section, for any new plan or plan newly covered by section 4021 of the Act, the first premium form and payments due for the first year of coverage shall be filed on or before the latest of—

(i) In the case of plan years beginning before January 1, 1988:

(A) The last day of the seventh month following the beginning of the plan year;

(B) 90 days after the date of the plan's adoption;

(C) 90 days after the date on which the plan became effective for benefit accruals for future service; or

(D) 90 days after the date on which the plan became covered by section 4021 of the Act; and

(ii) In the case of plan years beginning on or after January 1, 1988:

(A) The fifteenth day of the eighth full calendar month following the month in which the plan year began or, if later, in which the plan became effective for benefit accruals for future service;

(B) 90 days after the date of the plan's adoption; or

(C) 90 days after the date on which the plan became covered by Title IV of the Act pursuant to section 4021 of the Act.

(9) For any plan that changes its plan year, the premium form and payments for the short plan year are due in accordance with the provisions of paragraphs (a)(1) through (a)(7) of this section. Premium forms and payments for the plan year that follows a short plan year shall be filed on or before the later of 30 days after the date on which the amendment to change the plan year was adopted, or the date specified in the applicable paragraph as follows:

(i) For plan years beginning before January 1, 1985, the last day of the seventh month following the close of the preceding short plan year; and

(ii) For plan years beginning on or after January 1, 1985, up to and including plan years beginning on December 31, 1985—

(A) If the plan has fewer than 10,000 participants for the plan year, as determined under paragraph (a)(10) of this section: the last day of the seventh month following the close of the preceding short plan year; or

(B) If the plan has 10,000 or more participants for the plan year, as determined under paragraph (a)(10) of this section: the last day of the second month following the close of the preceding short plan year; and

(iii) For plan years beginning on or after January 1, 1986, up to and including plan years beginning on December 31, 1987—

(A) If the plan has fewer than 500 participants for the plan year, as determined under paragraph (a)(10) of this section: the last day of the seventh month following the close of the preceding short plan year; or

(B) If the plan has 500 or more participants for the plan year, as determined under paragraph (a)(10) of this section: the last day of the second month following the close of the preceding short plan year.

(iv) For plan years of multiemployer plans beginning on or after January 1, 1988—

(A) If the plan has fewer than 500 participants for the plan year, as determined under paragraph (a)(10) of this section, the fifteenth day of the eighth full calendar month following the month in which the premium payment year begins; or

(B) If the plan has 500 or more participants for the plan year, as determined under paragraph (a)(10) of this section, the last day of the second month following the close of the prior plan year.

(10) For purposes of paragraphs (a)(5), (a)(6), (a)(7), (a)(9), (b)(4), (b)(5), and (b)(6) of this section, the number of participants in a plan year is determined as of the following dates:

(i) If the plan year is the plan's second plan year, the first day of the first plan year; or

(ii) If the plan year is the plan's third or a subsequent plan year, the last day of the second preceding plan year.

(b) *Reconciliation due date.* The plan administrator of each covered plan shall file the premium reconciliation form prescribed by this part, in accordance with the instructions accompanying the form, no later than the date specified in the applicable paragraph as follows:

(1) For plan years beginning before September 2, 1976: two years and 30 days after the beginning of the plan year;

(2) For plan years beginning on or after September 2, 1976, up to and including plan years beginning on December 31, 1976: one year and 30 days after the beginning of the plan year;

(3) For plan years beginning on or after January 1, 1977 up to and including plan years beginning on December 31, 1977· seven months after the close of the plan year; or

(4) For plan years beginning on or after January 1, 1985, up to and including plan years beginning on December 31, 1985, if the plan has 10,000 or more participants for the plan year, as determined under paragraph (a)(10) of this section: the last day of the seventh month following the close of the prior plan year.

(5) For plan years beginning on or after January 1, 1986, up to and including plan years beginning on December 31, 1987 if the plan has 500 or more participants for the plan year, as determined under paragraph (a)(10) of this section: the last day of the seventh month following the close of the prior plan year.

(6) For plan years of multiemployer plans beginning on or after January 1, 1988, if the plan has 500 or more participants for the plan year, as determined under paragraph (a)(10) of this section, the fifteenth day of the eighth full calendar month following the month in which the premium payment year begins.

(c) *Continuing obligation to file.* The obligation to file the form prescribed by this subpart and to pay any premiums due continues until plan assets are distributed under a termination procedure or until a trustee is appointed under section 4042 of the Act, whichever occurs earlier. The entire premium computed under this subpart is due, irrespective of whether the plan is entitled to a refund for a post-1988 short plan year (in the case of certain multiemployer plans) pursuant to § 2610.33(d).

(d) *Improper filings.* Any form not filed in accordance with this subpart, not filed in accordance with the instructions contained in the form, not accompanied by the required premium payment, or otherwise incomplete, may, in the discretion of the PBGC, be returned in whole or in part to the plan administrator and treated as not having been filed.

(e) *Transitional rule for multiemployer plans.* For the plan year in which September 26, 1980, falls ("the enactment year"), the premium determined under § 2610.33 is due on the date determined under paragraphs (a)(3) or (a)(4) of this section, unless the enactment year begins before July 1, 1980. If the enactment year begins before July 1, 1980, the premium is due in two installments as follows:

(1) The multiemployer plan shall pay, on the date determined under paragraph (a)(3) or (a)(4) of this section, a premium of fifty cents for each individual who is a participant in the plan on the last day of the preceding plan year; and

(2) The plan shall pay, within 30 days after PBGC issues a notice of the additional premium due under § 2610.33, such additional premium. However, if the plan fails to pay the amount described in paragraph (e)(1) before January 31, 1981, the additional premium shall be due on the earlier of 30 days after the PBGC issues a notice of the additional premium or March 31, 1981.

Appendix A to Part 2610—Late Payment Interest Charges

The following table lists the late payment interest rates under § 2610.7(a) for the specified time periods:

From—	Through—	Interest rate (percent)
September 2, 1974.	June 30, 1975	6
July 1, 1975	January 31, 1976	9
February 1, 1976	January 31, 1978	7
February 1, 1978	January 31, 1980	6
February 1, 1980	January 31, 1982	12
February 1, 1982	December 31, 1982	20
January 1, 1983	June 30, 1983	16
July 1, 1983	December 31, 1984	11
January 1, 1985	June 30, 1985	13
July 1, 1985	December 31, 1985	11
January 1, 1986	June 30, 1986	10
July 1, 1986	September 30, 1987	9
October 1, 1987	December 31, 1987	10
January 1, 1988	March 31, 1988	11
April 1, 1988	September 30, 1988	10
October 1, 1988	March 31, 1989	11
April 1, 1989		12

Appendix B to Part 2610—Interest Rates For Valuing Vested Benefits

The following table lists the required interest rates to be used in valuing a plan's vested benefits under § 2610.23(b) and in calculating a plan's adjusted, vested benefits under § 2610.23(c)(1):

For premium payment years beginning in—	Required interest rate
January 1988	7.30
February 1988	7.06
March 1988	6.74
April 1988	6.90
May 1988	7.16
June 1988	7.38
July 1988	7.20
August 1988	7.31
September 1988	7.46
October 1988	7.25
November 1988	7.11
December 1988	7.22
January 1989	7.21
February 1989	7.14
March 1989	7.21
April 1989	7.34
May 1989	7.22

The required interest rate listed above is equal to 80% of the annual yield for 30-year Treasury constant maturities, as reported in Federal Reserve Statistical Release G.13 and H.15, for the calendar month preceding the calendar month in which the premium payment year begins.

Issued in Washington, DC this 29th day of June 1989.

Elizabeth Dole,

Chairman, Board of Directors, Pension Benefit Guaranty Corporation.

Issued on the date set forth pursuant to a resolution of the Board of Directors authorizing its chairman to issue this final rule.

Carol Connor Flowe,

Secretary, Board of Directors Pension Benefit Guaranty Corporation.

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July 10, 1989

Part IV

Administrative Conference of the United States

1 CFR Parts 302, 305, and 310

Recommendations and Statement of the Administrative Conference Regarding Administrative Practice and Procedure

ADMINISTRATIVE CONFERENCE OF THE UNITED STATES

1 CFR Parts 302, 305 and 310

Recommendations and Statement of the Administrative Conference Regarding Administrative Practice and Procedure

AGENCY: Administrative Conference of the United States.

ACTION: Recommendations, a statement and bylaw amendment.

SUMMARY: The Administrative Conference of the United States, at its Thirty-ninth Plenary Session, adopted six recommendations, a statement, and a bylaw amendment.

Recommendation 89-1, Peer Review and Sanctions in the Medicare Program, recommends changes to the procedures used by the Medicare program's peer review organizations (PROs) and related procedures of the Department of Health and Human Services. The changes are designed to improve the accessibility of PRO-related policies, the fairness and firmness of PRO-recommended sanctions imposed on providers and practitioners, and the effectiveness of PRO safeguards for beneficiary rights.

Recommendation 89-2, Contracting Officers' Management of Disputes, urges steps to increase the ability and authority of contracting officers to resolve contract disputes. Recommended steps include agency encouragement of the use of alternative dispute resolution (ADR) techniques by contracting officers in resolving contract disputes and increased training of contracting officers in ADR techniques.

Recommendation 89-3, Conflict-of-Interest Requirements for Federal Advisory Committees, urges Congress to establish special conflict-of-interest rules for members of federal advisory committees. First, the Conference recommends a uniform minimal disclosure requirement for all advisory committee members, whether or not they are classified as special government employees. Second, the Conference recommends that agencies be required to determine which of their advisory committee members are special government employees when they charter a committee, and it recommends new criteria for making this determination.

Recommendation 89-4, Asylum Adjudication Procedures, endorses the creation of a new Asylum Board, located within the Executive Office of Immigration Review (Department of Justice), which would consist of an adjudication division, an appellate division, and a documentation center. These changes to the process for adjudicating asylum claims are intended to foster increased expertise and independence of the adjudicators and to assure fair and expeditious adjudications.

In Recommendation 89-5, Achieving Judicial Acceptance of Agency Statutory Interpretations, the Conference recommends that agencies use certain procedures when they adopt interpretations of statutes that are intended to be definitive on judicial review under the deference test set forth by the U.S. Supreme Court in *Chevron U.S.A.* v. *Natural Resources Defense Council,* 467 U.S. 837 (1984).

Recommendation 89-6, Public Financial Disclosure by Executive Branch Officials, calls upon Congress to review and amend the Ethics in Government Act's executive branch public financial disclosure requirements, consistent with an appropriate balance of the benefits and costs of such disclosure. The Conference recommends lowering the threshold level for the reporting of a covered individual's liabilities from the $10,000 to $1,000, which is the current level for the reporting of assets. Other recommended changes include (1) reducing the number of categories of value for the reporting of an individual's assets and (2) requiring that gifts be reported in broad categories of value instead of precise amounts.

A Statement, Mass Decisionmaking Programs: The Alien Legalization Experience, describes the Immigration and Naturalization Services' implementation of the Alien Legalization Program authorized by the Immigration Reform and Control Act of 1986. The statement suggests improvements that can be made by the INS in the remaining phases of the legalization program, and lessons that can be applied in future mass decisionmaking programs by the INS or by other agencies.

The bylaw amendment authorizes the Chairman of the Conference, subject to Council approval, to appoint special counsels to advise the Conference in areas of their expertise. The amendment also specifies the privileges of Conference senior fellows, special counsels and liaison members.

Recommendations and statements of the Administrative Conference are published in full text in the **Federal Register** upon adoption. Complete lists of recommendations and statements, together with the texts of those deemed to be of continuing interest, are published in the Code of Federal Regulations (1 CFR Parts 305 and 310).

DATES: These recommendations, statement and bylaw were adopted June 15-16, 1989, and issued June 30, 1989.

FOR FURTHER INFORMATION CONTACT: Jean R. Conrad, Librarian and Information Officer or Jeffrey S. Lubbers, Research Director (202-254-7065).

SUPPLEMENTARY INFORMATION: The Administrative Conference of the United States was established by the Administrative Conference Act, 5 U.S.C. 571-576. The Conference studies the efficiency, adequacy, and fairness of the administrative procedures used by federal agencies in carrying out administrative programs, and makes recommendations for improvements to the agencies, collectively or individually, and to the President, Congress, and the Judicial Conference of the United States (5 U.S.C. 574(1)).

At its Thirty-ninth Plenary Session, held June 15-16, 1989, the Assembly of the Administrative Conference of the United States adopted six recommendations and one statement, the texts of which are set out below. The texts of recommendations will be transmitted to the affected agencies and, if so directed, to the Congress of the United States. The Administrative Conference of the United States has advisory powers only, and the decision on whether to implement the recommendations must be made by each body to which the various recommendations are directed.

The transcript of the Plenary Session will be available for public inspection at the Conference's offices at Suite 500, 2120 L Street, NW Washington, DC.

List of Subjects

1 CFR Part 302

Administrative practice and procedure.

1 CFR Parts 305 and 310

Administrative practice and procedure, Government ethics, Health care procedures, Immigration procedures, Judicial review.

PART 302—BYLAWS OF THE ADMINISTRATIVE CONFERENCE OF THE UNITED STATES

1. The authority citation for Part 302 continues to read as follows:

Authority: 5 U.S.C. 552, 571-576.

2. Paragraph (e) of 1 CFR 302.2 is revised to read as follows:

§ 302.2 Membership.

(e) *Senior Fellows.* The Chairman may, with the approval of the Council, appoint persons who have served as members of the Conference for eight or more years, or former Chairmen of the Conference, to the position of senior fellow. The terms of senior fellows shall terminate at 2-year intervals in even-numbered years. Senior fellows shall have all the privileges of members, but may not vote, except in committee deliberations, where the conferral of voting rights shall be at the discretion of the committee chairman.

3. Paragraph (f) is added to 1 CFR 302.2, to read as follows:

(f) *Special Counsels.* The Chairman may, with the approval of the Council, appoint persons who do not serve under any of the other official membership designations, to the position of special counsel. Special counsels shall advise and assist the membership in areas of their special expertise. Their terms shall terminate at 2-year intervals in odd-numbered years. Special counsels shall have all the privileges of members, but may not vote, except in committee deliberations, where the conferral of voting rights shall be at the discretion of the committee chairman.

4. Section 302.4 is revised to read as follows:

§ 302.4 Liaison arrangements.

The Chairman may, with the approval of the Council, make liaison arrangements with representatives of the Congress, the judiciary, federal agencies that are not represented on the Conference, and professional associations. Persons appointed under these arrangements shall have all the privileges of members, but may not vote, except in committee deliberations, where the conferral of voting rights shall be at the discretion of the committee chairman.

PART 305—RECOMMENDATIONS OF THE ADMINISTRATIVE CONFERENCE OF THE UNITED STATES

PART 310—MISCELLANEOUS STATEMENTS

1. The authority citation for Part 305 continues to read as follows:

Authority: 5 U.S.C. 571–576.

2. The table of contents to Part 305 of Title 1 CFR is amended to add the following new sections:

Sec.
305.89–1 Peer Review and Sanctions in the Medicare Program (Recommendation No. 89–1).
305.89–2 Contracting Officers' Management of Disputes (Recommendation No. 89–2).
305.89–3 Conflict-of-interest requirements for Federal Advisory Committees (Recommendation No. 89–3).
305.89–4 Asylum Adjudication Procedures (Recommendation No. 89–4).
305.89–5 Achieving Judicial Acceptance of Agency Statutory Interpretations (Recommendation No. 89–5).
305.89–6 Public Financial Disclosure by Executive Branch Officials (Recommendation No. 89–6).

3. The authority citation for Part 310 continues to read as follows:

Authority: 5 U.S.C. 571–576.

4. The table of contents to Part 310 of Title 1 CFR is amended to add the following new section:

Sec.
310.14 Mass Decisionmaking Programs: The Alien Legalization Experience.

5. New §§ 305.89–1 through 305.89–6 are added to Part 305, to read as follows:

§ 305.89–1 Peer Review and Sanctions in the Medicare Program (Recommendation 89–1).

As the Administrative Conference noted in Recommendation 86–5 [1] the Medicare program relies heavily on implementation of federal requirements by localized carriers, intermediaries and, increasingly, peer review organizations (PROs).

The PRO system was created in 1982. It is made up of state-wide, Physician-controlled organizations under individual contracts with the Department of Health and Human Services (HHS). These contracts are negotiated pursuant to a general contractual "Scope-of-Work promulgated by HHS every three years. PROs are delegated a number of important responsibilities under the Medicare system. They identify substandard, unnecessary or inappropriate services rendered to Medicare beneficiaries, and oversee education and corrective actions for substandard providers (e.g., hospitals) and medical practitioners. They also recommend to HHS that it sanction providers and practitioners when they find seriously improper practices, deny Medicare payment for inappropriate or unnecessary services, and protect the rights of beneficiaries.

This recommendation follows the suggestion made in Recommendation 86–5 that the PRO program was deserving of further study. It recognizes the evolutionary nature of the PRO's role in Medicare, and the administrative difficulties posed for HHS in overseeing this decentralized program—especially since new legislative directions affecting the program appear regularly, often contained in year-end omnibus budget reconciliation acts. Nevertheless, the Conference urges the Department (and, where necessary, Congress) to make changes designed to improve the accessibility of PRO-related policies, the fairness and firmness of PRO sanctions imposed on providers and practitioners, and the effectiveness of PRO safeguards for beneficiary rights.

In Paragraph A of the Recommendation, the Conference urges several enhancements of HHS' current practices in disseminating, making accessible, and soliciting comments on, PRO program guidelines of general applicability, including the scopes of work, manuals, and the criteria and norms used to evaluate medical care. Paragraph B seeks to promote improvements in the PRO's assigned duty of investigating complaints by beneficiaries, and urges Congress to allow PROs to act in response to oral complaints.

