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Wednesday
March 17, 1999

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

WASHINGTON, DC

WHEN: March 23, 1999 at 9:00 am.

WHERE: Office of the Federal Register
Conference Room
800 North Capitol Street, NW.
Washington, DC
(3 blocks north of Union Station Metro)

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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.

OFFICE OF GOVERNMENT ETHICS

5 CFR Part 2635

RIN 3209–AA04

Standards of Ethical Conduct for Employees of the Executive Branch

AGENCY: Office of Government Ethics (OGE).

ACTION: Final rule; amendments.

SUMMARY: The Office of Government Ethics is amending portions of the regulation governing standards of ethical conduct for executive branch employees on seeking other employment, to conform with interpretive advice and to improve clarity.

EFFECTIVE DATE: April 16, 1999.

FOR FURTHER INFORMATION CONTACT: G. Sid Smith, Senior Associate General Counsel, Office of Government Ethics; telephone: 202–208–8000; TDD: 202–208–8025; FAX: 202–208–8037.

SUPPLEMENTARY INFORMATION: On August 26, 1998, the Office of Government Ethics (OGE) published proposed minor amendments to the standards of ethical conduct for executive branch employees (5 CFR part 2635), to codify interpretive advice and clarify intended meaning in subpart F (Seeking Other Employment) and in the definition of ''receive'' at § 2635.807 of subpart H (Outside Activities). See 63 FR 45415–45417. We received only one comment, which related exclusively to the proposed amendment to § 2635.807. Upon further consideration, and in view of separate concerns about other provisions of § 2635.807, we have decided not to make the proposed definitional revision in § 2635.807 at this time. If, in the future, OGE decides to revive that proposal, we will issue a new proposed rule revision, with opportunity for comments.

No comments were received concerning subpart F, so OGE is herewith publishing the proposed amendments to subpart F as a final rule, with no changes, effective April 16, 1999. A summary of those amendments follows.

Subpart F

Subpart F of the standards of ethical conduct regulation, as promulgated for codification at 5 CFR part 2635 in 1992, implemented certain provisions of a criminal statute and an Executive order, specifically: (1) 18 U.S.C. 208, restricting employees' official participation in matters wherein a person or organization with whom they are negotiating for or have an arrangement concerning prospective employment has a financial interest, and (2) sections 101(h) and 101(j) of Executive Order 12674, directing employees to act impartially in official matters and not to engage in seeking or negotiating for outside employment that conflicts with official duties and responsibilities. Because these provisions of the criminal statute and Executive order are so closely related, they were combined for implementation at subpart F, with a requirement generally for disqualification from participation in certain matters when an employee is ''seeking other employment,'' a term that encompasses both negotiating and other specified lesser contacts.

The existing language of § 2635.601 and § 2635.602 in that subpart suggests that coverage may be limited to situations where the employee's ''performance or nonperformance of official duties will affect'' the financial interests of a prospective employer. A somewhat more accurate test, for purposes of 18 U.S.C. 208, is contained in the existing § 2635.604(a), § 2635.605(a), and § 2635.606(a), which is that coverage extends to participation in ''a particular matter that has a direct and predictable effect'' on those financial interests. The criminal statute does not limit its application to situations where one's performance of official duties will affect a financial interest, but instead focuses on whether a matter in which the employee participates will affect the financial interest. Further, the statute is triggered only if the effect on the financial interest will be direct and predictable.

This variation among sections of the regulation was an unintended result of the process by which provisions on prospective employment in the criminal statute and Executive order were implemented jointly. As questions from ethics officials have arisen concerning these apparent discrepancies, OGE has advised that the requirements of 18 U.S.C. 208 control. In order to more clearly align the provisions of subpart F with that advice and the criminal statute, OGE is amending § 2635.601 and § 2635.602 accordingly, by this current rulemaking.

Additionally, amendments in this current rulemaking to § 2635.601, § 2635.602, § 2635.604, § 2635.605, and § 2635.606 clarify initially in each section that the restrictions apply only when the employee would be ''participating personally and substantially'' in a particular matter. These modifications will further ensure that subpart F is consistent with 18 U.S.C. 208 and in conformance with OGE advice.

Matters of Regulatory Procedure

Executive Order 12866

In promulgating these final rule amendments, the Office of Government Ethics has adhered to the regulatory philosophy and the applicable principles of regulation set forth in section 1 of Executive Order 12866, Regulatory Planning and Review. These amendments have also been reviewed by the Office of Management and Budget under that Executive order.

Regulatory Flexibility Act

As Director of the Office of Government Ethics, I certify under the Regulatory Flexibility Act (5 U.S.C. chapter 6) that this rulemaking will not have a significant economic impact on a substantial number of small entities, because it primarily affects Federal executive branch agencies and their employees.

Paperwork Reduction Act

The Paperwork Reduction Act (44 U.S.C. chapter 35) does not apply, because this rulemaking does not contain any information collection requirements that require the approval of the Office of Management and Budget.

List of Subjects in 5 CFR Part 2635

Conflict of interests, Executive branch standards of ethical conduct, Government employees.

Approved: December 7, 1998.

Stephen D. Potts,

Director, Office of Government Ethics.

For the reasons set forth in the preamble, the Office of Government Ethics is amending part 2635 of subchapter B of chapter XVI of title 5 of the Code of Federal Regulations, as follows:

PART 2635—[AMENDED]

1. The authority citation for part 2635 continues to read as follows:

Authority: 5 U.S.C. 7301, 7351, 7353; 5 U.S.C. App. (Ethics in Government Act of 1978); E.O. 12674, 54 FR 15159, 3 CFR, 1989 Comp., p. 215, as modified by E.O. 12731, 55 FR 42547, 3 CFR, 1990 Comp., p. 306.

§ 2635.601 [Amended]

2. Section 2635.601 is amended by removing the words ''who otherwise would be affected by the performance or nonperformance of the employees' official duties.'' from the end of the first sentence and adding the words ''whose financial interests would be directly and predictably affected by particular matters in which the employees participate personally and substantially.'' in their place, and by adding the new sentence ''See § 2635.402 and § 2640.103 of this chapter.'' between the second and third sentences.

§ 2535.602 [Amended]

3. Section 2635.602 is amended by removing the words ''the employee's official duties would affect'' from the first sentence of the undesignated introductory text and adding the words ''particular matters in which the employee will be participating personally and substantially would directly and predictably affect'' in their place, and by removing the words ''affected by the performance or nonperformance of his official duties'' from the first sentence of the note following the undesignated introductory text and adding the words ''affected directly and predictably by particular matters in which he participates personally and substantially'' in their place.

4. Section 2635.603 is amended by revising paragraph (d) to read as follows:

§ 2635.603 Definitions.

* * * * *

(d) *Direct and predictable effect, particular matter, and personal and substantial* have the respective meanings set forth in § 2635.402(b)(1), (3), and (4).

§ 2635.604 [Amended]

5. Section 2635.604 is amended by adding the words ''personally and substantially'' after the word ''participate'' in the first sentence of paragraph (a).

§ 2635.605 [Amended]

6. Section 2635.605 is amended by adding the words ''personally and substantially'' after the word ''participate'' in the first sentence of paragraph (a), and by adding the words ''personally and substantially'' after the word ''participate'' in the first sentence of paragraph (b).

§ 2635.606 [Amended]

7. Section 2635.606 is amended by removing the words ''taking official action'' from the first sentence of paragraph (a) and adding the words ''participating personally and substantially'' in their place.

[FR Doc. 99–6492 Filed 3–16–99; 8:45 am]

BILLING CODE 6345–01–U

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 52

[Docket No. 98–123–3]

RIN 0579–AB10

Pseudorabies in Swine, Payment of Indemnity; Technical Amendment

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Interim rule; technical amendment and notice of extension of comment period.

SUMMARY: In an interim rule published in the **Federal Register** on January 15, 1999, and effective as of January 12, 1999, we established animal health regulations to provide for the payment of indemnity by the United States Department of Agriculture for the voluntary depopulation of herds of swine known to be infected with pseudorabies. Although we provided in our interim rule that a premises that has been depopulated of swine may not be restocked for at least 30 days following cleaning and disinfection, it was our intent to also allow an official pseudorabies epidemiologist to allow restocking in less than 30 days or to require a waiting period longer than 30 days as warranted or necessary. In this amendment we are clarifying that intent.

DATES: This amendment is effective March 11, 1999. We invite you to comment on Docket No. 98–123–2 as amended by this docket. We will consider all comments that we receive by April 16, 1999.

ADDRESSES: Please send your comment and three copies to: Docket No. 98–123–2, Regulatory Analysis and Development, PPD, APHIS, Suite 3C03, 4700 River Road, Unit 118, Riverdale, MD 20737–1238.