Paragraph C recommends invigorating the process of investigating and adjudicating sanctions against health care practitioners and providers charged with violations of their obligations under the Medicare program. The current sanction process begins when a PRO gives formal notice to the practioner or provider involved that it considers that poor quality care may have been rendered or that other violations have occurred. The PRO is required to have at least one quite formalized meeting with the practitioner or provider to discuss the allegations that the care rendered either "failed in a substantial number of cases substantially to comply" with the statutory obligations to render proper medical care, or "grossly and flagrantly violated such obligations in one or more instances. 42 U.S.C. § 1320c–5(b). (In the former type of case, at least two meetings are required.) If, after the meeting, the PRO believes that violations have occurred, it recommends to the HHS Office of Inspector General (OIG) that a sanction be imposed, either in the form of an exclusion from participation in the Medicare program for some period of time, or a civil monetary penalty of no more than the amount of the cost of medically improper or unnecessary services. If the OIG agrees that violations have occurred, and in addition finds that the practitioner or provider is unwilling or unable to comply with the obligations to render proper care, the OIG may impose one of these sanctions. If the sanction is exclusion, it becomes effective fifteen days after notice.[2] The sanction is appealable to an ALJ, then to the Appeals Council; judicial review is subsequently available.

This recommendation seeks to balance the vital interest in protecting the health and safety of program beneficiaries and the need to assure fairness to the accused provider or practitioner whose livelihood is at stake and whose services might be needed. The Conference urges that the current PRO sanction process be streamlined. It also urges that all providers and practitioners, not just some, be permitted to seek a stay of an HHS order to exclude them from the Medicare program, in a proceeding akin to that of a temporary restraining order at the administrative law judge adjudication stage of that process. However, the burden would

[1] ACUS Recommendation 86–5, *Medicare Appeals*, 1 CFR 305.86–5.

[2] Certain practitioners in rural areas are permitted to have the exclusion stayed, pending OIG proof that the practitioner would pose a "serious risk" to program beneficiaries if allowed to remain in the program during the pendency of the administrative appeal.

be on the practitioner or provider to show that no serious risk would be posed to beneficiaries during the pendency of the administrative appeal. The Conference also urges changes that, while maintaining the requirement that the OIG prove that violations have occured, would eliminate the additional requirement of proving that the practitioner or provider is unwilling or unable to comply with the obligations to provide quality care. The offenses or oversights, which have been found both by peers (PROs) and regulators (OIG) to be substantial or gross and flagrant, already serve as indicators of inability or unwillingness to comply. Under the current law, before excluding a provider or practitioner on the basis of these findings, the government must bear an additional evidentiary burden that is inappropriate for this type of proceeding. It must prove what amounts to a speculative negative—that violators would be unwilling or unable to comply with the law in the future. The apparent result of this evidentiary requirement has been to chill the initiation of exclusion proceedings against providers and practitioners who are providing improper care or otherwise violating the law. Further, the Conference recommends legislative changes to provide for meaningful civil money penalties, as well as for the current sanction of exluding providers and practitioners from the program. It should be noted that the Conference views the changes in the sanction procedure contained in this paragraph as a unified package, one that in its present form balances conflicting interests but that will become unbalanced if any one significant portion were not to be accepted.

Paragraph D urges changes in the PRO statute and regulations to ensure that beneficiaries are better informed of their rights to appeal decisions concerning their lack of coverage or discharge from a hospital or other facility, and that they will not be discharged until such appeals are resolved. Paragraph E covers the PRO's role in denials of payment for care determined to be unnecessary, substandard or rendered in an inappropriate setting. It recommends that HHS implement in final rules 1985 legislation concerning PRO denials for substandard care.[3] It also urges HHS to amend its rules to require that PROs not make any final decisions affecting payment without adequate review by medical practitioners who are qualified in the relevant area. Finally, Paragraph F urges HHS to take steps to permit PROs to share information with provider facilities and state medical boards.

Recommendation

A. *Publication and Dissemination of PRO Program Guidelines.* 1. HHS should enhance its current practice of publishing and disseminating all Peer Review Organization (PRO) program rules having a substantial effect on providers, medical practitioners and beneficiaries by taking the following steps:

(a) Notice-and-comment procedures should be used for rulemaking except when the agency for good cause finds that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.[4]

(b) Proposed PRO "scopes of work" and any generally applicable modifications or interpretations of the responsibilities of PROs during a contract cycle should be published in the **Federal Register** and disseminated to relevant interest groups. Interested parties should be allowed 30–45 days of commenting, unless explicit Congressional deadlines would be contravened thereby, or unless there is good cause for immediate implementation.

(c) HHS should make PRO contracts, manual instructions, and other guidelines of general applicability regarding the PRO program readily available to the public at convenient locations, including social security offices. HHS should publish an updated list of such materials in the Federal Register at least quarterly.

2. HHS should encourage PROs to use outreach and consensus-building techniques analogous to negotiated rulemaking when they are developing criteria and norms for PRO review of the quality, necessity and appropriateness of medical care.[5] HHS should further encourage PROs to make these criteria and norms consistent nationwide.

B. *PRO Investigations of Beneficiary Complaints.* 1. Congress and HHS should coordinate the system of PRO review of beneficiary complaints concerning quality of services with other federal and state regulatory schemes. Initially, priority consideration should be given to complaint investigations in the hospital setting, where PROs have the most expertise and where alternative means to investigate complaints are least available.

2. Congress should amend 42 U.S.C. 1320c–3(a)(14) to permit PROs to investigate and otherwise act on oral complaints concerning the quality of services. Until it does so, HHS should require PROs to receive such oral complaints from beneficiaries or witnesses, and reduce them to writing, before acting on them.

3. HHS should require PROs to use investigative techniques that, so far as may be feasible, protect from disclosure the identity of complainants who do not expressly and voluntarily consent to such disclosure. Where the identity of a complainant who desires anonymity cannot be kept confidential, the PRO should give the complainant the option of withdrawing the complaint in lieu of disclosure, although the PRO may at its discretion continue to investigate the underlying problem.

4. HHS should amend the PRO Scope of Work to conform to the 1986 Omnibus Budget Reconcilation Act by requiring PROs to inform beneficiaries fully regarding the final disposition of all complaints, whether involving providers or practitioners. PROs also should be required promptly to inform providers and practitioners of the final disposition of investigations involving them.

5. HHS should establish guidelines and a significantly more expedited schedule than the current several-month process for PROs to complete initial investigations of complaints of potentially life-threatening quality deficiencies. HHS also should establish procedures for receiving and acting on requests for intervention in cases where PROs do not process complaints on a timely basis.

C. *Sanctions Against Providers or Practitioners Who Have Provided Improper or Unnecessary Services.* Congress should streamline the sanction process by taking the following interrelated steps to promote heightened enforcement, while preserving fairness to the accused provider or practitioner.

1. HHS should seek to ensure greater uniformity among PROs through training and the development of a model sanction referral form. To preserve needed healthcare resources, HHS and the PROs should continue to emphasize education and corrective action rather than sanctions as the primary means of addressing quality problems. HHS should also amend its rules (a) to require that, once a PRO determines that there is a quality problem for which a sanction is the appropriate intervention, it immediately start the sanction process, and (b) to provide that, ordinarily, there will be only one formal meeting between the PRO and the accused provider or practitioner after the sanction proceeding has been initiated.

2. Congress should amend the PRO statute to offer all providers and practitioners (urban and rural), upon their receipt of an HHS notice of exclusion pursuant to 42 U.S.C. 1320c–5(b), the opportunity for a preliminary hearing and decision. Such a proceeding would be conducted by an ALJ on the issue of whether the provider or practitioner would pose a serious risk to

[3] On January 18, 1989, HHS published proposed rule covering this subject. 54 Fed. Reg. 1956.

[4] See ACUS Recommendation 83–2, *The "Good Cause" Exemption from APA Rulemaking Requirements*, 1 CFR § 305.83–2.

[5] See ACUS Recommendations 82–4, 85–5, Procedures for Negotiating Proposed Regulations, 1 CFR § 305.82–4, 85–5.

patients during the pendency of the subsequent ALJ proceeding on the merits of the exclusion. The preliminary hearing would be in the nature of a temporary restraining order proceeding, and would arise and be conducted according to the following procedures:

(a) If, within 10 days of receipt of notice of the exclusion, the provider or practitioner appeals the decision of the HHS Office of Inspector General (OIG) imposing an exclusion, a preliminary hearing on the "serious risk" issue should take place before the exclusion takes effect.

(b) If the provider or practitioner establishes at the preliminary hearing that continued participation in the Medicare program pending the ALJ's decision on the underlying appeal will not pose a serious risk to patients, or that such participation can be restricted to preclude such risk, the HHS exclusion order shall be stayed or modified by the ALJ until the ALJ issues a final decision on the merits of the exclusion.

(c) The ALJ must render the preliminary decision on the "serious risk" issue as quickly as possible but within no more than 30 days after the filing of the appeal, and a final decision on the exclusion within a time period reflecting assignment of the highest priority to the adjudication.

3. Congress should retain the requirement in 42 U.S.C. 1320c-5(b)(1) that sanctions be based on determinations that a practitioner or provider has either (A) "failed in a substantial number of cases substantially to comply" with statutory obligations to render appropriate and quality care, or (B) "grossly and flagrantly violated such obligations in one or more instances. However, Congress should eliminate the separate and additional requirement in 42 U.S.C. 1320c-5(b)(1) that the OIG must determine the provider's or practitioner's "unwillingness or lack of ability substantially to comply" with program obligations before imposing sanctions on the provider or practitioner.

4. Currently the PRO statute [42 U.S.C. 1320c-5(b)(3)] limits monetary penalties to "the actual or estimated cost of medically improper or unnecessary services. In order to provide for a wider range of sanctions, Congress should amend the PRO statute to allow the OIG to assess a substantial civil money penalty for each violation against providers and practitioners who are found to have grossly and flagrantly violated their obligations on one or more occasions, or to have substantially violated such obligations in a substantial number of cases. The OIG should be given the discretion to impose such monetary penalties in addition to an exclusion where appropriate.

5. HHS should assign PRO sanction cases to ALJs attached to the Departmental Appeals Board (who currently hear other sanction cases in the Department) rather than to Social Security ALJs, as is the current practice.

D. *Notice to Beneficiaries of Noncoverage.* 1. Congress should amend 42 U.S.C. § 1320c-3(e)(3) to assure that hospitalized beneficiaries who appeal the hospital's notice of noncoverage by noon of the day following receipt of the notice, should not have such coverage discontinued until the PRO rules on their request for review.

2. HHS should amend the PRO regulations to assure that, at the time a hospital informs beneficiaries of its decision to discharge them or of the discontinuance of coverage, they are informed of their discharge appeal rights under the PRO program.

3. The notice of a right to appeal should be on a form drafted by HHS (developed in consultation with beneficiary organizations and other interested parties), and should include a concise and easily understood statement of the basic beneficiary right to a no-liability appeal to the PRO. If the current system of separate appeal tracks (depending on whether the hospital and attending physician concur or not) is retained, separate notices should be given for each track to avoid the confusion caused by a notice that describes multiple procedures.

E. *PRO Denials of Payment for Substandard or Unnecessary Care.* 1. HHS should proceed expeditiously to final rulemaking to implement PRO authority, contained in 42 U.S.C. § 1320c-3(a)(2), to deny payment to practitioners or providers for care that does not meet professionally recognized standards.

2. HHS should require by regulation that PROs not make final utilization review denials (denials of payment for care that has been determined to be unnecessary or rendered in an inappropriate setting) until a proposed denial and the response to it by the affected provider or practitioner have been reviewed by at least one practitioner qualified by professional training and experience relevant to the matters in controversy. Although HHS should at a minimum apply the same standard to reviews of denials of payment for failure to meet professional standards of care, it may be appropriate in this context to require that the review be performed by a physician practicing in the same care specialty.

F *PRO Sharing of Information.* 1. HHS should issue PRO manual instructions and amend the Scope of Work in order to implement the Congressional mandate requiring the sharing of information among the PROs and state medical boards and licensing authorities regarding practitioners and providers who violate quality standards, and should modify its current confidentiality and disclosure regulations to require that a copy of any PRO final sanction recommendation be provided to such bodies. HHS should explore the feasibility of including sanction recommendations in the National Practitioner Data Bank.

2. HHS should amend PRO regulations to require PROs to share with hospitals information about confirmed violations of quality of care standards involving doctors on the staffs of such hospitals, including the contents of corrective action plans.

§ 305.89-2 Contracting Officers' Management of Disputes (Recommendation 89-2).

An increasing number of problems in the management of government contracts are now referred to lawyers, accountants, and judges for resolution. This accelerating trend has tended to deemphasize the responsibility of the agency contracting officers, who (in most agencies) have traditionally played a key role in the procurement process, including dispute handling. Many contracting officers ("COs") today are subject to restrictive regulations and close oversight that can inhibit their willingness to negotiate settlements. For this and other reasons, many cases proceed to needless litigation that are in fact susceptible to prompt, direct resolution by COs at an early stage when parties are often less entrenched and more congizant of program interests.[2]

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[1] Conference Recommendation 87-11, *Alternatives for Resolving Government Contract Disputes*, 1 CFR § 306.87-11, describes one aspect:

"The dispute handling system established by the Contract Disputes Act begins with the contracting officer ("CO"), an agency official whose function is to enter into and administer government contracts. Any claim arising out of contract is to be presented to the CO. The CO has a dual role: to represent the government as a party to the contract, but also to make initial decisions on claims subject to certain procedural safeguards. If the dispute is not amicably resolved, the CDA requires the CO to issue a brief written decision stating his or her reasons. A contractor dissatisfied with a CO's decision may appeal either to an agency board of contract appeals or directly to the U.S. Claims Court, where proceedings become considerably more formal.

[2] This report addresses only dispute resolution during contract performance; it does not extend to controveries which arise during the contract formation process.

Several Conference studies have demonstrated opportunities for improving agencies' resolution of contract disputes consonant with the Contract Disputes Act's [3] goal of expeditious resolution without disrupting performance.[4] While a few agencies have experimented with alternative means of dispute resolution at the appeal level, these methods are even more likely to be useful prior to issuance of a contracting officer decision. This potential has been neglected. Current training for COs does not address ADR and gives minimal attention to negotiation skills. These methods serve the agency by helping to expedite dispute handling. They serve the parties by keeping outcomes in the control of the contracting parties, preserving cooperative business relations, avoiding litigation (and the concomitant loss of control as to results), and—most important—allowing the parties to return to concentrating on productive work rather than conflict.

This recommendation builds on an earlier one (87-11), in which the Conference focused primarily on possible uses for consensual means of resolving contract disputes at the appeal level. It identified the decreased authority of COs as a major factor contributing to the inefficiency and cost of resolving many conflicts. Recommendation 87-11 (in pertinent part) calls for (1) legislation, an executive order, by the Office of Federal Procurement Policy, policy statement, and Federal Acquisition Regulation changes to encourage COs, before issuing a decision likely to be unacceptable to a claimant, to explore use of ADR to resolve their differences; (2) agency adoption of policies encouraging ADR and regular use of rules or notices to alert COs and other parties to ADR availability; (3) agency designation of an employee to serve as an ADR specialist in connection with contract disputes; and (4) agency attention to the need to offer training in negotiation and other ADR skills to COs and others involved in contract disputes.

The instant recommendation seeks to go further to enhance the CO's ability and authority in the resolution of contract disputes. Calling for CO training in negotiation and dispute handling, as well as increased use of ADR techniques as part of a CO's decisionmaking process, it supplements the prior recommendation by focusing on the integration of consensual dispute resolution into already existing dispute and training systems at the CO level, overcoming obstacles to ADR use, and practical guidance in improving CO-level dispute resolution.

Recommendation

1. Agencies with significant acquisition activity, acting in consultation with expert groups, should encourage COs, and other key personnel involved in the resolution of contract disputes, to make greater efforts routinely to consider and utilize ADR to help resolve claims. Since dispute resolution at the CO level is very much a shared activity, these persons may include progrm and project managers, attorneys, auditors, engineers, specialists in pricing, packaging, production, maintenance and quality control, and other technical experts or contracting officials. These agencies should undertake comprehensive programs of promotion ADR at the CO level. The programs should include application of ADR techniques in specific test cases, conduct of training, case screening, and information and guidance for personnel and contractors.

2. Agency heads should direct senior officials within the acquisition hierarchy to act as proponents for dispute resolution, with the specific mission of developing more effective contact dispute resolution practices. Agencies with extensive acquisition activity should designate a senior official within the acquisition hierarchy with the specific mission of developing more effective contract disputes resolution practices. This official's mission would include challenging barriers to wider ADR use, educating disputants in industry and government, and improving understanding and use of ADR procedures at the CO level.

3. The Federal Acquisition Regulation should be amended to describe specifically the full range of dispute resolution methods available for consideration by the parties at or before the time a claim is presented to the CO for resolution under the Contract Disputes Act.

4. COs involved in the disputes process should be specifically evaluated, as part of the annual performance evaluation cycle, on their effectiveness in managing contract disputes.

5. In addition to those techniques set forth in Recommendation 87-11, agencies should be encouraged to use the following specific methods in CO-level disputes:

(1) Employing factfinding to offer an advisory decision, or designating a CO who was not involved in the disputed issues, or a particular distinguished government official or other knowledgeable person, to make an advisory decision;

(b) Employing minitrial or other processes to permit a structured presentation of facts and arguments to the CO or other government officer with authority to settle;

(c) Agreeing in advance that disputes arising under a particular contract will be voluntarily submitted to an expert or panel for nonbinding opinion as soon as a disagreement occurs; and

(d) Encouraging agency COs to employ the services of mediators or other neutrals to enhance negotiations to settle contract disputes.

6. Board of Contract Appeals judges should take greater advantage of opportunities to suggest returning to the CO cases which evidently should be pursued more vigorously for settlement.

7 ADR training programs, for both industry and government personnel, should be integrated into existing management training programs, as follows:

(a) Training should focus on the use of these techniques as tools to improve the contract formation and contract administration process, so as to abate conditions which later lead to disputes, and to expedite decisionmaking under the Contract Disputes Act.

(b) Training should reflect the fact that negotiation is a key dispute resolution method, and that most COs would become more effective professionals by devoting increased training and attention to these methods. The Federal Acquisition Institute and other government entities specializing in acquisition training should devote increased attention to listening and communications skills, use of "interest" and "principled" rather than "positional" bargaining, and systematic attention to negotiation techniques. The training should also enable a CO to engage in meaningful discussion with a contractor by first working as a "team builder" to develop a coherent intraagency position that takes into account the views and needs of attorneys, auditors, program managers, engineers and others within the agency. Consistent with best management practice and the Packard Commission Report for greater efficiency in procurement,[6] the training should

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41 U.S. Code 601-613; 5 U.S.C. 5108(c)(3); 28 U.S.C. 1346(a)(2), 149(a)(2), 2401(a), 2414, 2510, 2517, 31 U.S.C. 1304(a)(3)(C) (1982); enacted November 1, 1978 by Pub. L. No. 95-563, 92 Stat. 2383.

Section 33.204 of the Federal Acquisition Regulation, which guides agency procurement practices, includes the following possible inducement to ADR:

"In appropriate circumstances, the contracting officer, before issuing decision on a claim, should consider the use of informal discussions between the parties by individuals who have not participated substantially in the matter in dispute, to aid in resolving the differences.

This suggestion for a "fresh look" at the issues recognizes the potential usefulness of an objective evaluation.

They include arbitration, mediation, minitrial, factfinding, convening, facilitation and negotiation. These are defined in the Appendix to Conference Recommendation 86-3, *Agencies' Use of Alternative Means of Dispute Resolution*, 1 CFR 306.86-3.

A Quest for Excellence, Final Report by the President's Blue Ribbon Commission on Defense Management (June 1986).

encourage the CO, even without the assistance of a third-party neutral, to avert appeals by reducing the number of situations where disputes, encumbered by internal disagreements or incoherent positions, are passed on to boards of contract appeals.

(c) Professional organizations concerned with the public contract disputes process, such as the American Bar Association, Federal Bar Association, and National Contract Management Association, should develop and encourage increased learning opportunities in effective dispute resolution techniques for representatives of the government and private sector.

§ 305.89-3 Conflict-of-Interest Requirements for Federal Advisory Committees (Recommendations 89-3).

The Law and practice regarding conflict-of-interest requirements for federal advisory committee members have developed from the interaction of three statutory schemes: the Federal Advisory Committee Act, the conflict-of-interest laws, and the federal personnel laws. However, none of these statutory schemes was drafted to deal specifically with conflict-of-interest standards for government advisers.

In 1982 the Office of Government Ethics issued guidance to agencies that sought to meld a coherent analytical framework from the three statutory schemes. In determining whether the conflict-of-interest laws applied, the Office distinguished between those advisers who were selected as committee members because of their individual qualifications, and were thus deemed to be special government employees (SGE's), and those who instead were selected as representatives of nongovernmental groups or organizations (or in some cases, as independent contractors). While this guidance has reduced the confusion somewhat, the determination of a committee member's status as an SGE or a representative of a nongovernmental group or organization remains difficult, and agency practice in classifying advisory committee members as SGE's or representatives varies greatly and often appears arbitary.

The classification of an advisory committee member as an SGE or a representative is significant because only the former are subject to the conflict-of-interest and financial disclosure laws. The most significant of these laws for advisory committee members is Section 208 of Title 18, United States Code, which makes it a criminal offense to participate "personally and substantially" as a government employee "through decision" recommendation, the rendering of advice, investigation, or otherwise in any particular matter in which to his knowledge, he, his spouse, minor child, partner, organization has a financial interest. The term "particular matter" in Section 208 has been interpreted broadly by the Department of Justice and the Office of Government Ethics to extend to all discrete matters that are the subject of agency action, including rulemaking and general policy matters.[2]

Section 208 is especially a problem for advisory committee members. Often they have been selected precisely because they are especially well qualified to provide advice concerning problems in a particular field in which they themselves may be active both professionally and financially.

Because of its breadth, Congress provided for agency waivers of Section 208's prohibition, either by rule or on a case-by-case basis, where the appointing official makes a determination that the employee's interest is too remote or insubstantial to affect the integrity of his or her services. Agencies, however, may be unable or reluctant under current law to grant a waiver where a financial interest is significant, even though the agency concludes that any bias arising from that interest will be offset through committee balance, disclosure of the interest, or the individual's status as only an adviser and not as a decisionmaker.

Faced with the specter of criminal liability and the limitations of waivers, or simply for administrative convenience, some agencies have adopted a policy of declaring most or all of their advisory committee members to be interest group representatives, rather than SGE's, except in the clearest cases. Thus, in practice, agencies may be requiring too little disclosure from members who are not SGE's, while imposing significant burdens, principally potential criminal liability, on those members who are SGE's.

In this recommendation the Conference urges the establishment of a uniform minimal disclosure requirement for all advisory committee members, whether or not they are classified as SGE's.[3] The recommendation seeks to balance the government's and the public's need for information to evaluate potential conflicts of interest and the burden placed on the individual who agrees to serve on an advisory committee, frequently without pay.

The Conference also recommends that Congress direct agencies to determine, when chartering or renewing the charter of an advisory committee, whether or not the committee's responsibilities require indentifying its members as special government employees for purposes of the conflict-of-interest laws. The recommendation (¶ 2) includes criteria for making this determination. This approach places the burden of foreseeing and preventing conflicts of interest on the agency that seeks an individual's services on an advisory committee, rather than on the individual asked to serve, as does reliance on § 208 waivers.

This recommendation does not extend to privately established advisory committees that are utilized for advice in particular matters because the members of these committees are not appointed by a federal agency. Consequently, an agency's relationship with such committees must be considered on a *ad hoc* basis. Nevertheless, the Conference believes agencies should be alert to possibilities for bias or self-interest in the advice of utilized committees and, where appropriate, should request information respecting the affiliations and interests of the members.

Recommendation

1. *Disclosure by Advisory Committee Members.* (a) Congress should require that each individual selected to serve on a federal advisory committee, excluding a regular government employee, furnish to the agency or appointing authority at the time of the appointment or designation—

(1) The identity of the individual's principal employment;

(2) A list of positions held (whether paid or unpaid) and any contractual relationships for the performance of services with any corporation, company, firm, partnership or other business enterprise, any non-profit organization, any labor organization, or any educational or other institution whose activities or purposes may be (or may forseeably become) relevant to the purposes and functions of the advisory committee as determined by the agency or appointing authority and described in the committee charter;

(3) The identity, but not value or amount, of any other sources of income or any interests in a trade or business, real estate, or other asset held for investment or production of income, exceeding $1,000 in value which are relevant to the purposes and functions of the advisory committee as determined by the agency or appointing authority and described in the committee charter;

(b) Advisory committee members should be required to file updated disclosure reports annually.

(c) The agency or appointing authority should make publicly available the information furnished pursuant to subparagraphs (a)(1) and (a)(2) above. The financial information described in subparagraph (a)(3) should ordinarily be held confidential unless the member consents to its release or the agency determines after consulting with the

5 U.S.C. App. I.

[2] The test of whether a financial interest exists with respect to the matter is whether the government action in which the employee participates will have a "direct and predictable effect" on the entity in question. Participation in the presence of known conflict constitutes a violation of Section 208, whether or not the employee's action furthers or is likely to further his or her financial interest.

[3] The Conference recognizes that advisory committee members who are classified as special government employees may be required to furnish financial information pursuant to regulations of the appointing agency or the Office of Government Ethics. It is further noted that the Office of Government Ethics has under consideration a proposed regulation governing financial disclosure for all government employees, including special government employees.

member that public disclosure is required in the public interest.

2. *Classification of Advisory Committee Members.* Congress, by amendment to the Federal Advisory Committee Act or other pertinent statute, should require that each agency determine, when chartering or renewing the charter of an advisory committee, whether its responsibilities are such as to require some or all of its members to be identified as special government employees for purposes of the conflict-of-interest laws. Congress should require the agency to consult with the Office of Government Ethics in making such a determination, and it should direct the agency to be guided by the following considerations—

(a) Ordinarily, where an advisory committee is expected to provide advice of a general nature from which no preference or advantage over others might be gained by a particular person or organization, the members of the committee need not be special government employees.

(b) The members of an advisory committee which renders advice with respect to the agency's disposition of particular matters involving a specific party or parties should be considered special government employees.

(c) The principal consideration in classifying an advisory committee member should be the nature of the committee's function rather than whether or not the member receives compensation.

3. *Coverage.* This recommendation applies to advisory committees which are established and whose members are appointed or designated by the federal government, and to advisory committees whose operations are funded by the government. It does not apply to privately established advisory committees which are "utilized" by the federal agencies in particular matters.

4. *Technical Amendment.* Congress should amend 18 U.S.C. 207(g) to provide that a partner of a special government employee shall not be barred from any representational activity because of that employee's participation in a particular matter where the employee himself would not be barred from such representation by 18 U.S.C. 203 or § 205.

§ 305.89-4 Asylum Adjudication Procedures (Recommendation 89-4.

Providing asylum to the persecuted is a vital and treasured part of the American humanitarian tradition. It deserves reaffirmation and continued commitment. The asylum process, however, can also become a misused exception in the nation's immigration laws, especially in a time of improved transcontinental travel and communications. Two important public values thus come into conflict in the asylum program. On the one hand stands the promise of refuge to the persecuted; on the other stands the demand for reasonable assurance of national control over the entry of aliens. This tension becomes acute whenever application numbers rise.

In the 1970s, the United States received approximately 2000 applications for asylum each year. By 1988, that number had risen to approximately 60,000 applications. The Immigration and Naturalization Service (INS) projects 100,000 applications in 1989. Government expenditures for coping with the increase have risen rapidly, both for adjudication and for detaining or otherwise arranging to shelter and feed the applicants. But this is necessarily only a stopgap measure. It would be far more cost effective in the long run to devote the resources necessary to improve asylum adjudication procedures.

Although it should be possible to distinguish qualified from unqualified asylum applicants and thereby both honor the humanitarian tradition and avoid misuse of the asylum provision, several factors hinder our ability to do so. First, the "well-founded fear of persecution" standard, upon which asylum is based, is far from self-defining; there is no uniform understanding of its application to particular cases. Second, judgments about the relative risks faced by asylum seekers upon return to their native countries are unavoidably affected by preconceptions about what conditions may be like in those countries. It may also be misleading to posit a sharp distinction between economic migrants and political refugees. Asylum seekers represent a spectrum of motivations, and many leave their home countries because of a mix of political and economic reasons. Third, the facts upon which adjudication must rest are elusive, largely because they turn on conditions in distant countries. Moreover, the individual applicant, often inarticulate and uneasy, may be the only available witness to the specific events that underlie the claim. Therefore, credibility determinations can be crucial, but they are complicated by barriers to effective crosscultural communication. Improvements in the system must make allowance for all these difficulties.

The central standard for determining whether an applicant will be granted asylum derives from the definition of refugee" contained in a United Nations (UN) treaty, the 1951 Convention relating to the Status of Refugees, amended by its 1967 Protocol. Under section 208 of the Immigration and Nationality Act (INA), the Attorney General may, in his descretion, provide asylum to applicants who establish that they have a "well-founded fear of persecution" in the home country because of race, religion, nationality, membership in a particular social group, or political opinion. Additionally, section 243(h) of the INA establishes a mandatory country-specific protection which is known as *nonrefoulement.* Section 243(h) provides that the government may not return an alien to a country where his "life or freedom would be threatened" on any of the same five grounds. Under current administrative practice, the most important test has become the "well-founded fear" standard, because people granted asylum status are necessarily shielded against removal from the United States.

Historically, the United States has employed a mix of adversarial and nonadversarial procedures for deciding on asylum and *nonrefoulement* claims. Currently, "walk-in" claims are adjudicated by examiners in the district offices of the INS after an essentially nonadversarial interview. It typically lasts about twenty minutes as the interviewer reviews the application form (I-589) and the applicant's supporting information, and also prepares and issues work authorization papers (provided that the claim is adjudged "nonfrivolous"). The file is then sent to the State Department for its advisory views. The applicant is given fifteen days to respond to any recommendation by the State Department to deny the application. Subsequently, an INS examiner will review the file and issue a decision. This process may take eight months or more. Informal review of district office decisions is provided by the Asylum Policy and Review Unit (APRU), a small office in the Department of Justice created in April 1987

Denials in the district office are not appealable, but unsuccessful applicants may renew the application in adversarial exclusion or deportation proceedings before an immigration judge, who will consider the matter de novo. These judges are officials in the Executive Office of Immigration Review (EOIR), which is wholly separate from INS but is also a part of the Department of Justice. Aliens who do not file for asylum until such proceedings have started have no access to the district office; they will be heard only by an immigration judge.

The immigration judge's ruling on asylum is appealable to the Board of Immigration Appeals (BIA), which is also located in EOIR. Appeals can easily consume a year or more, largely because of delays in receiving transcripts of immigration court hearings. No further administrative appeals are possible at the instance of the applicant, but on rare occasions, cases are considered by the Attorney General personally upon certification or referral. Judicial review of individual asylum denials almost always occurs as part of the review of exclusion or deportation orders under section 106 of the INA.

Administrative adjudication alone involves five distinct administrative units (the District Office, the State Department, APRU, the Immigration Judges, and BIA), only two of which see the applicant in person. This multiplicity of agencies spreads resources thin, resources that should be concentrated efficiently so as to improve the quality of the procedure and assure that genuine refugees are granted asylum.

Adjudication of an asylum claim through the various administrative and judicial levels requires several months and often consumes years. Such delays increase the attraction for marginal applicants because applicants can enjoy substantial benefits, including work authorization and freedom of movement, throughout the period their claim is pending.

Deterrents such as detention or limitations on work authorization could be used to minimize this magnet effect. Those measures, however, carry substantial disadvantages. Primarily, they are indiscriminate in their impact and may fall most heavily on genuine refugees who have already suffered greatly. These measures also entail higher costs for the federal government, especially when asylum claims remain pending for lengthy periods.

The Conference believes that fair but speedy conclusion of adjudication, leading either to a grant of asylum or to an enforceable removal order, is crucial to any healthy asylum adjudication system. This objective can be promoted through attention to two elements. First, delay derives in part from the point of two separate rounds of de novo consideration of asylum claims. One unified initial asylum proceeding should be established instead. (If the alien has other defenses to deportation or exclusion, those other defenses should continue to be heard by immigration judges in contemporaneous and separate proceedings). Second, additional delay derives from the qualified right to counsel as specified by current statutes and regulations, which provide for counsel in exclusion or deportation cases "at no expense to the government" Because so many applicants are indigent, delays often result from the need to accommodate the schedules of those attorneys who are willing to take the cases on a pro bono basis—a problem that is compounded when applications increase in a particular geographic location. A healthy system of asylum adjudication must be able to schedule hearings expeditiously, even if pro bono counsel are not immediately available in sufficient numbers. Fairness must be sought, therefore, through hearing procedures, training, and monitoring that assure a special role for the adjudicator in developing a complete record when the applicant is not represented.

The conference also believes that a healthy asylum adjudication process must foster the greatest possible accuracy as well as public confidence that decisions are rigorous, professional, and unbiased. Reliance on a specialized adjudicative board without routine reference of applications to the State Department would serve these ends and minimize any perception that asylum decisions are influenced by political considerations. Additionally, arrangements must be made to provide the adjudicators with information concerning foreign country conditions that is as accurate and complete as possible, derived from a wide variety of sources, both to help dislodge any preconceptions and to foster systematic expertise for use in developing the record and making the ultimate judgment on the claim.

For several years the Department of Justice has been considering amended asylum regulations that would serve many of these ends. A version proposed in August 1987 [52 Fed. Reg. 32552] would have established a specially-trained corps of adjudicators, responsible to the INS Central Office rather than to the district directors, and it would have eliminated de novo reconsideration of asylum claims by immigration judges. These regulations drew criticism, in part because of concern about the professionalism and independence of the adjudicators, and the Department responded with modified proposed regulations in April 1988 [53 Fed. Reg. 11300] that retained the new corps of adjudicators but also restored the availability of de novo consideration before the immigration judges. Those regulations are still pending in the Attorney General's office and the Department has encouraged this study and analysis.

Recommendation

The Attorney General should adopt regulations creating a new asylum adjudication process that would eliminate much of the duplication and division of responsibility associated with the current complicated system. Resources should be applied to enhance the professionalism, independence, and expertise of the adjudicators, and to assure fair and expeditious adjudications, so that genuine refugees may be speedily given a secure status and unqualified applicants, absent circumstances which would allow them to remain in this country, may be promptly deported.

I. Creation of a New Asylum Board

The Attorney General should create a new Asylum Board located, for administrative purposes, within the Executive Office of Immigration Review (EOIR) of the Department of Justice and consisting of an adjudication division, an appellate division, and a documentation center. The chairperson of the Asylum Board would be responsible for administrative support and supervision of the operation of all three units.

A. *The Adjudication Division*—1. *Jurisdiction.* All claims for asylum under section 208 of the Immigration and Nationality Act (INA) or withholding of deportation under INA section 243(h) (hereinafter collectively "asylum claims) should be heard exclusively by asylum adjudicators in the adjudication division of the Asylum Board.

2. *Nature of the asylum hearing.* Asylum claim proceedings should be recorded.[1] The asylum adjudicator should be responsible for developing a complete record of the specific facts relating to the applicant's claim, including those which might support a grant of asylum and those which might cast doubt on the claim or on the applicant's credibility. Care should be taken to assure the service of skilled interpreters. The adjudicator should be responsible for most of the questioning, with a reasonable and adequate opportunity for additional questioning and entry of relevant information, including the presentation of witnesses, by the applicant and counsel. The Immigration and Naturalization Service (INS) should not be represented as an opposing party in the proceedings.

3. *Representation of applicants.* Applicants should be encouraged to secure counsel (or a qualified nonattorney representative) to develop the initial claim and to provide representation during the asylum proceedings. Although reasonable accommodation should be provided for counsel to be obtained, proceedings should not be unduly delayed, because expeditious initial decisions are essential.