Please state that your comment refers to Docket No. 98–123–2.

You may read any comments that we receive on these dockets in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue, SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.

APHIS documents published in the **Federal Register**, and related information, including the names of organizations and individuals who have commented on APHIS rules, are available on the Internet at http://www.aphis.usda.gov/ppd/rad/webrepor.html.

FOR FURTHER INFORMATION CONTACT: Dr. Keith Hand, Senior Staff Veterinarian, VS, APHIS, 4700 River Road Unit 41, Riverdale, MD 20737–1231; (301) 734–8073.

SUPPLEMENTARY INFORMATION:

Background

In an interim rule published in the **Federal Register** on January 15, 1999, and effective as of January 12, 1999 (64 FR 2545–2550, Docket No. 98–123–2), we established animal health regulations to provide for the payment of indemnity by the United States Department of Agriculture for the voluntary depopulation of herds of swine known to be infected with pseudorabies. Although we provided in our interim rule that a premises that has been depopulated of swine may not be restocked for at least 30 days following cleaning and disinfection of the premises, it was our intent to allow an official pseudorabies epidemiologist to allow restocking in less than 30 days or to require a waiting period longer than 30 days before restocking.

We included the 30-day waiting period in the interim rule in order to ensure that the vacated premises was completely free of the pseudorabies virus before being repopulated with

healthy animals. Generally, we consider 30 days to be a sufficient amount of time for the elimination of any pseudorabies virus that might remain on the premises after cleaning and disinfection. However, a premises that has been adequately cleaned and disinfected may, in some cases, not need a 30-day waiting period to ensure that the virus has been eliminated. Conversely, it is possible that it might not be entirely safe to restock a premises until more than 30 days have elapsed following cleaning and disinfection.

It was our intent to allow an official pseudorabies epidemiologist familiar with the individual premises and the cleaning and disinfection done on that premises to determine whether any reduction or addition to the 30-day waiting period was warranted or advisable for that premises. Therefore, we are adding language to § 52.4 to clarify that intent.

This technical amendment is consistent with procedures outlined in our ''State-Federal-Industry Program Standards for Pseudorabies Eradication.'' (A copy of the standards can be obtained by contacting the person listed above under **FOR FURTHER INFORMATION CONTACT**.) At the onset of our accelerated pseudorabies eradication program, we advised States participating in the eradication program that we would proceed in accordance with our existing program standards. The language we are adding to the regulations is consistent with the existing standards.

Comments sent to us on our January 15, 1999, interim rule (Docket No. 98–123–2) were required to be received on or before March 16, 1999. To allow the public enough time to comment on this technical amendment as it relates to the interim rule, we are extending the period during which we will accept comments on Docket No. 98–123–2.

List of Subjects in 9 CFR Part 52

Animal diseases, Pseudorabies, Swine, Indemnity payments, Transportation.

Accordingly, we are amending 9 CFR part 52 as follows:

PART 52—SWINE DESTROYED BECAUSE OF PSEUDORABIES

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

Authority: 21 U.S.C. 111–113, 114, 114a, 114a-1, 120, 121, 125, and 134b; 7 CFR 2.22, 2.80, and 371.2(d).

2. Section § 52.4 is revised to read as follows:

§ 52.4 Disinfection of premises, conveyances, and materials.

All premises, including barns, stockyards and pens, and all cars and other conveyances, and the materials on any premises or conveyances used to house or transport swine for which indemnity is paid under this part must be cleaned and disinfected under the supervision of an APHIS employee after removal of the swine from the known infected herd. Premises may be restocked with swine 30 days following an approved cleaning and disinfection, unless an official pseudorabies epidemiologist determines that a shorter or longer period of time is adequate or necessary to protect new animals against infection. The owner to whom the indemnity is paid will be responsible for expenses incurred in connection with the cleaning and disinfection, except for cleaning and disinfection of the conveyances used to transport the swine to the location of disposal.

Done in Washington, DC, this 11th day of March 1999.

Craig A. Reed,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 99–6491 Filed 3–16–99; 8:45 am]

BILLING CODE 3410–34–P

SECURITIES AND EXCHANGE COMMISSION

17 CFR Parts 202, 240, 242 and 249

[Release No. 34–40760A; File No. S7–12–98]

RIN 3235–AH41

Regulation of Exchanges and Alternative Trading Systems; Correction

AGENCY: Securities and Exchange Commission.