4. *Use of official notice of country conditions.* Asylum adjudicators should develop substantial cumulative expertise regarding country conditions, to be used in developing the record, and should be responsible for posing illuminating questions to the applicant and other witnesses, for evaluating evidence, and for reaching the ultimate determination about likely risks to the applicant upon return to the home country. The accepted standards for official notice, in accordance with the Administrative Procedure Act, should govern use of such information. Ordinarily, these standards will simply require an adequate statement of reasons for accepting or rejecting the asylum claim, reflecting such expertise. In instances when specific and detailed facts developed from the documentation center or other sources (and not from information supplied by the applicant) appear to be crucial, the applicant should be given notice of intent to deny based on such information, along with an opportunity to offer information or argument in rebuttal.

5. *The adjudicators.* Asylum adjudicators should be recruited from among attorneys possessing adjudicative skills and appropriate judgment and temperament, with close attention given to those who are familiar with international relations and refugee affairs and who are sensitive to the difficulties of cross-culture communication. Adjudicators should receive salary, benefits, and guarantees of adjudicative independence equivalent to those of immigration judges, and they should be assigned no other enforcement or adjudication responsibilities. The adjudicators should

[1] The Administrative Conference recommends experimentation with other methods for creating record that would maintain flexibility but preserve objectivity, professionalism, and fairness to the applicant.

[2] The Administrative Conference takes no position on the possible application of the Equal Access to Justice Act to asylum proceedings.

be given thorough and ongoing training, especially on techniques for fairly conducting this specialized type of proceeding and on conditions in those countries from which a substantial number of asylum applications is received. If, alternatively, a separate Asylum Board is not created and the adjudication assignment is given to immigration judges, then such judges should be assigned to a separate unit in EOIR.

B. Appellate Division—1. *Composition and functions.* The appellate division of the Asylum Board should consist of the chairperson and two additional members, assisted by staff attorneys and other support personnel. The division's principal responsibilities should be to consider appeals filed by persons denied asylum at the initial stage, in light of the administrative record compiled before an adjudicator, and such other information as the applicant may wish to submit or of which official notice may be taken. The division, however, should also monitor cases, and should have the authority to require certification to it of selected cases, either granting or denying asylum, in order to foster consistency, fairness, and political neutrality. It will thus absorb the principal functions now performed by the Asylum Policy and Review Unit.

2. *Certification or referral to the Attorney General.* The Attorney General should retain the authority to review decisions of the Asylum Board, upon formal certification or referral or *sua sponte.*

3. *Expeditious completion of appeals.* A high priority should be placed on completing all asylum appeals expeditiously, preferably within three months of filing. The Department of Justice should ensure that transcripts, where required, are made from recorded hearings in a timely fashion.

C. *Documentation Center.* A documentation center, staffed with regional specialists, should maintain current and detailed information on country conditions, from both governmental and nongovernmental sources, periodically compile and publish usable summaries on selected countries, and respond to requests for more specific information received from officials of the Asylum Board. Special effort should be devoted to assuring complete compilations of ongoing reports from established nongovernmental human rights organizations, and to drawing upon information from documentation centers in other countries. Information and procedures developed by other countries can be particularly useful in minimizing start-up costs. The center's collections and publications shall be accessible to the public.

D. *Role of the Department of State and the United Nations High Commissioner for Refugees.* The Department of Justice should take advantage of resources, assistance, and information available through the State Department and the United Nations High Commissioner for Refugees (UNHCR). In particular, arrangements should be made with both to assist in training adjudicators and to augment information available through the documentation center.

If it so requests, on an across-the-board or country-specific basis, the State Department should receive notice of individual asylum applications, so that it may offer its judgment, in particular, about appropriate responses in sensitive, such cases, as those involving foreign government officials.

II. Detention

Where detention of asylum seekers is deemed necessary,[3] the Department should limit it to short-term detention in "asylum processing centers" as recommended by the Select Commission on Immigration and Refugee Policy. Such centers should also keep families together wherever possible, minimize the length of detention, provide assistance in securing representation, and otherwise foster conditions which reflect that the purpose of detention is not punitive.

III. Deportation

The Department of Justice should ensure that individuals denied asylum are removed promptly if they are otherwise excludable or deportable, subject to any policy decision by the Attorney General to grant extended voluntary departure to nationals of particular countries.

IV Judicial Review

Judicial review of asylum denials should be available as part of the review under section 106 of the INA for orders of deportation or exclusion. Appropriate arrangements therefore should be made to combine, for purposes of judicial review, the record of proceedings before the Asylum Board with that of the regular deportation or exclusion proceedings before the immigration judges and the Board of Immigration Appeals.

[3] The Administrative Conference does not take a position on the suitability of detention in asylum proceedings.

§ 305.89-5 Achieving Judicial Acceptance of Agency Statutory Interpretations (Recommendation 89-5).

Agencies continually interpret the statutes they administer. Their interpretations are expressed in a great variety of formats—including, among others, legislative regulations, adjudicatory opinions, court briefs, interpretive rules, policy statements, staff instructions, correspondence, informal advice, press releases, guidance manuals, testimony before Congress, speeches, and internal memoranda. This recommendation addresses the relationship between the procedures used by an agency in interpreting a statute and the role of the courts in statutory interpretation.

Interpretation of a statute presents a question of law, traditionally the province of the judicial branch (see the scope of review provision of the APA, 5 U.S.C. 706). However, for many years courts have accorded respectful attention or even controlling effect to interpretations of statutes made by the agencies that administer them. In some situations, in which the courts reserve the power to arrive independently at their own interpretations, they will give respectful consideration to an agency's construction but may reject it, even if it seems reasonable. In other cases, courts consider themselves bound to accept an agency's interpretation outright, provided only that it is consistent with the statute and is reasonable. The law governing judicial acceptance of agency statutory interpretations is now dominated by *Chevron U.S.A.* v. *Natural Resources Defense Council,* 467 U.S. 837 (1984). In that case, one involving legislative rulemaking, the Supreme Court laid out a general framework for reviewing agency interpretations of statutes. First, the court is to determine whether Congress has directly spoken to the precise question at issue. If the intent of Congress is clear, the court (like the agency) must give effect to the congressional intent. Where Congress' intent is not clear, however, the court must determine whether the agency's interpretation is based on a reasonable construction of the statute. Chevron thus requires a reviewing court to accept an agency interpretation that (a) is not contrary to statute or specific statutory intent and (b) is reasonable.

When an agency issues a legislative rule or interprets its statute in a formal adjudication, its interpretation of the statute it administers is entitled to judicial acceptance under the *Chevron* standard. Similarly, acceptance under the *Chevron* standard is appropriate if the reviewing court finds a congressional delegation of authority to make definitive interpretations in an informal format such as the informal agency staff ruling involved in *Ford Motor Credit Co.* v. *Milhollin,* 444 U.S. 555 (1980). But agencies rarely possess congressionally delegated authority to make definitive interpretations, carrying the force of law, by informal means. Thus, when an agency states its interpretation of a statute in an informal format, it should understand that courts ordinarily will not be bound to accept such an interpretation.

This is not to say that reviewing courts may ignore an agency interpretation set forth

in an informal format. Numerous decisions of courts at all levels indicate that the views of the agencies charged with responsibility for administering a statute are accorded weight and may be highly influential in shaping courts' decisions. In this way courts retain the advantage of administrative agencies' expertise and remain free to adopt agencies' interpretations, even though not required to do so.

Even when interpretations are expressed informally, however, agencies have in some instances successfully asserted that these interpretations should be accepted as definitive by the courts, without consideration of whether the agency possesses the authority to make binding interpretations in the format it has used.

When an agency interprets a statute without using procedures authorized by Congress for the development of definitive statutory interpretations, it should not expect that its interpretation will be entitled to judicial acceptance as definitive. Procedures so authorized by Congress, in almost all cases, will be relatively formal ones that ensure some level of public participation and encourage reasoned and thoughtful decisionmaking by the agencies. However, this recommendation is not intended to discourage agencies and their staffs from using informal means to keep the public apprised of their views on questions of statutory interpretation. It is often useful and appropriate for agencies to provide informal guidance of this type. The agency may reasonably expect that interpretations like these are entitled to such special consideration as their nature and the circumstances of their adoption warrant. But it is important for both agencies and courts to remember that these informal expressions should not be accorded the same weight as definitive agency interpretations.

This recommendation relates solely to the procedures that should be preconditions to agencies' assertion of the *Chevron* standard of review. It thus takes no position concerning any other aspect of the *Chevron* standard.

Accordingly, the Administrative Conference recommends that the following process be observed.

Recommendation

In developing an interpretation of a statute that is intended to be definitive, an agency should use procedures such as rulemaking, formal adjudication, or other procedures authorized by Congress for, and otherwise appropriate to, the development of definitive agency statutory interpretations.

§ 305.89-6 Public Financial Disclosure by Executive Branch Officials (Recommendation 89-6).

Public financial disclosure by federal officials is intended to make it possible to monitor actual or potential conflicts of interest of such officials. This, in turn, may deter public officials from even considering conduct that would present the appearance of a conflict of interest. However, these benefits of public financial disclosure must be balanced against the burdens imposed on the federal officials who are subject to them.

Determining appropriate public financial disclosure requirements requires an assessment and accommodation of three concerns: the relevance of the information to conflicts of interest which might be faced by the individual in his or her official capacity; the practical burden faced by an individual who must assemble and report information accurately (including whether a nominee or employee would reasonably be expected to have at hand the information which he or she is required to report); and the psychological burden imposed on an individual who must make his or her financial status publicly available to others (i.e., whether public disclosure constitutes an excessive invasion of privacy).

The Administrative Conference has studied the Ethics in Government Act's executive branch financial disclosure requirements (codified at 5 U.S.C. 201-209) and in this recommendation urges Congress to make specific changes to those requirements, consistent with an appropriate balance of the benefits and costs of such disclosure.

This recommendation is not made with the intention of generally requiring either more or less disclosure of public officials. Rather, the Conference's goal is to rationalize the Ethics in Government Act's requirements and eliminate those that appear to bear no reasonable relationship to the Act's purposes. On the one hand, the recommendation increases disclosure by reducing the current threshold level for the reporting of a covered individual's liabilities from $10,000 to $1,000, to be consistent with the current threshold level of $1,000 for the reporting of assets (¶ 2 b (1)). On the other hand, the recommendation would lessen disclosure by reducing the number of categories of value for the reporting of assets from the current six to two, which the Conference believes is sufficient for conflict-of-interest analysis and the maintenance of public confidence in the integrity of executive branch officials (¶ 2 b (2)).

Because the Act's executive branch financial disclosure provisions are so detailed, this recommendation has been organized to clearly distinguish between current provisions that the Conference believes generally further the Act's purposes and, therefore, should be retained, and those provisions that appear unnecessary to achieve the Act's purposes and, therefore, should be eliminated or changed. However, in recommending the retention of particular provisions, the Conference does not mean to imply that such provisions cannot be improved. To the contrary, the Conference urges the Congress to systematically review the coverage and language of all of the Act's public financial disclosure provisions, and to rewrite those that can be made clearer and simpler.

To illustrate, the Conference recommends continuation of the current requirement that nominees for positions covered by the Act report the source of all earned income in excess of $5,000 received by a reporting individual from one source in the two years preceding the year of filing (¶ 2a(2)). However, the current statutory provision (5 U.S.C. 202(a)(6)(B)) requires reporting of such compensation paid "in any of the two calendar years prior to the calendar year during which the individual files his first report If strictly applied, a nominee who filed a report in October of 1989 would be required to disclose such compensation for calendar years 1987 and 1988, but not for the period in 1989 prior to his or her entering government service. This theoretical gap in coverage should be closed whether or not in practice it has proven to be a problem.

The same statutory provision exempts from the "over-$5,000 from one source" disclosure requirement the reporting of "any information with respect to any person for whom services were provided by any firm or association of which such individual was a member, partner, or employee unless such individual was *directly involved* in the provision of such services. 5 U.S.C. 202(a)(6)(B) (emphasis added). In redrafting this provision, Congress should consider either defining the term "directly involved" or delegating to the Office of Government Ethics the responsibility to clarify its meaning by regulation, especially as applied to individuals who provide services to others, such as lawyers. Therefore, although the Conference supports the retention of the substance of this and other of the Act's financial reporting provisions, it is clear that improvements to the language and coverage can be made.

Because of its limited mandate,[1] the Conference takes no position on the public financial disclosure requirements applicable to legislative and judicial branch officials. However, the similarity of those requirements to executive branch requirements suggests the desirability of reviewing and possibly amending legislative and judicial branch requirements as well.

Recommendation

1. **Persons Required To File.** a. *Positions For Which Coverage Should Be Retained.* Congress should continue to require the following categories of executive branch personnel to make public financial disclosure:

(1) The President, Vice President, and nominees for and incumbents in positions which require Senate confirmation;

(2) Full-time officers and employees of the executive branch (including independent agencies) whose positions are classified as GS-16 or above or who are paid at or above the minimum rate of pay fixed for GS-16;

(3) Each member of a uniformed service whose pay grade is at or in excess of O-7·

(4) The Postmaster General, Deputy Postmaster General, each Governor of the United States Postal Service, and each Postal Service and Postal Rate

[1] The Conference is authorized by statute to study and make recommendations relating to administrative procedure used by administrative agencies in carrying out administrative programs, 5 U.S.C. § 574.

Commission officer or employee whose rate of pay equals or exceeds the minimum rate of basic pay for GS-16;

(5) Each administrative law judge appointed pursuant to 5 U.S.C. § 3105; and

(6) All other employees determined by the Director of the Office of Government Ethics to be in positions equal in responsibility to those normally classified at GS-16 or above.

b. *Positions For Which Coverage Should Be Removed.* Congress should amend the Ethics in Government Act to remove the reporting requirement, except as may be required under subsection c below, from the following persons:

(1) Candidates for the offices of President and Vice President who are not receiving federal funds under the federal election laws and who are not government officials otherwise required to report; [2]

(2) Special government employees; [3] and

(3) Designated agency ethics officers whose rate of pay or other responsibilities would not otherwise subject them to the reporting requirement.

c. *Administrative Extensions of Coverage.* Congress should amend the Ethics in Government Act to permit the Director of the Office of Government Ethics to extend the reporting requirement, on a position or categorical basis, to any officer, employee or special government employee of the executive branch not covered by the Act, whose position is determined by the Director to present an unusual opportunity for conflicts of interest.

d. *Administrative Exemption From Coverage.* Congress should amend the Ethics in Government Act to permit the Director of the Office of Government Ethics to exempt from the reporting requirement those positions included in subsection a above whose responsibilities are identified by their agencies and determined by the Director to be unlikely to place their incumbents in situations of conflict of interest.

e. *Review of Coverage Extensions and Exemptions.* Congress should require the Office of Government Ethics annually to review, based on the recommendaton of the designated agency ethics officials, all determinations currently in effect under c and d above.

2. Information Required To Be Filed.

a. *Reporting Requirements That Should Be Retained.* Congress should leave the Ethics in Government Act unchanged in the following respects:

(1) *Reporting by Both Incumbent and Nominated Officials.* Congress should continue to require both *incumbent* executive branch officers and employees whose positions are covered by the Ethics in Government Act, and *nominees* for those positions, to disclose publicly the following categories of information:

(a) the identity of any interest in a trade or business or asset held for investment or production of income, if the value of the interest exceeds $1,000;

(b) the identity of all positions held by the reporting individual as an officer, director, trustee, partner, proprietor, representative, employee or consultant of any corporation, company, firm, partnership, or other business enterprise, any non-profit organization, any labor organization, or any educational or other institution other than the United States, but not including positions held in religious, social, fraternal, or political entities, or positions solely of an honorary nature; and

(c) the date, parties to, and terms of any future employment arrangements negotiated by the reporting individual, leaves of absence during the period of federal service, continuing payments from a former employer, or continuing participation in a former employer's welfare or benefit plan.

(2) *Reporting Only by Nominated Officials.* In addition to the information required to be reported by incumbent and nominated executive branch officers and employees under subsection (1) above, Congress should continue to require that nominees for positions covered by the Ethics in Government Act report the source of all earned income in excess of $5,000 received by the reporting individual from one source in the two years preceding the one in which the nominee files, and a brief description of the services for which the compensation was paid. As current law provides, this requirement should not apply to information about any person for whom services were provided by the firm or association of which the nominee was a member, partner, or employee, unless the nominee was directly involved in the provision of such services.

(3) *Reporting Only by Incumbent Officials.* In addition to the information required to be reported by incumbent and nominated executive branch officers and employees under subsection (1) above, Congress should continue to require covered incumbent executive branch officers and employees to disclose the following categories of information: [4]

(a) the source, type and amount of non-governmental earned income received by the reporting individual, including honoraria, which in the aggregate exceeded $100; and

(b) the date and a brief description of each purchase, sale or exchange of real property, stocks, bonds, commodities futures or other property with a value over $1,000, *except* (i) transactions between the reporting individual and a spouse or dependent children, (ii) transactions involving a personal residence of the reporting individual or the individual's spouse, and (iii) transactions involving an investment in the nature of a cash equivalent (*e.g.*, a money market fund, certificate of deposit, or personal bank account.)

(4) *Interests of Spouses and Dependent Children.* The present statutory provisions on reporting of the interests of spouses and dependent children of the reporting official should be retained.

b. *Reporting Requirements That Should be Changed.* Congress should amend the Ethics in Government Act to change the reporting requirements in the following ways:

(1) *Liabilities.* The present requirement of reporting the identity of liabilities in excess of $10,000 owed by the reporting individual should be changed to a requirement of reporting liabilities in excess of $1,000, the same value which the statute now uses for reporting of assets. As present law provides, the reporting requirement should not extend to the individual's home mortgage, loans for the purchase of personal property which are secured by the property purchased and which do not exceed the value of the security, sums owed to a relative, and revolving charge accounts with a balance less than a specified amount at the end of the reporting period (currently $10,000).

(2) *Categories of Value.* The present requirement that assets, liabilities, and transactions in assets above the $1,000 threshold be reported in numerous categories of value should be

[2] The Conference recognizes that candidates for these offices are not executive branch officials; nonetheless, this recommendation addresses coverage of candidates because they are included in the current statute setting forth executive personnel financial disclosure requirements.

It is noted that the Administrative Conference has recommended minimal financial disclosure for all members of federal advisory committees, including those members who are special government employees. *See* ACUS Recommendation 89-3, Conflict-of-Interest Requirements for Federal Advisory Committees, 1 CFR § 305.89-3.

Under current practice individuals who joined the government in the preceding calendar year are only required to report this information for their period of government service and not before.

eliminated. However, in order to distinguish large interests from those of lesser significance, the reporting individual should be required to state whether each particular asset, liability or transaction was in excess of a specified higher amount (*e.g.*, $50,000 or $100,000 each).

(3) *Sources of Earned Income Prior to Government Service.* The requirement that all nominees for covered positions report the source, type and amount of non-government earned income which they received in the year prior to entering government service should be eliminated, except for amounts in excess of $5,000 received from one source (*see* 2 a (2) above).

(4) *Income from Assets Otherwise Reported.* The requirement that both incumbents and nominated officials report income in excess of $100 from each of their investments should be eliminated because the assets themselves are already reported.

(5) *Reimbursements and Gifts.* (i) *Reporting Period.* The date after which all covered reimbursements and gifts should be required to be reported should be the date on which the official is nominated for or appointed to the position covered by the Ethics in Government Act, not the date the official takes office.

(ii) *Reimbursement and Gifts of Travel or Entertainment.* The threshold amount for reporting reimbursements and gifts of transportation, lodging, food or entertainment, other than personal hospitality from an individual, received by the reporting individual from any source other than a relative during the reporting period should be changed from $250 per year to a per event amount (*e.g.*, $100 or $150) to avoid reporting de minimis information. The statute should be amended further to require, in addition to the source and a brief description, the reporting of the value or amount of such reimbursements or gifts in broad categories (*e.g.*, under $1,000; $1,000 to $10,000; over $10,000) in accordance with regulations issued by the Office of Government Ethics.

(iii) *All Other Covered Gifts.* The requirement of reporting all gifts to the reporting individual, other than gifts of transportation, lodging, food or entertainment, which aggregated more than $100 in value over the reporting period, excluding gifts from relatives of the reporting individual, and not aggregating gifts of $35 or less in calculating the $100, should be retained. However, the statute should be amended to require, in addition to the source and a brief description, the reporting of the value or amount of such gifts in broad categories (*e.g.*, under $1,000; $1,000 to $10,000; over $10,000) in accordance with regulations issued by the Office of Government Ethics.

6. New § 310.14 is added to Part 310, to read as follows:

§ 310.14 Statement on mass decisionmaking programs: The alien legalization experience.

The Alien Legalization Program, authorized under the Immigration Reform and Control Act of 1986, created a program to allow certain aliens present illegally in the United States to convert their status to that of a legal resident. The program is administered by the Immigration and Naturalization Service and has a short and defined lifetime, which is heading toward completion. The legalization program contains two separate pieces: the "section 245A program, for aliens who have been in the country since January 1, 1982; and the "special agricultural worker" program, for alien farmworkers who worked in specified agricultural employment for at least 90 days during a specified period. The application period for the "section 245A program ran from May 5, 1987 through May 4, 1988. The application for the SAW program ran from June 1, 1987 through November 30, 1988. Although the INS has acted on most of the cases, some are likely to remain pending for months. Moreover, as described below, the second phase of the process is still ongoing.

The Administrative Conference has studied the INS's processing of alien legalization applications from the standpoints of what improvements can be made by the INS in the remaining phases of the legalization program itself, and what lessons can be applied in future mass decisionmaking programs by the INS or by other agencies. This Statement does not address the merits of litigation over the regulatory ground rules of the program, but only the procedures for handling the applications themselves.

Description of the Process

The Alien Legalization Program has been administered by the INS using a framework of local Legalization Offices (LOs) (107 of them across the country) and four Regional Processing Facilities (RPFs) to process the more than three million applications for legalization that were received. Applications are filed with the LOs, where interviews are conducted and recommendations for action are made. The files are then sent to a central processing center in London, Kentucky, following which they are forwarded to one of the four RPFs across the country. The RPFs make the determinations on the applications, based on the file material. Appeal of a denial of legalization status is available to the Legalization Appeals Unit (LAU) in Washington, D.C., and is based on the "administrative record. 8 U.S.C. 1255a(f)(3)(B).

The legalization process has two phases. The first phase is to determine whether an applicant qualifies for legalization. The second phase, which applies only to qualified section 245A applicants, involves a determination whether they qualify for permanent resident alien status. (In the agricultural program, permanent resident alien status is automatic.) The initial application period for both programs is now closed, and the INS has processed a large number, although not all, of those applications.

The "remote decisionmaking" system employed in the Alien Legalization Program involves decisionmaking at the four RPFs rather than at local levels. This system has provided more consistency in decisions than other, more decentralized systems within the INS. Having the determination made by a person removed from the individual who actually interviewed the applicant reduced the potential subjectivity of decisionmakers. Because interviewers at the local levels knew that their files would be examined in virtually every case, the quality of work in the files has been relatively high. There are also suggestions that the system of regional facilities promoted cost-efficiency.

The RPF remote decisionmaking system, however, has not been without problems. The elimination of direct contact between the decisionmaker and the applicant, which helps eliminate bias or prejudice, also eliminates the opportunity for first-hand credibility determinations by the ultimate decisionmaker. The RPFs also have been very isolated from the public, making it difficult for applicants or their representatives to acquire information about the status of cases, among other things. The RPFs have had only limited access to legal advice from INS attorneys, requiring them in at least one facility to seek advice from the LAU, which is the appellate unit that reviews appeals of their decisions. There have been some difficulties relating to the interaction between the LOs and the RPFs, and relating to the provision of adequate notice to applicants at different stages of the program. There also has been reported an unexpectedly high incidence of fraudulent applications, particularly in the agricultural worker program, which the RPFs were not equipped to handle.

Overall, however, the system for deciding legalization applications appears to be working fairly well. The results among the regions have been quite consistent so far. The INS has been able to process large numbers of the applications, particularly in the first phase of the section 245A program. Moreover, the INS has recognized many of the problems, and taken steps to address them.

From the INS experience, it is possible to derive some lessons, not only from other INS programs in the future, but for other agencies that may consider using a system of remote decisionmaking for a large volume of cases. There are also a number of lessons that can be drawn about the Alien Legalization Program in particular. While that program is nearing completion, to the extent that these comments refer to elements of the program that are ongoing, the Conference encourages the INS to implement the suggestions to the extent possible and to the extent that it has not already done so.

Conclusions

A. The Conference encourages agencies, including the INS, to consider using remote decisionmaking where there is a large volume of cases to be decided on the basis of objectively verifiable information within a written file, particularly where bias, prejudice or other subjectivity may be a significant problem. This system appears to promote consistency among decisionmakers, perhaps because of the more centralized nature of the process, and the fact that it is easier for a small group of managers to confer on a regular basis about the decisionmaking process. Agencies should, in implementing such a system, consider the following suggestions:

1. In a remote decisionmaking system in which a file prepared on a local level will be the basis for decisionmaking, there must be clear guidelines as to what are the necessary contents of the file, and the use of standardized forms and checklists is encouraged.

2. Where the local office is making a preliminary recommendation to the remote decisionmaking center, the local office should be instructed to provide an explanation for its recommended decision that is sufficient to provide the remote center with the maximum benefit of the local office's information and interaction with the applicant or other interested person whose case is being determined (hereinafter "applicant"). Appropriate forms or formats (e.g., computer entry) should be designed to ensure that the necessary information is transmitted in a uniform manner to assist in review and retrieval.

3. It is important that adequate information be available to the applicants and their representatives concerning their cases. To facilitate this, case tracking systems capable of responding to inquiries should be developed. Applicants should be clearly informed of the process relating to their cases, and be given adequate notice of each step that requires or provides an opportunity for action or participation on their part.

4. To avoid the appearance or actuality of conflict, it is important that the remote decisionmaking centers have adequate access to legal advice relating to the merits of matters before them from agency legal staff other than from the appellate unit, if any, that reviews appeals of their decisions.

5. Ensuring imput from local personnel on credibility issues is of particular importance. It may be useful to consider ways of videotaping or otherwise recording interviews where the applicant's credibility is at issue.

6. Where helpful, the decisionmakers at remote decisionmaking centers should be provided the opportunity to work for a short period of time at a local office, giving them first-hand experience in interviewing applicants, in order to provide them a better sense of the implications of the information they receive.

7 The remote decisionmaking centers' managers should consult with each other regularly on substantive and procedural matters, in order to ensure that their actions are consistent.

8. It is important that the system be able to provide new or amended instructions to the local offices quickly, so that consistency can be maintained and the benefits of experience transmitted.

B. With respect to the Alien Legalization Program specifically, the Conference encourages the INS to implement or continue to implement the following suggestions to the extent that they refer to elements of the program that are ongoing:

1. Action should be taken to ensure that information concerning individual applications for legalization is readily available to the applicant or his or her representative. INS should:

(a) Establish a method of tracking cases that would enable applicants or their representatives to obtain information expeditiously concerning the status of their cases;

(b) Ensure that applicants are clearly informed concerning all of the steps required to complete the legalization process, both initially and as actions are taken on their applications, particularly where further action on their part may be called for;

(c) Recognize the need to extend completion times where applicants are unable to fulfill educational requirements due to a shortage of educational facilities or programs;

(d) Supplement existing mail communication with applicants, including through the use of broadcast media. Particular attention should be paid to the mobility of many applicants, as well as to the fact that applicants have not always understood the multiple-step nature of the process, and thus have not realized that INS may be seeking to communicate with them.

2. INS should ensure that RPFs have sufficient access to legal advice from INS attorneys; however, the RPFs should not seek legal advice from the Legalization Appeals Unit (LAU), the office that reviews appeals of RPF decisions.

3. INS should consider making the following modifications in the way applications are processed by the Legalization Offices (LOs) and RPFs:

(a) Including in the recommendation forms used by the LOs an additional option, "recommended scrutiny" in order to assure that the RPF reviews the application, without having to recommend denial for lack of another option.

(b) Arranging for the following in cases where fraud is suspected:

(i) Reinterviewing applicants whose cases have not been decided; in the case of SAW applicants, such interviews should be done by specially-trained decisionmakers with knowledge of agriculture.

(ii) Using video cameras to tape remaining interviews, in order to have a record on which credibility can be better assessed.

(iii) Assigning remaining cases at the RPFs to specially trained teams of decisionmakers; in the case of SAW applicants, such decisionmakers should be trained to review agricultural cases and the types of fraud that may appear in such cases.

(c) Considering whether LO personnel should have more direct impact on legalization decisions, since they are the ones who actually have the opportunity to assess the credibility of applicants.

Michael W. Bowers,

Deputy Research Director.

Dated: June 30, 1989.

[FR Doc. 89-15898 Filed 7-7-89; 8:45 am]

BILLING CODE 6110-01-M

federal register

Monday
July 10, 1989

Part V

Department of Transportation

Federal Aviation Administration

14 CFR Part 1 et al.
TCAS II and Windshear Implementation Schedules; Notice of Public Meeting

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Parts 1, 91, 121, 125, 129, and 135

[Docket No. 25954]

TCAS II and Windshear Implementation Schedules

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of public meeting.

SUMMARY: This notice announces a meeting to provide the public the opportunity to discuss possible changes to existing regulations requiring installation and use of an airborne collision avoidance system known as TCAS II, and airborne windshear warning and escape path flight guidance systems. Specific subjects on which public discussion is planned include whether changes to the TCAS II installation schedule are desirable; whether a new schedule should include a time-phased equipage requirement and, if so, what fraction of the fleet should be equipped with TCAS II by which dates; whether the Government should include an operational evaluation phase in the TCAS II schedule and, if so, who should participate; whether the airbone windshear warning and escape path flight guidance equipage requirements should be modified as requested in a petition from the Air Transport Association; and whether the equipage schedule for airborne windshear warning and escape path flight guidance equipage schedule should be modified to be compatible with that adopted for TCAS II equipage. The Federal Aviation Administration (FAA) recognizes that provisions of the Airport and Airway Safety and Capacity Expansion Act of 1987 governing the TCAS II equipage schedule differ from some of the changes to be discussed at this meeting, but anticipates the possibility of statutory changes in the near future that may provide authority for some or all of the changes listed. In the event that those statutory changes are enacted into law, it is essential that regulatory action proceed immediately. The objective of this meeting is to provide all interested parties an opportunity to comment on these issues so that, when and if the statutory changes become law, the Agency can promptly move to issue a final rule based in part upon the information received at this meeting. The FAA will consider all comments prior to taking such action.

DATES: The public meeting will be held on August 16, and August 17 1989, if necessary, from 9:00 a.m. to 3:00 p.m. Comments must be received on or before August 23, 1989.

ADDRESSES: The public meeting will be held in the 3rd floor auditorium, FAA, 800 Independence Avenue SW Washington, DC 20591.

Comments on the subjects in this notice should be submitted, in triplicate, to: Federal Aviation Administration, Office of the Chief Counsel, Attention: Rules Docket [AGC-10], Docket No. 25954, 800 Independence Avenue, SW Washington, DC 20591. Comments delivered must be marked Docket No. Comments may be examined in Room 915G weekdays between 8:30 a.m. and 5:00 p.m., except on Federal holidays.

FOR FURTHER INFORMATION CONTACT: Frank Rock, Aircraft Engineering Division, AIR-120, FAA, 800 Independence Avenue SW Washington, DC 20591, Telephone (202) 267-9567

SUPPLEMENTARY INFORMATION:

TCAS II Discussion

The Federal Aviation Administration (FAA) published the Traffic Alert and Collision Avoidance System (TCAS) Final Rule (54 FR 940; January 10, 1989) in compliance with the Airport and Airway Safety and Capacity Expansion Act of 1987 Public Law 100-223. Prior to the publication of the final rule and in response to numerous questions on the implementation schedule of TCAS, the Subcommittee on Aviation of the Senate Committee on Commerce, Science and Transportation requested the Office of Technology Assessment (OTA) to assess whether the FAA, manufacturers, and airlines have the capability to comply with the TCAS II schedule enacted by Congress and to identify any other important issues raised by the final rule. In addition to interviews and visits to the FAA, manufacturers, and airlines, OTA invited representatives from airframe and avionic manufacturers, airline labor unions, repiar and alteration stations, FAA, and NASA to a 1-day workshop, January 12, 1989, to assist OTA in evaluating the information that had been provided by the aviation community, as well as to obtain a variety of perspectives on TCAS. Subsequently, OTA issued a special report, in February 1989, entitled "Safer Skies With TCAS.

The House Subcommittee on Aviation held a hearing May 4, 1989, on Collision Avoidance System Equipment and Compliance Deadlines. The hearing covered issues involving the legislatively mandated installation of TCAS II.

Testimony at this hearing, and the OTA report, suggested that airlines could experience implementation difficulties that would make it desirable to revise the current schedule. Further, a fairly large-scale operational evaluation program was recommended by OTA and a number of witnesses, to ensure that a large number of TCAS units can be installed and operated as designed in the air traffic environment.

Based on the OTA report, and testimony presented at the May 4, 1989, hearing, the FAA seeks public comment on the following modified TCAS II schedule, which will be considered in the event Congress modifies the statutory mandate:

Date	Required equipage
December 30, 1990	20% of all civil aircraft with more than 30 passenger seats operated by airlines who operate more than 30 or more such aircraft under the provisions of 14 CFR Parts 121 and 129.
December 30, 1991	50% of all civil aircraft with more than 30 passenger seats operated by airlines who operate under the provisions of 14 CFR Parts 121 and 129.
December 30, 1993	100% of all civil aircraft with more than 30 passenger seats operating in the United States.

The FAA also seeks public comment on the need to conduct an operational test and evaluation program during 1990, during which approximately 6 months of in-use data would be collected to ensure practicability of the production of TCAS II systems and to assess their impact, in large numbers, on the safe and efficient operation of the air traffic control system, as recommended by the OTA.

Windshear Discussion

An extended compliance date for TCAS II would, in terms of efficiency and cost effectiveness, be incompatible with the current installation schedule for airborne windshear warning and escape flight path guidance equipment, in that some carriers would have to take aircraft out of service for two cycles of retrofit. In addition, the FAA has received a petition from the Air Transport Association (Docket No. 25924) requesting that an extended compliance schedule for installing windshear warning and flight guidance systems be based on fleet compliance rather than the currently mandated phased schedule. The ATA also requests

that the FAA remove the requirement that certain older aircraft be retrofitted with flight guidance systems. If the TCAS II schedule is revised, the FAA solicits comments at this public meeting on whether the windshear-equipment retrofit schedule should also be revised to make it compatible with the TCAS II schedule, and whether escape path flight guidance requirements should be modified as requested by the petitioner.

Need for This Meeting

The present requirements of the Federal Aviation Regulations call for completion of the TCAS II installations by December 30, 1991, and the airborne windshear warning and escape path flight guidance equipment installations by January 2, 1991, unless extensions are granted extending the compliance date to January 4, 1993. Testimony of a number of witnesses at the May 4, 1989, hearing of the Aviation Subcommittee, as well as the independent evaluation by the OTA, suggest that uniform attainment of the TCAS II schedule as presently required may not be feasible. Since time is becoming critically short to permit reasonable scheduling of the TCAS II retrofit installations, it would be necessary for the FAA to move as quickly as possible following enactment of any legislation that amends the compliance dates to establish a new retrofit schedule so that TCAS II equipment could receive the widest possible usage in the shortest period of time consistent with a prudent operational phase-in of this new equipment. In doing so, the Agency seeks to consider other issues that, if they are to be addressed, must be considered with any modifications to the TCAS II schedule. These issues include those discussed above concerning the appropriate phase-in of the TCAS II installation schedule, establishment of the operational evaluation program, and modifications to the windshear equipment requirements and installation schedule. The purpose of this meeting is to provide for the widest possible public comment on these complex issues in a short period of time.