ACTION: Correction to final regulations.

SUMMARY: This document contains corrections to the final regulations which were published Tuesday, December 22, 1998, (63 FR 70844). The regulations related to regulation of exchanges and alternative trading systems.

EFFECTIVE DATE: April 21, 1999, except §§ 242.301(b)(5)(i)(D) and (E) and §§ 242.301(b)(6)(i)(D) and (E), which shall become effective on April 1, 2000.

FOR FURTHER INFORMATION CONTACT: Kevin Ehrlich, Attorney, at (202) 942–0778, Division of Market Regulation, Securities and Exchange Commission, 450 Fifth Street, N.W., Washington, DC 20549–1001.

SUPPLEMENTARY INFORMATION:

Background

The final regulations that are the subject of these corrections relate to the regulation of exchanges and alternative trading systems.

Need for Correction

As published, the final regulations contain a rule designation which was previously designated by another final rule. In the final rules for OTC derivatives dealers, published on Tuesday, November 3, 1998, new Rule 17a–4(b)(10) was adopted and became effective on January 4, 1999. The final rules for the regulation of exchanges and alternative trading systems erroneously also designated a new Rule 17a–4(b)(10). This correction redesignates the Rule 17a–4(b)(10) contained in the regulation of exchanges and alternative trading systems release as Rule 17a–4(b)(11) and makes the necessary changes throughout the release text and final rules.

Under section 553(b), notice of proposed rulemaking is not required when the agency for good cause finds that notice and public procedure thereon are ''impracticable, unnecessary, or contrary to the public interest.'' Because the amendments adopted today are technical corrections to clarify the rule designations, the Commission finds that publishing the amendments for comment would be unnecessary. The rule being amended was adopted after notice and the opportunity for public comment.

Under section 553(d), publication of a substantive rule not less than 30 days before its effective date is required except as otherwise provided by the agency for good cause. For the same reasons as described above with respect to notice and opportunity for comment, the Commission finds that there is good cause for having the rule become effective on April 21, 1999.

The Paperwork Reduction Act of 1995 [1] does not apply to this rulemaking since these correcting amendments do not require any ''collection of information.''

Section 23(a)(2) of the Exchange Act [2] requires the Commission to consider the anti-competitive effects of any rules it adopts thereunder, and to balance them against the benefits that further the purposes of the Act. Furthermore, section 2 of the Securities Act [3] and section 3 of the Exchange Act,[4] as

[1] 44 U.S.C. 3501 *et seq.*

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

[3] 15 U.S.C. 77b.

[4] 15 U.S.C. 78c.

amended by the recently enacted National Securities Markets Improvements Act of 1996,[5] provide that whenever the Commission is engaged in rulemaking and is required to consider or determine whether an action is necessary or appropriate in the public interest, the Commission shall also promote efficiency, competition, and capital formation. Because the amendments here do not effect any substantive change in the rules they do not have any anti-competitive effects. Because they correct mistakes or clarify ambiguity present in the Commission's rules, they serve to promote efficiency, competition, and capital formation, and are therefore in the public interest.

Correction of Publication

Accordingly, the publication on December 22, 1998 of the final regulations which were the subject of FR Doc. 98–33299 beginning on page 70844 is corrected as follows:

1. On page 70845 in the first column under XII. in the table of contents, ''D. Rule 17a–4(b)(10)'' is corrected to read ''D. Rule 17a–4(b)(11)''.

2. On page 70909 in the second column, line 11 of the last paragraph, ''17a–4(b)(10)'' is corrected to read ''17a–4(b)(11)''.

3. On page 70911 in the third column, 9th line from the bottom in the last paragraph, ''Rule 17a–4(b)(10)'' is corrected to read ''Rule 17a–4(b)(11)''.

4. On page 70913 in the second column, heading ''D. Rule 17a–4(b)(10)'' is corrected to read ''D. Rule 17a–4(b)(11)'' and lines 5 and 11 of the last paragraph, ''Rule 17a–4(b)(10)'' is corrected to read ''Rule 17a–4(b)(11)''.

5. On page 70913 in the third column in the first line, ''Rule 17a–4(b)(10)'' is corrected to read ''Rule 17a–4(b)(11)''.

6. On page 70919 in the third column, the last line of instruction 11, ''paragraph (b)(10)'' is corrected to read ''paragraph (b)(11)''.