Meeting Procedures

The meeting will be informal in nature and will be conducted by representatives of the FAA. Representatives from the FAA will present a formal briefing on options for changes in the schedule, depending on the outcome of proposed legislation. All other participants will be given an opportunity to make a presentation.

The meeting will be open to all persons on a space-available basis. There will be no admission fee or charge to attend.

Any person wishing to make a presentation to the FAA will be asked to sign in and estimate the amount of time needed for such presentation; this will permit allocation of an appropriate amount of time for each presenter. The FAA may allocate the time available for each presentation in order to accommodate all speakers. The FAA will make every effort to see that everyone on the list has an opportunity to address the panel. The meeting may be adjourned at any time if all persons present have had the opportunity to speak.

Any person who wishes to present a position paper at the meeting to the FAA pertinent to the topics, TCAS rule extension, phased-in implementation schedule, operational flight evaluation program, and windshear equipment installation schedule, may either submit all written comments prior to the meeting by mailing such comments to the address listed above or by presenting the papers at the meeting.

The meeting will be recorded to ensure that each respondent's comments are noted accurately. A copy of the comments will be placed in the docket.

Agenda

Opening Remarks and Discussion of Meeting Procedures
Public Presentations
  TCAS II Schedule and Operational Evaluation Program
  Windshear Schedule and Older Aircraft Issues
Closing Comments.

Issued in Washington, DC, on July 3, 1989.

Anthony J. Broderick,

Associate Administrator for Regulation and Certification.

[FR Doc. 89-16053 Filed 7-7-89; 8:45 am]

BILLING CODE 4910-13-M

federal register

Monday
July 10, 1989

Part VI

Department of Transportation

Federal Aviation Administration

14 CFR Part 108

Security Directives and Information Circulars; Final Rule and Request for Comment

Explosives Detection Systems for Checked Baggage; Notice of Proposed Rulemaking

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 108

[Docket No. 25953; Amdt. No. 108-6]

RIN 2120-AD14

Security Directives and Information Circulars

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule and request for comment.

SUMMARY: This final rule provides for the issuance of Security Directives and Information Circulars to enable air carriers and the security community to coordinate responses to threats against civil aviation. This rule also requires mandatory compliance with the countermeasures prescribed in Security Directives and prohibits the release of the information contained in both Security Directives and Information Circulars to unauthorized persons. This action is necessary to simplify and expedite existing procedures, to ensure that appropriate officials take specific measures to counter terrorism directed at civil aviation, and to prohibit the unauthorized disclosure of sensitive security information. This regulation is intended to increase protection of passengers and crewmembers traveling in air transportation and air commerce.

DATES: Effective July 10, 1989. Comments must be submitted by August 9, 1989.

ADDRESSES: Comments on this final rule should be mailed or delivered, in triplicate, to: Federal Aviation Administration, Office of the Chief Counsel, Attention: Rules Docket (AGC-10), Room 915-G, Docket No. [25953], 800 Independence Ave. SW., Washington, DC 20591.

Comments may be examined in the Rules Docket, Room 915-G, weekdays (except Federal holidays) between 8:30 a.m. and 5 p.m.

FOR FURTHER INFORMATION CONTACT: Quinten T. Johnson, Civil Aviation Security Division (ACS-100), Office of Civil Aviation Security, Federal Aviation Administration, 800 Independence Ave. SW Washington, DC 20591; telephone (202) 267-8058.

SUPPLEMENTARY INFORMATION:

Background

The dramatic increase in international terrorism since the 1970's has also affected civil aviation. The explosion and crash of Pan American World airways (Pan Am) Flight 103 in Lockerbie, Scotland, in December 1988 illustrate the vulnerability of civil aviation to terrorist acts. The threat is both sophisticated and multifaceted.

In order to support aviation security efforts, the FAA Intelligence Division analyzes classified and unclassified information on threats against civil aviation. This information comes from a variety of sources, including air carriers, law enforcement agencies, and other Federal agencies. If the Intelligence Division determines the information is credible, it disseminates it to air carriers. Prior to the adoption of today's regulation, notification was made through Security Bulletins that discussed both general security concerns, for which there were no specific remedies, and specific threats which could be countered by particular remedies. Since 1986, 93 bulletins have been issued, approximately one-third of which addressed specific threats for which countermeasures were possible. Air carriers, however, were not required to acknowledge Security Bulletins or comply with the actions recommended in them.

Security Bulletins were sent to U.S. air carrier corporate security officers, the Air Transport Association of America, certain other Federal agencies, and FAA security personnel. In addition, the State Department transmitted the Security Bulletins to appropriate overseas posts. Upon receipt of the Security Bulletins, each air carrier's corporate security officer determined whether any further dissemination was necessary. Occasionally, the FAA included its own recommendations for specific actions. Although the FAA believes the air carriers have been responsive to the actions recommended by Security Bulletins, mandatory compliance requires amendments to the air carrier's overall security program.

The Civil Aviation Security Program, referenced in the Federal Aviation Regulations (FAR), was initated in 1973. Part 108 of the FAR was promulgated in 1981 (46 FR 3782; January 15, 1981) and requires certain U.S. air carriers to adopt and use FAA-approved security programs to screen passengers and property, control access to airplanes and facilities, and prevent criminal acts against civil aviation. The FAA can amend an individual carrier's security program if it determines that there is an emergency requiring immediate action to protect safety in air transportation or air commerce (see § 108.25), and compliance with such amendments is mandatory. It is not customary, however, for the FAA to amend a carrier's overall security program with flight-specific, date-specific, or site-specific information. Information of this type has been distributed through the Security Bulletin system.

On April 3, 1989, Secretary of Transportation Samuel K. Skinner announced a number of aviation security initiatives to ensure protection of travelers on U.S. air carriers. Among these initiatives, and the subject of a separate rulemaking action, was the commitment to propose requiring the widespread deployment of explosives detection systems. Another initiative, the establishment of a mandatory Security Directive system, is the subject of this rulemaking action.

Discussion of the Amendments

When threats against civil aviation become known, it is crucial that the information and any appropriate countermeasures be disseminated as soon as possible to air carrier security personnel. A system that will allow the FAA to disseminate critical threat information and, when necessary, establish mandatory security countermeasures responsive to that threat in a single document, will improve and simplify the current process. In order to ensure that the wide variety of threats can be effectively countered, the FAA will issue two kinds of security alerts—Information Circulars and Security Directives.

Information Circulars will be used to notify U.S. air carriers of general situations for which FAA will not prescribe mandatory countermeasures. The purpose of Information Circulars will be to provide air carriers with general information relevant to a civil aviation security.

Security Directives will be used to notify U.S. air carriers of information on specific credible threats that are limited by such factors as location, number or identity of carriers, method of attack, or duration of time. Security Directives will set forth mandatory countermeasures and will eliminate the need to amend the air carriers' ongoing security programs. Air carriers will be required to acknowledge receipt of Security Directives and to notify the FAA of how they implemented the countermeasures prescribed by the FAA. In unusual situations, such as when an air carrier is precluded from implemenitng the prescribed countermeasures, the air carrier shall submit alternative countermeasures for the approval of the Director of Civil Aviation Security. The air carrier is required to submit any proposed alternative measures within the time period specified in the Security Directive. Air carriers will also be required to distribute the information to

the personnel specified in Security Directives and to others with an operational need to know. Personnel with an operational need to know are those personnel with security-related responsibilities for air transportation operations affected by the Security Directive. Such personnel could include the in-flight security coordinator (ISC) (pilot in command), the ground security coordinator (GSC), airline and airport security personnel, and Federal, State, or local law enforcement officials.

In order to protect the sensitive nature of Security Directives and Information Circulars, their availability will be restricted to air carriers and personnel with an operational need to know, and release of any information contained in them without the prior written authorization of the Director of Civil Aviation Security will be prohibited.

By adopting a two-tiered system for disseminating threat information, the FAA believes the civil aviation security community will be better able to distinguish between information that is general in nature and that which has been assessed to require a specific security response. As a result, the security community and the air carriers will have a better understanding of how to coordinate their actions in response to specific threats. By prohibiting unauthorized disclosure, the FAA will be able to protect intelligence sources and ensure that countermeasures can be effectively implemented.

Good Cause Justification for Immediate Adoption and No Notice

Under the current regulatory scheme, the FAA may amend an air carrier's approved security program and require the carrier to take certain steps that address a specific threat to civil aviation security. However, the FAA has determined that the most effective method of ensuring that threats are addressed in a complete and uniform manner requires amendment of Part 108 of the Federal Aviation Regulations. Because the general level of the threat to U.S. air carriers operating in air commerce and air transportation could rapidly increase, the FAA has determined that good cause exists to make this final rule effective in less than 30 days. In addition, this final rule is being adopted without prior notice and opportunity for public comment. For the reasons stated above and because immediate action is necessary to protect passengers and crewmembers traveling in air transportation, the FAA believes prior notice and opportunity for public comment are impracticable and, furthermore, are contrary to the public interest.

The Regulatory Policies and Procedures of the Department of Transportation (44 FR 11034; February 26, 1979) provide that, to the maximum extent possible, operating administrations of the Department of Transportation (DOT) should provide an opportunity for public comment on regulations issued without prior notice. Thus, the FAA has provided a 30-day period during which interested persons may comment on the final rule.

Procedure for Submitting Comments

In accordance with the Regulatory Policies and Procedures of the Department of Transportation (44 FR 11034, February 26, 1979), interested persons are invited to comment on this final rule by August 9, 1989. Comments should identify the regulatory docket number and be submitted in triplicate to the Rules Docket (see **ADDRESSEES**). Commenters wishing the FAA to acknowledge receipt of their comments must include a self-addressed, stamped postcard containing the following statement: "Comments to Docket No. 25953" All comments will be available for examination, both before and after the closing date, in the Rules Docket.

Paperwork Reduction Act

Information collection requirements in Part 108 have previously been approved by the Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act of 1980 (Pub. L. 96–511) and has been assigned OMB control number 2120–0098. The slight additional paperwork burden associated with § 108.18 was approved by OMB as an amendment to 2120–0098.

Regulatory Evaluation Summary

The following is a summary of the final cost impact and benefit assessment of a regulation amending FAR Part 108, Airplane Operator Security, to require that U.S. air carrier operators comply with measures to counter terrorist threats against civil aviation as prescribed in FAA Security Directives. Under the new requirements, air carriers will be required to acknowledge receipt of Security Directives within the time specified, distribute Security Directives to the appropriate individuals, implement mandatory countermeasures as furnished by individuals, implements mandatory countermeasures as furnished by the FAA (or, in unusual situations, alternative countermeasures if approved by the Director of Civil Aviation Security), and report to the FAA on those actions taken to comply with the Security Directives.

The FAA has determined that these amendments will affect approximately 20 air carriers, including both scheduled air carriers and demand charter service air carriers. The major impact is expected to be on six of these air carriers with significant operations to the Middle East, Europe, and South Asia, since most of the threats pertain to these parts of the world. These air carriers will receive most of the Security Directives issued by the FAA. The remaining air carriers have infrequent service to these areas, and thus, are expected to receive and be required to process only a small share of the Security Directives issued. The regulatory evaluation prepared for this rule estimates that the total cost of compliance to the affected U.S. air carriers is $48,260 in 1989 dollars; the present value of this amount is $29,654 over a 10-year period using a discount rate of 10 percent.

The primary benefits of these amendments will be the prevention of potential fatalities, injuries, and property losses resulting from criminal acts and acts of terrorism perpetrated against domestic aviation interests. The FAA has not been able to quantitatively estimate the extent to which this rule will be effective in deterring acts of criminal violence, air piracy, and sabotage. The FAA believes, however, that the estimated costs of compliance will be fully recovered if only one life, based on a generally accepted statistical value of a minimum of $1,000,000, is saved during that period as a result of the prevention of such acts. In addition to the estimated quantifiable benefits associated with the prevention of fatalities, injuries, and property losses during the 10-year period following its implementation, an unquantifiable benefit of this amendment will accrue to the affected air carriers based on the public perception of the additional safety. The increase in public confidence will likely result in increased air travel and revenues. The FAA recognizes that the benefits of these amendments are derived from both the system of distributing and processing Security Directives to U.S. carriers and implementation of mandatory security measures contained in Security Directives by U.S. air carriers. The FAA has estimated the cost to U.S. air carriers associated with distributing and processing Security Directives because this system is an essential part of, and integrally related to, achievement of the benefits of reduced fatalities, injuries, and property losses.

Regulatory Flexibility Determination

The FAA has determined that, under the criteria of the Regulatory Flexibility

Act (RFA), these amendments will not have a significant economic impact on a substantial number of small entities. The RFA requires agencies to specifically review rules that may have a "significant economic impact on a substantial number of small entities. None of the scheduled air carriers impacted by this rule are small entities. A portion of the charter air carriers which will be impacted by this rule are small entities. The estimated annual cost to these charter carriers from this regulation is $127 per company. This is significantly less than the threshold for significant economic impact. Even if twice the number of Security Directives were issued to these small entities, the total cost would still be significantly less than the threshold. Accordingly, it is certified that the amendment to Part 108 will not have a significant economic impact, positive or negative, on a substantial number of small entities and no further regulatory flexibility analysis is required.

Trade Impact Statement

This rule is expected to have no impact on trade opportunities for either U.S. firms doing business overseas or foreign firms doing business in the United States. These amendments affect only certain domestic air carriers subject to Part 108 of the FAR. Since the cost to these air carriers is small, there is expected to be no impact on trade opportunities for either U.S. firms overseas or foreign firms in the United States.

Federalism Implications

The amendments contained in this final rule revise the manner by which the FAA communicates security information and mandatory procedures to U.S. carriers. The FAA has determined that the final rule 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. In accordance with Executive Order 12612, the FAA has determined that this final rule does not have sufficient federalism implications to warrant preparation of a Federalism Assessment.

Conclusion

For reasons discussed in the preamble, it is certified that this final rule 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. In addition, because the final rule will not result in an annual effect on the economy of $100 million or more or result in a significant increase in consumer prices, the FAA has determined that the final rule is not a major rule under the criteria of Executive Order 12291. Since the final rule involves issues of substantial interest to the public, however, the FAA has determined that it is significant under the Regulatory Policies and Procedures of the Department of Transportation (44 FR 11034; February 26, 1979).

List of Subjects in 14 CFR Part 108

Airplane operator security, Aviation safety, Air transportation, Air carriers, Airlines, Security measures, Transportation, Weapons.

The Amendments

In consideration of the foregoing, the Federal Aviation Administration amends Part 108 of the Federal Aviation Regulations (14 CFR Part 108) as follows:

PART 108—AIRPLANE OPERATOR SECURITY

1. The authority citation for Part 108 continues to read as follows:

Authority: 49 U.S.C. 1354, 1356, 1357 1358, 1421, 1424, and 1511; 49 U.S.C. 106(g) (revised, Pub. L. 97-449, January 12, 1983).

2. Section 108.1 is amended by adding paragraph (a)(4) to read as follows:

§ 108.1 Applicability.

(a)

(4) Each certificate holder who receives a Security Directive or Information Circular and each person who receives information from a Security Directive or an Information Circular issued by the Director of Civil Aviation Security.

3. Part 108 is amended by adding § 108.18 to read as follows:

§ 108.18 Security Directives and Information Circulars.

(a) Each certificate holder required to have an approved security program for passenger operations shall comply with each Security Directive issued to the certificate holder by the Director of Civil Aviation Security, or by any person to whom the Director has delegated the authority to issue Security Directives, within the time prescribed in the Security Directive for compliance.

(b) Each certificate holder who receives a Security Directive shall—

(1) Not later than 24 hours after delivery by the FAA or within the time prescribed in the Security Directive, acknowledge receipt of the Security Directive;

(2) Not later than 72 hours after delivery by the FAA or within the time prescribed in the Security Directive, specify the method by which the certificate holder has implemented the measures in the Security Directive; and

(3) Ensure that information regarding the Security Directive and measures implemented in response to the Security Directive are distributed to specified personnel as prescribed in the Security Directive and to other personnel with an operational need to know.

(c) In the event that the certificate holder is unable to implement the measures contained in the Security Directive, the certificate holder shall submit proposed alternative measures, and the basis for submitting the alternative measures, to the Director of Civil Aviation Security for approval. The certificate holder shall submit proposed alternative measures within the time prescribed in the Security Directive. The certificate holder shall implement any alternative measures approved by the Director of Civil Aviation Security.

(d) Each certificate holder who receives a Security Directive or Information Circular and each person who receives information from a Security Directive or Information Circular shall—

(1) Restrict the availability of the Security Directive or Information Circular and information contained in the Security Directive or the Information Circular to those persons with an operational need to know; and

(2) Refuse to release the Security Directive or Information Circular and information regarding the Security Directive or Information Circular to persons other than those with an operational need to know without the prior written consent of the Director of Civil Aviation Security.

(Approved by the Office of Management and Budget under control number 2120-0098)

Issued in Washington, DC, on July 6, 1989

James B. Busey,

Administrator.

[FR Doc. 89-16260 Filed 7-6-89; 8:45 am]

BILLING CODE 4910-13

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 108

[Docket No. 25956; Notice No. 89-18]

RIN 2120-AD12

Explosives Detection Systems for Checked Baggage

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This notice proposes to amend the airplane operator security regulations to require U.S. air carriers required to conduct screening under a security program to use an explosives detection system (EDS), approved by the Administrator, to screen checked baggage on international flights. These procedures are designed to prevent the carriage of explosives aboard aircraft. Additionally, the FAA specifically requests comments on whether any final rule should require an EDS to screen checked baggage on domestic flights, as well as whether installation should be restricted to fewer flights, in operations selected on a threat-driven basis. The FAA expects to phase-in the implementation of this proposed rule, with 100 percent screening of international checked baggage at approximately 40 airports located in the United States and abroad as the goal for the initial implementation period. Following the initial implementation, the FAA foresees extending the applicability of explosives detection screening under an air carrier's approved security program to all checked baggage on all international flights. This action is needed due to the increased sophistication of terrorist acts, and it responds to Congressional legislation enacted on June 30, 1989. The intended effect is to increase the safety of passengers and crewmembers aboard U.S. air carriers conducting international flights.