7. On page 70920 in the first column at the first line, the designation ''(10)'' is corrected to read ''(11)''.

8. On page 70920 in the first column in the first paragraph, lines 11 and 16, ''(b)(10)'' is corrected to read ''(b)(11)''.

Dated: March 11, 1999.

Jonathan G. Katz,

Secretary.

[FR Doc. 99–6411 Filed 3–16–99; 8:45 am]

BILLING CODE 8010–01–P

[5] Pub. L. 104–290, 106, 110 Stat. 3416 (1996).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 201

[Docket No. 77N–094W]

Over-the-Counter Drug Products Containing Analgesic/Antipyretic Active Ingredients for Internal Use; Required Alcohol Warning; Final Rule; Compliance Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; compliance date.

SUMMARY: The Food and Drug Administration (FDA) is establishing a compliance date of October 22, 1999, for the regulation that published in the **Federal Register** of October 23, 1998 (63 FR 56789). The regulation established warning statements that advise consumers with a history of heavy alcohol use to consult a physician for advice about the use of OTC internal analgesic/antipyretic drug products. The compliance date applies to all affected OTC drug products, whether marketed with or without an approved application. FDA is taking this action in response to correspondence and a citizen petition requesting more time to relabel these products.

DATES: 21 CFR 201.322, published on October 23, 1998 (63 FR 56789), is effective April 23, 1999; but compliance is not required until October 22, 1999.

FOR FURTHER INFORMATION CONTACT: Gerald M. Rachanow, Center for Drug Evaluation and Research (HFD–560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2307.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of November 14, 1997 (62 FR 61041), FDA published a proposed amendment of part 201 (21 CFR part 201) to establish alcohol warnings for all OTC drug products labeled for adult use containing internal analgesic/antipyretic active ingredients. The agency stated that it may change the wording of the proposed warnings or not require them as a result of comments filed in response to the proposal. Because it wished to encourage the voluntary use of the proposed warning statements, the agency advised that manufacturers would be given ample time after publication of a final rule to use up any labeling printed in conformance with the proposal (62 FR 61041 at 61052).

In the **Federal Register** of October 23, 1998 (63 FR 56789), FDA issued a final rule amending part 201 and establishing in § 201.322 a required alcohol warning for OTC drug products containing internal analgesic/antipyretic active ingredients. The final rule requires manufacturers to add certain new warnings for any OTC drug product, labeled for adult use, containing any internal analgesic/antipyretic active ingredients (including, but not limited to, acetaminophen, aspirin, carbaspirin calcium, choline salicylate, ibuprofen, ketoprofen, magnesium salicylate, naproxen sodium, and sodium salicylate) alone or in combination and marketed with or without an approved application. The wording of the warnings in the final rule was different than the wording in the proposal. The final rule specified an effective date of April 23, 1999, for any OTC drug product subject to this section.

II. Summary of Comments Received

In response to the final rule, the agency received several comments (Ref. 1) and a citizen petition (Ref. 2) requesting more time to implement the new required alcohol warnings and a mechanism by which manufacturers may petition the agency for a variance or extension of time to comply with the regulation's 6-month implementation date. The comments were submitted by several large manufacturers of brand name OTC internal analgesic/antipyretic drug products and a manufacturer of a large number of private label OTC internal analgesic/antipyretic drug products. The comments stated that relabeling procedures generally take longer than the 6 months provided for in the final rule and that the companies simply lack the needed manpower and equipment to comply by April 23, 1999.

The comments added that the implementation period for the new rule must ensure that label integrity is not compromised or done haphazardly. The comments stated that 6 months is an insufficient period of time for a number of companies to accomplish the relabeling, and the short timeframe does not promote emphasis on labeling integrity and good manufacturing practice compliance. All of the comments expressed concern that numerous products could become unavailable and estimated significant loss of inventory if required to implement the labeling change by April 23, 1999.

One comment requested permission to use up all existing supplies of labeling that contain the precise alcohol warning contained in an agency letter dated March 14, 1996 (Ref. 3). Another

comment, submitted by a manufacturer, stated that it would implement the new alcohol warnings by the effective date and that other affected companies should also be required to meet that date (Ref. 4).

The agency held a public meeting on January 20, 1999 (Ref. 5), to hear the views of interested parties regarding the implementation date of the rule. At this meeting, one large private label manufacturer of internal analgesic/antipyretic drug products stated that it would not be able to meet the April 23, 1999, implementation date, and that if the deadline were not extended a real possibility existed that there would be a national shortage of certain products that it manufactures. Another manufacturer at the meeting stated that it would be able to comply by the implementation date.

III. The Agency's Response

As stated in the final rule, the agency considers the lack of sufficient alcohol warnings to be a significant public health issue. However, additional information (Refs. 6 through 11) that the agency has obtained since publication of the final rule suggests that the agency may have underestimated the number of individual label changes that some manufacturers will have to make. This information also indicates that there may be a significantly greater disparity in the effect of the required labeling upon manufacturers than originally anticipated. For these reasons, FDA now believes that the original 6-month implementation period would not provide adequate time for many manufacturers of affected products to relabel a significant number of their products and that strict adherence to the April 23, 1999, effective date might result in short-term shortages of some of these important OTC drug products, which are widely used by many consumers. Consequently, the agency believes that establishing a compliance date for the regulation, until October 22, 1999, will provide sufficient time for industry to implement the labeling revisions required for these OTC internal analgesic/antipyretic drug products.

The agency does not believe that there should be an open-ended period, as one comment requested, to use up existing supplies of labeling that contain an alcohol warning that was implemented voluntarily in response to an agency letter dated March 14, 1996 (Ref. 3). Rather, FDA believes that there should be a date certain after which all products initially introduced or initially delivered for introduction into interstate commerce contain the new warnings. Further, because of the importance of the alcohol warnings, the agency continues to encourage all affected manufacturers to bring their labeling into compliance with the final rule as promptly as possible.

Because this document merely establishes a compliance date, FDA finds that notice and comment procedures are unnecessary and not in the public interest (5 U.S.C. 553(b) and (d)). Moreover, because of the need for the agency to publish this document before the original April 23, 1999, effective date, notice and comment rulemaking would be impracticable for this document.

IV. Analysis of Impacts

The economic impact of the final regulation was discussed in the final rule (63 FR 56789 at 56798 to 56799). This document will provide additional time for companies to relabel affected products and will reduce label obsolescence, as there will be additional time to use up more existing labeling. Thus, setting a compliance date of October 22, 1999, should reduce the economic impact on industry significantly.

FDA has examined the impacts of this final rule (establishment of the compliance date) under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles set out in the Executive Order. The final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. This final rule sets a compliance date, which will provide manufacturers additional time to use up existing product labeling. Accordingly, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

V. Paperwork Reduction Act of 1995

FDA concludes that the labeling requirements in this document are not subject to review by the Office of Management and Budget because they do not constitute a ''collection of information'' under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Rather, the labeling statements are a ''public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)).

VI. Environmental Impact

The agency has determined under 21 CFR 25.31(c) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. References

The following references are on display in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested parties between 9 a.m. and 4 p.m., Monday through Friday.

1. Comment Nos. C20, C21, and C22, Docket No. 77N–094W, Dockets Management Branch.

2. Comment No. CP1, Docket No. 77N–094W, Dockets Management Branch.

3. Letter from D. Bowen, FDA, to R. Soller, Nonprescription Drug Manufacturers Association, Coded LET2, Docket No. 77N–094W, Dockets Management Branch.

4. Comment No. C19, Docket No. 77N–094W, Dockets Management Branch.

5. Comment No. MM, Docket No. 77N–094W, Dockets Management Branch.

6. Letter from K. Rothschild, FDA, to D. Jespersen, Perrigo, coded LET3, Docket No. 77N–094W, Dockets Management Branch.

7. Letter from K. Rothschild, FDA, to H. McCain, Whitehall-Robins, coded LET4, Docket No. 77N–094W, Dockets Management Branch.

8. Comment No. C23, Docket No. 77N–094W, Dockets Management Branch.

9. Comment No. C24, Docket No. 77N–094W, Dockets Management Branch.

10. Letter from K. Rothschild, FDA, to H. McCain, Whitehall-Robins, coded LET5, Docket No. 77N–094W, Dockets Management Branch.

11. Comment No. C25, Docket No. 77N–094W, Dockets Management Branch.

Dated: March 11, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99–6447 Filed 3–12–99; 12:40 pm]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Bacitracin Methylene Disalicylate Soluble

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Alpharma Inc. The supplemental NADA provides for using soluble bacitracin methylene disalicylate (BMD) powder to make a medicated drinking water for replacement chickens as an aid in the prevention and control of necrotic enteritis.