DATE: Comments must be submitted on or before August 7 1989.

ADDRESSES: Comments on this notice should be mailed, in triplicate, to: Federal Aviation Administration, Office of the Chief Counsel, Attention: Rules Docket (AGC-10), Docket No. 25956, 800 Independence Avenue SW Washington, DC 20591. Comments delivered must be marked Docket No. 25956. Comments may be examined in Room 915G weekdays between 8:30 a.m. and 5 p.m., except on Federal holidays.

FOR FURTHER INFORMATION CONTACT: Quinten T. Johnson, Civil Aviation Security Division (ACS-100), Office of Civil Aviation Security, Federal Aviation Administration, 800 Independence Avenue, S.W Washington, DC 20591; telephone (202) 267-8058.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of these proposed rules by submitting such written data, views, or arguments as they may desire. Comments relating to the environmental, energy, federalism, or economic impact that might result from adopting the proposals in this notice are also invited. Substantive comments should be accompanied by cost estimates. Comments should identify the regulatory docket or notice number and should be submitted in triplicate to the Rules Docket address specified above. All comments received on or before the closing date for comments specified will be considered by the Administrator before taking action on this proposed rulemaking. The proposals contained in this notice may be changed in light of the comments received. All comments received 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 substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket. Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must include a preaddressed, stamped postcard on which the following statement is made: "Comments to Docket No. 25956. The postcard will be date stamped and mailed to the commenter.

Availability of NPRM's

Any interested person may obtain a copy of this NPRM by submitting a request to the Federal Aviation Administration, Office of Public Affairs, Attention: Public Inquiry Center (APA-430), 800 Independence Avenue, S.W Washington, DC 20591, or by calling (202) 267-3484. Requests must identify the notice number of this NPRM.

Persons interested in being placed on the mailing list for future NPRM's should request from the above office a copy of Advisory Circular No. 11-2A, Notice of Proposed Rulemaking Distribution System, which describes the application procedure.

Background

Statement of the Problem

Attacks against international civil aviation have increased in sophistication over the past decade. As a result, security has become an even greater concern of the aviation community. In recent years, sophisticated explosive devices have been used to damage or destroy civilian airliners resulting in the loss of many lives. For example, 259 people on board Pan American World Airways (Pan Am) Flight 103 plus 11 persons on the ground in Lockerbie, Scotland, were killed by the explosion and subsequent crash of that airliner.

The attack against Pan Am 103, as well as other similar incidents, demonstrate the increasing need to protect the safety and security of passengers, aircraft, and crewmembers aboard U.S. air carriers. Effective explosives detection equipment would help address this need.

History

The FAA's Civil Aviation Security Program, initiated in 1973, requires certain U.S. air carriers to conduct security screening of passengers and their carry-on baggage to prevent or deter the carriage aboard aircraft of any explosive, incendiary, or deadly or dangerous weapon on or about any individual's person or accessible property. Part 108 of the Federal Aviation Regulations (FAR) (14 CFR Part 108), which pertains to U.S. air carriers, was promulgated in 1981 (46 FR 3782; January 15, 1981).

For many years, the passenger screening system was very effective in countering the threat to domestic and international civil aviation, which primarily came from hijackers. In recent years, this threat has expanded to include aircraft bombings. To meet this threat, new methods of detection are required to detect explosive devices.

The U.S. Government has actively supported research and development efforts in explosives detection. For example, over the last 4 years, the FAA has spent over $30 million on research and development related to explosives detection. The need for more effective explosives detection equipment also has received worldwide attention. In February 1989, the International Civil Aviation Organization (ICAO), convened a special session of its Council to discuss acts of sabotage directed against international civil aviation and the need to expedite research and development on the detection of explosives. In March, ICAO

held a meeting of world experts in explosives detection to address the issue. Similar discussions have taken place in European organizations.

There have been significant technological advancements made in explosives detection equipment. The FAA has tested several of these systems, and has decided to purchasse six Thermal Neutron Analysis (TNA) units for initial installation at selected airports. The TNA equipment was tested at San Francisco International and Los Angeles International Airports and was shown to have the highest degree of explosives detection capability currently possible for detecting known civilian and military explosives, manufactured here and abroad.

On March 24, 1989, the Victims of Pan Am Flight 103, an unincorporated association of 300 persons whose relatives were killed on that flight, petitioned the FAA to, among other things, require "that all checked baggage be examined by physical inspection, a TNA device, or a colorized electronic x-ray. While the notice addresses that aspect of the petition, it does not address other issues raised by the Victims of Pan Am Flight 103 petition. Hence, this action is not intended to dispose of that petition, a summary of which has been published in the **Federal Register** for comment so that all issues can be thoroughly discussed by interested commenters [54 FR 24354; June 7 1989].

Related Activities

The tragedy of Pan Am Flight 103 is a global reminder that civil aviation, despite detailed and sophisticated security procedures, is still vulnerable to criminal or terrorist acts. A comprehensive review of security procedures has been conducted to determine where existing procedures may be improved and where new procedures may be warranted. On April 3, 1989, Secretary of Transportation Samuel K. Skinner announced a number of aviation security initiatives to ensure protection of travelers at airports in the United States and other countries. Most significant among these initiatives was the commitment to propose requiring the widespread deployment of explosives detection systems (EDS). A second major initiative, the establishment of a mandatory security bulletin system, is the subject of a separate rulemaking action.

Congressional Activity

On June 30, 1989, the President signed legislation that included a provision relating to the installation and use of explosive detection equipment [sic]. The legislation, Pub. L. 101-45, provided that "Not later than thirty days after the date of the enactment of this Act, the Federal Aviation Administrator shall initiate action, including such rulemaking or other actions as necessary, to require the use of explosive detection equipment that meets minimum performance standards requiring application of technology equivalent to or better than thermal neutron analysis technology at such airports (whether located within or outside the United States) as the Administrator determines that the installation and use of such equipment is necessary to ensure the safety of air commerce. The Administrator shall complete these actions within sixty days of enactment of this Act[.]" As a result of the Congressionally-mandated timeframe for final action, the comment period in this rulemaking is shorter than usually provided.

Current Requirements

Presently, Part 108 requires each holder of an FAA air carrier operating certificate required to conduct screening to use the procedures, facilities, and equipment described in its approved security program to prevent or deter carriage aboard airplanes of any explosives, incendiaries, or deadly or dangerous weapons.

General Discussion of the Proposals

The FAA is proposing to amend Part 108 to require air carriers conducting scheduled or public charter operations in international service with aircraft having a passenger seating configuration of more than 60 seats to use an EDS that meets performance criteria and standards developed by the Administrator to screen checked baggage under the certificate holder's approved security program. Although not part of the current proposal, the FAA is considering the advisability of extending EDS screening to domestic flights as well. Therefore, the FAA asks commenters to address this issue. Any final rule adopted in this proceeding could include EDS on domestic flights. However, the current proposal, if adopted, would require air carriers to use an EDS to detect explosives only in international operations.

If adopted, the following minimum performance criteria would be established for the system:

1. The system must be automated.
2. It must detect defined quantities and configurations of FAA-defined explosives.
3. It must be safe for operators and baggage.

More detailed information about the capabilities and use of the system would be incorporated into each air carrier's approved security program. In accordance with 14 CFR § 191.5, the FAA will not publish the full performance criteria or detailed operational information in any document generally available to the public. The Director of Civil Aviation Security has determined that disclosure of this information would be detrimental to the safety of persons traveling in air transportation or intrastate air transportation.

For the same reasons, the specific locations and numbers of the units would not be available to the public. It is the FAA's intent to require deployment initially at the busiest international airports in the United States and at designated airports outside the United States that are served by U.S. air carriers. This would potentially require installation of EDS at approximately 40 airports located in the United States and abroad. The specific compliance dates, locations, and phase-in schedule would be described in each air carrier's approved security program. The FAA and the Department of Transportation have initiated discussions with foreign governments and will continue to consult with foreign governments to facilitate implementation of these procedures.

No matter which alternative is selected, the FAA expects to phase-in the implementation of this proposed rule, with 100 percent screening of international checked baggage at designated airports as the goal for the initial implementation period. Following the initial implementation, the FAA foresees extending the applicability of explosives detection screening under an air carrier's approved security program to all checked baggage on all international flights unless a more limited installation alternative is selected, in which case EDS screening would apply to additional flights on a threat-driven basis. Although not part of the current proposal, the FAA is also seeking comments on the advisability of extending the EDS requirements to all checked baggage on all domestic flights as well. The proposed rule is a broad enablement for the FAA to require air carriers to use an EDS. If this proposed rule is issued without change as a final rule, the FAA would have authority to require U.S. air carriers, by amending each air carrier's approved security program, to use an EDS to screen all checked baggage on all international flights for which screening is required.

In determining whether and when to require the installation of EDS units at particular airports beyond the initial deployment described above, the FAA would consider a variety of factors. These factors would include where necessary the successful consultation with affected foreign governments, as well as the level of vulnerability at the particular location and the projected level of usage of the EDS equipment. The level of usage is a function of the number of passengers enplaned and is therefore related to the cost per passenger of EDS screening for flights from that location.

In order to elicit public participation and to get the broadest spectrum of response regarding the economic costs and benefits involved in acquiring and using state-of-the-art EDS, the FAA has initiated this rulemaking action. State-of-the-art EDS are expensive to acquire and to operate. The use of such systems may have other effects as well; for example, their use on domestic flights may require earlier check-in times than currently required. However, the FAA analysis projects that the number of EDS at affected airports would be sufficient to minimize passenger delay and avoid disruptions. The FAA requests comments on the degree to which EDS should be used for various types of flights.

Section 108.7

New paragraph (b)(8) of this section would require certificate holders to describe in their approved security program the procedures, facilities, and equipment used by the certificate holder to comply with the new EDS requirements.

Section 108.20

This new section would mandate that certificate holders required to conduct screening under an approved security program use an approved EDS to detect explosives in checked baggage on international flights under the air carrier's approved security program. Because of the costs involved and the fact that different categories of airports would require varying numbers of these systems, this proposal would not require each individual certificate holder to own an EDS, and would not preclude use of each EDS by several air carriers.

Regulatory Evaluation Summary

This section summarizes the preliminary cost and benefit assessment of a proposed revision to Part 108 of the Federal Aviation Regulations that would require U.S. air carriers required to conduct screening under an approved security program to use an explosives detection system (EDS) approved by the Administrator, to screen checked baggage on international flights. The proposed addition of new paragraph 108.7(b) would require affected air carriers to use explosives detection systems in accordance with the provisions established by the Administrator and contained in their approved security programs. Since the FAA is also requesting comment in broadening the scope of coverage to include screening domestic baggage with EDS, a preliminary evaluation of the cost and benefit of such an extension is included. In addition, the evaluation considers the cost and benefits of a narrower EDS system, in which screening would be conducted only for international operations at airports selected on a threat-driven basis.

The primary objective of this proposed rule is the prevention of criminal acts or acts of terrorism against U.S. air carriers by individuals using explosive devices. Toward this end, the FAA has conducted extensive research aimed at detecting explosives. This research has concentrated on EDS devices, including the Thermal Neutron Analysis (TNA) system and vapor detection systems, as well as advanced x-ray systems. The TNA device is the most advanced explosives detection system now available. Therefore, the FAA has elected to analyze three alternative solutions for explosives detection using TNA systems over the 10-year period of 1990 to 1999. These are:

I. *Domestic and International Alternative.* Install EDS at 427 airports in the U.S. and at airports in 95 foreign countries over a 10-year phase-in period. (100% checked baggage screening of U.S. domestic and international flights, eventally requiring 1,250 DES by 1999.)

II. *International Alternative (The Current Proposal).* Install only enough EDS to screen U.S. carrier international flights at domestic and foreign airports over a three year phase-in period. (100% checked baggage screening of all U.S. international flights, eventually requiring 400 EDS by 1999.)

III. *Threat-Driven Alternative.* Install 200 EDS at an unspecified number of domestic and foreign airports over a three year phase-in period, based on a threat-driven approach. (100% checked baggage screening of all international flights at selected airports, eventually requiring 270 EDS to be installed by 1999.)

Alternative II is the Alternative being proposed. The costs and number of machines being proposed in Alternative III are a subset of those in Alternative II. Alternative I is presented to provide information about and to invite comment on extending the EDS requirement to domestic flights.

The methods and assumptions used in the analyses for the alternatives revisions affecting Part 108 have been developed by the FAA. A major consideration guiding the conduct of this analysis is the assumption that 100% screening of checked baggage on flights where passenger screening is currently required would be conducted under all three scenarios at those airports where EDS are to be installed. The analyses assume enough machines to take into account peak hour travel and the projected growth in travel; this would ensure minimal delays. Preliminary cost factors were obtained from manufacturers and research organizations. Information for the formulation of benefits was obtained from the safety records of the International Civil Aviation Organization and the FAA. The costs and benefits of each of these Alternatives have been analyzed over the 10-year span of 1990 to 1999.

To estimate the potential benefits of the proposal and the Alternatives, the FAA reviewed the safety record for the 10 year period between 1979 and 1988. This review reveals that 19 separate criminal acts and incidents of terrorism using explosives were perpetrated against U.S. air carriers during this period. The FAA has classified these incidents into Class I and Class II categories. The Class I category includes those incidents, such as the explosion aboard Pan American Flight 103 that involve the loss of an entire aircraft and a large number of fatalities. Class II accounts for all other incidents in which airplanes were only partially damaged or the incident was partially averted such as explosions that occurred outside the aircraft (usually somewhere in the airport itself). These two types of incidents vary significantly both in terms of costs and their frequency. The FAA estimates that those Class II incidents that would occur over the 10 years from 1990 to 1999 would result in a discounted cost of $31.0 million.

The losses associated with Class I or major incidents would, of course, be substantially greater. For example, the loss on human life and property, and lost revenues for the loss of U.S. carriers market share associated with Pan American Flight 103 are estimated to have a present value range of $411.0 million to $520.0 million depending on the extent of market reduction. It is difficult to predict the extent to which international terrorism would increase.

Nevertheless, the FAA believes that in the absence of additional preventive measures, terrorists attacks against U.S. air carriers would continue. The FAA cannot predict the number and severity of future incidents. The frequency of such incidents would depend on several factors, including, but not limited to, the world-wide political climate, the skill and technical sophistication of terrorist organizations, and the success of efforts to avert these incidents. However, in this case, the present value of the benefit associated with the prevention of these incidents would be as high as $1.071 billion. Table I of this summary shows the estimated costs and benefits of these Alternatives:

TABLE I.—SUMMARY OF COSTS AND BENEFITS

[Net present value in millions of dollars]

Options	Estimated costs	Percentage of total incidents avoided for breakeven*	Calculations
Alternative I (Domestic and international alternative)	$1,004	94	$1,004/$1,071=94%
Alternative II (International alternative—the current proposal)	$476	45	$476/$1,071=45%
Alternative III (Threat-driven alternative)	$346	33	$346/$1,071=33%

Total incidents is equal to two Class I incidents and all Class II incidents avoided. The discounted present value of these incidents avoided is $1,071 million. The percentages do not represent a judgment of the relative effectiveness of each Alternative.

Table I examines how many Class I and Class II incidents would have to be prevented by each Alternative for the Alternatives to be cost beneficial. The percentages in the table do not represent a judgment of the relative effectiveness of each Alternative; they show the percentage of total incidents whereby each of the three Alternatives will have different breakeven points so as to become cost beneficial. The costs associated with each Alternative are compared with those benefits projected from avoiding two Class I incidents and a discounted present value of the $31 million worth of projected costs from Class II incidents. For the purposes of this analysis, this is the projected universe of incidents.

For the current proposal, Alternative II, to be cost beneficial, it would have to prevent nearly one-half (45 percent) of this projected set of Class I and Class II incidents. If EDS coverage is expanded to include domestic operations (Alternative I), this option would have to prevent nearly the entire set of Class I and Class II incidents to be cost effective. And, the costs associated with limiting installation of EDS to those international operations at airports selected on a threat-driven basis (Alternative III) is roughly one-third of the assumed set of incidents.

Because the number and potential severity of future attacks and the scope and location of international threats are difficult to predict and due to the sensitive nature of this proposal, the FAA has elected not to attempt to quantify which Alternative would be the most cost effective in reducing the risk of future terrorist attacks. For similar reasons, the FAA will not assign values to the probabilities of a Class I or Class II event for each Alternative scenario.

In addition to these quantifiable benefits, the FAA expects further significant unquantifiable benefits. The rule would result in public recognition of additional safety factors implemented by U.S. air carriers. The public's subsequent higher confidence levels should result in more passengers and higher revenues.

The deterrence of terrorist attacks against U.S. civil aviation also has very significant public and foreign policy benefits. An attack on an American aircraft disrupts the lives and plans of great numbers of people who have suffered no direct loss in the incident. (Indeed, this is presumably one of the goals of those who perpetrate acts of terrorism.) The FAA cannot calculate the cost of uncompleted business, disrupted education, and deferred vacations. Nevertheless, that cost is unquestionably significant, and it will be avoided if the public retains a high level of confidence in the safety of the air transportation system. Maintaining and improving the public's confidence is a central goal in this rulemaking.

The costs of compliance with the three Alternatives subject to this analysis are constructed on the assumption that EDS would be placed within the sheltered confines of affected airports in accordance with the configuration of the terminal and the needs of air carriers. There is uncertainty concerning the number of EDS that would require placement outdoors. The FAA has been unable to estimate the cost associated with protecting these systems from the effects of weather. Therefore, the FAA solicits information relating to the cost of sheltering EDS from the elements. In addition to comments on expanding the scope of EDS screening to domestic operations, or narrowing it to cover only operations selected on a threat-driven basis, specific comments are requested on the following issues:

1. The number of airports that would need to place EDS machines outdoors.

2. Estimates of costs associated with the construction of shelters.

The FAA requests information and comment about the technologies and systems for explosives detection. This information should address the maturity of the technology, the general capabilities of the system, the cost of the system, and the commercial availability of the system. Detailed, security sensitive information about the capabilities of various technologies should not be sent to the public docket, rather such security-sensitive information should be sent directly to the Director of Civil Aviation Security, FAA, 800 Independence Avenue SW Washington, DC 20591, ATTENTION: Explosives Detection System for Checked Baggage Rulemaking.

Initial Regulatory Flexibility Determination

The Regulatory Flexibility Act of 1980 (RFA) was enacted by Congress to insure that small entities are not unnecessarily and disproportionately burdened by Government regulations. The RFA requires Federal agencies to review rules that may have a "significant economic impact on a substantial number of small entities" Issuance of the proposed revision of Part 108 of the FAR would affect some small air carriers. The FAA's Order prescribing small entity size standards identifies a small air carrier as one with nine or fewer operating aircraft. According to the FAA data for the period ending December 31, 1988, there were 54 air carriers subject to the rules

of Part 121 that operated nine or fewer airplanes. These 54 carriers are the entities affected by the proposed rule.

The criteria for a "substantial number of small entities" is one-third of the small firms subject to the proposed rules, but no fewer than 11 firms. A review of the 54 small carriers engaged in scheduled and unscheduled service shows that only 10 firms would be subject to the proposal. Therefore, the proposed amendments to Part 108 would not affect a substantial number of small entities.

Trade Impact Statement

The FAA finds that this rule would only impact Part 121 operators and thus it is not likely to affect international trade. This proposed rule is expected to have no impact on trade opportunities for either U.S. firms doing business overseas or foreign firms doing business in the United States. While there would be an increased cost to U.S. air carriers as a consequence of this proposed rule, these increased costs would be offset by the increase of public confidence, the avoidance of incidents, and by the ability to reduce the use of certain costly security procedures now required by U.S. air carriers.

Federalism Implications

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.

Conclusion

For the reasons discussed in the preamble, and based on the findings in the Regulatory Flexibility Determination and the International Trade Impact Analysis, the FAA has determined that this proposed regulation is major under Executive Order 12291. In addition, the FAA certifies that this proposal, if adopted, would not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. This proposal is considered significant under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979). An initial regulatory impact analysis of this proposal, including a Regulatory Flexibility Determination and Trade Impact Analysis, has been placed in the docket. A copy may be obtained by contacting the person identified under **"FOR FURTHER INFORMATION CONTACT."**

List of Subjects in 14 CFR Part 108

Air carriers, Airports, Air safety, Air transportation, Aviation safety, Baggage, Safety, Security measures, Transportation.

The Proposed Amendments

In consideration of the foregoing, the Federal Aviation Administration proposes to amend Part 108 of the Federal Aviation Regulations (14 CFR Part 108) as follows:

PART 108—AIRPLANE OPERATOR SECURITY

1. The authority citation for 14 CFR Part 108 is revised to read as follows:

Authority: 49 U.S.C. 1354, 1356, 1357 1421, 1424, and 1511; 49 U.S.C. 106(g) (revised, Pub. L. 97–449, January 12, 1983).

2. Section 108.7 is amended by adding a new paragraph (b)(8) to read as follows:

§ 108.7 Security program: form, content, and availability.

(b)

(8) The procedures and a description of the facilities and equipment used to comply with the requirements of § 108.20 regarding explosives detection systems.

3. Part 108 is amended by adding § 108.20 to read as follows:

§ 108.20 Use of explosives detection systems

When the Administrator shall require by amendment under § 108.25, each certificate holder, required to conduct screening under a security program, shall use an explosives detection system that has been approved by the Administrator to screen checked baggage on international flights in accordance with the certificate holder's security program.

Issued in Washington, DC, on July 6, 1989.

Raymond A. Salazar,

Director of Civil Aviation Security.

[FR Doc. 89–16261 Filed 7–6–89; 4:40 pm]

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federal register

Monday
July 10, 1989

Part VII

The President

Proclamation 5996—Captive Nations Week, 1989

Executive Order 12680—Administration of Foreign Assistance and Related Functions and Arms Export Controls

Executive Order 12681—Exclusions From the Federal Labor-Management Relations Program

Federal Register
Vol. 54, No. 130
Monday, July 10, 1989

Presidential Documents

Title 3—

The President

Proclamation 5996 of July 6, 1989

Captive Nations Week, 1989

By the President of the United States of America

A Proclamation

Each July, we Americans celebrate our Nation's independence and the blessings of self-government. As we give thanks for the rights and freedoms that citizens of this Nation have enjoyed for more than 200 years, we also recall our obligation to speak out for oppressed peoples around the world. We thus pause during Captive Nations Week to remember in a special way those peoples who suffer from foreign domination and from ideologies that are inimical to the ideas of national sovereignty and individual liberty.

Today, the leaders of the Soviet Union and other Communist governments are discovering that the voices of those who long for freedom and self-determination cannot be silenced. Around the world, men and women in captive nations are calling for recognition of their basic human rights. Their calls—the undeniable expression of just aspirations—are beginning to be heard.

In Afghanistan, the nightmarish years of Soviet occupation are over, and the Afghan people's demand for self-determination is drawing closer to realization. Unfortunately, a decisive end to the Afghans' long ordeal remains elusive while a puppet regime in Kabul continues the proxy devastation of their war-ravaged homeland.

In Africa, the people of Angola have a real chance to find peace after years of violent struggle against the ruling Marxist-Leninist regime. Our hopes for national reconciliation in Angola will remain tempered, however, as long as armed Cuban mercenaries continue to stalk the forests and veldt of that land and other countries on the African continent.

Communist expansionism has been frustrated in Southeast Asia, and today there is new hope that the people of Cambodia, Laos, and Vietnam will regain some day their long-denied political and religious freedom. Such hope has also returned for many of our neighbors to the south. In Nicaragua and other Latin American nations, popular resistance to attempts at repression by local dictators—as well as resistance to political and military interference from Cuba and the Soviet Union—has proved to be formidable.

In Eastern Europe, even as we see rays of light in some countries, we must recognize that brutal repression continues in other parts of the region, including the persecution of ethnic and religious minorities.

This week, we recall with deep sadness the infamous Molotov-Ribbentrop pact between Nazi Germany and the U.S.S.R. that doomed Poland, Estonia, Latvia, and Lithuania to dismemberment and foreign domination. The United States refuses to accept the subsequent incorporation by the Soviet Union of the Baltic States during World War II. Since their forcible annexation in 1940, the people of Lithuania, Latvia, and Estonia have faced political oppression, religious persecution, and repression of their national consciousness. But decades of oppression have not broken the great spirit of the Baltic people and other victims of Soviet domination.

Hundreds of thousands of men and women around the world continue to demonstrate publicly their desire for liberty and democratic government,

demanding freedom of speech, assembly and movement, as well as the freedom to practice their religious beliefs without fear of persecution.

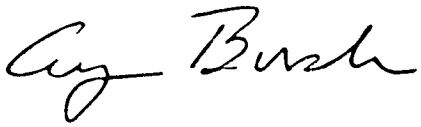
Their voices are being heard; there have been improvements in human rights practices by the ruling regimes in many of these countries. But justice demands that more positive steps be taken. The fundamental rights and dignity of individuals must be recognized in law and respected in practice; the peoples living in captive nations not only ask for but are entitled to lasting protection of their God-given rights.

The United States shall continue to call upon all governments and states to uphold the letter and the spirit of the United Nations Charter and the Helsinki Final Act until freedom and independence have been achieved for all captive nations.

Affirming all Americans determination to keep faith with those who are denied their fundamental rights, the Congress, by Joint Resolution approved July 17 1959 (73 Stat. 212), has authorized and requested the President to issue a proclamation designating the third week in July of each year as "Captive Nations Week.

NOW THEREFORE. I, GEORGE BUSH, President of the United States of America, do hereby proclaim the week beginning July 16, 1989, as Captive Nations Week. I call upon the people of the United States to observe this week with appropriate programs, ceremonies, and activities, and I urge them to reaffirm their devotion to the aspirations of all peoples for justice, self-determination, and liberty

IN WITNESS WHEREOF I have hereunto set my hand this sixth day of July, in the year of our Lord nineteen hundred and eighty-nine, and of the Independence of the United States of America the two hundred and fourteenth.



[FR Doc. 89-16298
Filed 7-7-89; 10:20 am]
Billing code 3195-01-M

Presidential Documents

Executive Order 12680 of July 5, 1989

Administration of Foreign Assistance and Related Functions and Arms Export Controls

By virtue of the authority vested in me as President by the Constitution and laws of the United States of America, including section 621 of the Foreign Assistance Act of 1961, as amended (22 U.S.C. 2381), and section 301 of Title 3 of the United States Code, and in order to delegate certain functions to the Secretary of State and the Secretary of Defense, it is hereby ordered as follows:

Section 1. Section 1-102(a) of Executive Order No. 12163, as amended, is further amended by amending paragraphs (9) and (10) to read as follows:

"(9) section 536 of the Foreign Operations, Export Financing, and Related Programs Appropriations Act, 1989 (Public Law 100-461), to be exercised by the Administrator of the Agency for International Development within IDCA, and

"(10) the first proviso under the heading 'Population, Development Assistance contained in Title II of the Foreign Operations, Export Financing, and Related Programs Appropriations Act, 1989 (Public Law 100-461), to be exercised by the Administrator of the Agency for International Development within IDCA.

Sec. 2. Section 1-201(a) of Executive Order No. 12163, as amended, is further amended by amending paragraphs (26), (27), (28), and (29) to read as follows:

"(26) sections 513, 526, 527 539, 556, 564, and 565 of the Foreign Operations, Export Financing, and Related Programs Appropriations Act, 1989 (Public Law 100-461);

"(27) the fourth proviso under the heading 'Southern Africa, Development Assistance contained in Title II of the Foreign Operations, Export Financing, and Related Programs Appropriations Act, 1989 (Public Law 100-461);

"(28) the proviso relating to tied aid credits under the heading 'Economic Support Fund' contained in Title II of the Foreign Operations, Export Financing, and Related Programs Appropriations Act, 1989 (Public Law 100-461), which shall be exercised in consultation with the Administrator of the Agency for International Development within IDCA,

"(29) subsection (c)(2) under the heading 'Foreign Military Sales Debt Reform contained in Title III of the Foreign Operations, Export Financing, and Related Programs Appropriations Act, 1988 (Public Law 100-202), and section 573(c) of that Act, both of which shall be exercised in consultation with the Secretary of Defense. In addition, section 573(c) shall be exercised in consultation with the Director of the United States Arms Control and Disarmament Agency·

Sec. 3. Section 1-201(a) of Executive Order No. 12163, as amended, is further amended by inserting the following new paragraphs at the end thereof:

"(30) Section 566(d) of the Foreign Operations, Export Financing, and Related Programs Appropriations Act, 1989 (as enacted in Public Law 100-461), which shall be exercised in consultation with the Secretary of Defense: and

"(31) sections 4101(b), 4205(d), 4307(a), and 4309 of the Anti-Drug Abuse Act of 1988 (Public Law 100-690). The Secretary of State in implementing the functions delegated to him under section 4205(d) shall consult with the Secretary of Defense.

Sec. 4. Section 1-301 of Executive Order No. 12163, as amended, is further amended by amending section (f) to read as follows:

"(f) The functions conferred upon the President under section 566(c) of the Foreign Operations, Export Financing, and Related Programs Appropriations Act, 1989 (Public Law 100-461)."

Sec. 5. Section 1 of the Executive Order No. 11958, as amended, is further amended:

(1) by inserting in the first paragraph "and related legislation," after "the Act,"

(2) by inserting the following new paragraphs at the end of the section:

"(q) Those under Section 2(b)(6) of the Export-Import Bank Act of 1945 (12 U.S.C. 635(b)(6)) to the Secretary of State."

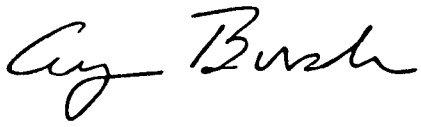
"(r) Those under Section 588(b) of the Foreign Operations, Export Financing, and Related Programs Appropriations Act, 1989 (Public Law 100-461), to the Secretary of Defense, except with respect to the determination of an emergency as provided by subsection (b)(3). The Secretary of Defense in implementation of the functions delegated to him under section 588(b) shall consult with the Secretary of State."

Sec. 6. Section 1(e) of Executive Order No. 11958, as amended, is further amended by inserting "and section 580 of the Foreign Operations, Export Financing, and Related Programs Appropriations Act, 1989 (Public Law 100-461)," after "Section 23 of the Act"

Sec. 7 Section 1(l) of Executive Order No. 11958, as amended, is further amended by striking out the semicolon at the end of the second sentence of paragraph (l) and inserting a period in lieu thereof, and by adding the following sentence at the end of paragraph (l):

"The authority to undertake activities to ensure compliance with established export conditions may be redelegated to the Secretary of Defense, or to the head of another department or agency as appropriate, which shall exercise such functions in consultation with the Secretary of State;"

Sec. 8. Section 2(a) of Executive Order No. 11958, as amended, is further amended by deleting "and" after "International Development Cooperation Agency" and inserting "and the Chairman of the Export-Import Bank," after "Arms Control and Disarmament Agency,"



THE WHITE HOUSE,
July 5, 1989.

[FR Doc. 89-16299
Filed 7-7-89; 10:21 am]
Billing code 3195-01-M

Presidential Documents

Executive Order 12681 of July 6, 1989

Exclusions From the Federal Labor-Management Relations Program

By the authority vested in me as President by the Constitution and laws of the United States of America, including Chapter 71 of title 5 of the United States Code, and having determined under section 7103(b)(1) of said Chapter, that certain subdivisions of the National Preparedness Directorate of the Federal Emergency Management Agency have as a primary function intelligence, counterintelligence, investigative, or national security work, and having determined that the provisions of chapter 71 of title 5 of the United States Code cannot be applied to certain subdivisions of the National Preparedness Directorate of the Federal Emergency Management Agency, in a manner consistent with national security requirements and considerations, it is hereby ordered that Executive Order No. 12171, as amended, is further amended by adding to Section 1-2 "Exclusions" the following new subsection 1-214:

"1-214. Subdivisions of the National Preparedness Directorate of the Federal Emergency Management Agency.

"(a) Office of Associate Director.

"(b) Office of Analysis and Support.

"(c) Office of Mobilization Preparedness.

"(d) The following offices of the Office of Systems Engineering.

"(1) Office of the Assistant Associate Director.

"(2) NEMS-DCWS Program Office.

"(3) Systems Design Division.

"(4) Telecommunications Systems Development Division.

"(5) Systems Support Division.

"(e) The following offices of the Office of Operations.

"(1) Office of the Assistant Associate Director.

"(2) Planning Division.

"(3) The following branches of the Readiness Division.

"(A) Exercise Branch.

"(B) Operations Branch.

"(C) National Warning Center.

"(D) Alternate National Warning Center.

"(4) Mobile Emergency Response Support Operations Divisions.

"(5) Federal Agency Support and Coordination Division.

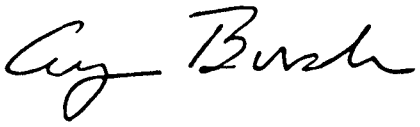
"(f) The following offices in the Office of Information Resource Management.

"(1) Office of the Assistant Associate Director.

"(2) Information Systems Policy, Planning and Evaluation Policy and Planning Branch.

"(3) Information Systems Application Branch.

"(4) EICC Support Center."



THE WHITE HOUSE,
July 6, 1989.

[FR Doc. 89-16301
Filed 7-7-89; 10:22 am]
Billing code 3195-01-M

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Monday, July 10, 1989

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CFR CHECKLIST

This checklist, prepared by the Office of the Federal Register, is published weekly. It is arranged in the order of CFR titles, prices, and revision dates.

An asterisk (*) precedes each entry that has been issued since last week and which is now available for sale at the Government Printing Office.

New units issued during the week are announced on the back cover of the daily **Federal Register** as they become available.

A checklist of current CFR volumes comprising a complete CFR set, also appears in the latest issue of the LSA (List of CFR Sections Affected), which is revised monthly.

The annual rate for subscription to all revised volumes is $620.00 domestic, $155.00 additional for foreign mailing.

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3 (1988 Compilation and Parts 100 and 101)	21.00	Jan. 1, 1989
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5 Parts:		
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[1] Because Title 3 an annual compilation, this volume and all previous volumes should be retained as a permanent reference source.

[2] No amendments to this volume were promulgated during the period Jan.1, 1988 to Dec.31, 1988. The CFR volume issued January 1, 1988, should be retained.

[3] No amendments to this volume were promulgated during the period Jan. 1, 1987 to Dec. 31, 1988. The CFR volume issued January 1, 1987 should be retained.

[4] No amendments to this volume were promulgated during the period Apr. 1, 1980 to March 31, 1988. The CFR volume issued as of Apr. 1, 1980, should be retained.

The July 1, 1985 edition of 32 CFR Parts 1–189 contains note only for Parts 1–39 inclusive. For the full text of the Defense Acquisition Regulations in Parts 1–39, consult the three CFR volumes issued as of July 1, 1984, containing those parts.

[6] No amendments to this volume were promulgated during the period July 1, 1986 to June 30, 1988. The CFR volume issued as of July 1, 1986, should be retained.

[7] The July 1, 1985 edition of 41 CFR Chapters 1–100 contains a note only for Chapters 1 to 49 inclusive. For the full text of procurement regulations in Chapters 1 to 49, consult the eleven CFR volumes issued as of July 1, 1984 containing those chapters.