EFFECTIVE DATE: March 17, 1999.

FOR FURTHER INFORMATION CONTACT: William T. Flynn, Center for Veterinary Medicine (HFV–133), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7570.

SUPPLEMENTARY INFORMATION: Alpharma Inc., One Executive Dr., Fort Lee, NJ 07024, filed supplemental NADA 65–470 that provides for use of BMD® Soluble (BMD soluble powder) to make a medicated drinking water for replacement chickens. Medicated drinking water containing the equivalent of 100 milligrams (mg) of bacitracin per gallon is used as an aid in the prevention of necrotic enteritis caused by *Clostridium perfringens* susceptible to BMD. Medicated drinking water containing the equivalent of 200 to 400 mg of bacitracin per gallon is used as an aid in the control of necrotic enteritis caused by *C. perfringens* susceptible to BMD. The supplemental NADA is approved as of February 2, 1999, and the regulations in § 520.154a (21 CFR 520.154a) are amended to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In addition, the specifications paragraph is revised to reflect that the 200 grams per pound concentration has been previously approved for use in all species as in § 520.154a(d).

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 520

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 520.154a [Amended]

2. Section 520.154a *Soluble bacitracin methylene disalicylate* is amended in paragraph (a) by removing the phrase ''paragraphs (d)(3) and (d)(4)'' and by adding in its place the phrase ''paragraph (d)'', and in paragraph (d)(2) by removing the heading ''Broiler chickens'' and by adding in its place ''Broiler and replacement chickens''.

Dated: February 26, 1999.

Margaret Ann Miller,

Acting Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 99–6458 Filed 3–16–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 556 and 558

New Animal Drugs For Use In Animal Feeds; Lasalocid

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Roche Vitamins, Inc. The supplemental NADA provides for use of a lower concentration lasalocid Type A medicated article to make a Type C rabbit feed used for prevention of coccidiosis and to provide for a tolerance for drug residues in rabbits.

EFFECTIVE DATE: March 17, 1999.

FOR FURTHER INFORMATION CONTACT: Estella Z. Jones, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7575.

SUPPLEMENTARY INFORMATION: Roche Vitamins, Inc., 45 Waterview Blvd., Parsippany, NJ 07054–1298, filed supplemental NADA 96–298 that provides for use of Bovatec® (15 percent lasalocid) in addition to previously approved use of Avatec® (20 percent lasalocid) Type A medicated articles to make 113 grams per ton lasalocid Type C rabbit feeds used for prevention of coccidiosis caused by *Eimeria stiedae*. The supplemental NADA is approved as of February 5, 1999, and the regulations are amended in 21 CFR 558.311(b)(4) to reflect the approval. The basis of approval is discussed in the freedom of information summary.

At this time, the human food safety data originally submitted in public master file 5042 for use of lasalocid in rabbits was reevaluated and a tolerance for drug residues in edible rabbit tissues is established in 21 CFR 556.347. Also, that section is revised to reflect current format.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this supplemental application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects

21 CFR Part 556

Animal drugs, Foods.

21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21

CFR parts 556 and 558 are amended as follows:

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

1. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

2. Section 556.347 is revised to read as follows:

§ 556.347 Lasalocid.

(a) [Reserved]

(b) *Tolerances*—(1) *Chickens*. A tolerance is established for lasalocid residues of 0.3 part per million (ppm) parent lasalocid (marker residue) in skin with adhering fat (target tissue).

(2) *Cattle*. A tolerance is established for lasalocid residues of 0.7 ppm parent lasalocid (marker residue) in liver (target tissue).

(3) *Sheep*. A tolerance for residues of lasalocid is not needed.

(4) *Rabbits*. A tolerance is established for lasalocid residues of 0.7 ppm parent lasalocid (marker residue) in liver (target tissue).

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

3. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

4. Section 558.311 is amended by revising paragraph (b)(4) to read as follows:

§ 558.311 Lasalocid.

* * * * *

(b) * * *

(4) 15 percent activity to No. 063238 for use in Type C rabbit feeds as in paragraph (e)(1)(xvi) of this section and for use in ruminant free-choice Type C feeds as in paragraphs (e)(2) and (e)(3) of this section.

* * * * *

Dated: February 23, 1999.

Andrew J. Beaulieu,

Acting Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 99–6461 Filed 3–16–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs For Use In Animal Feeds; Monensin and Virginiamycin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Elanco Animal Health, a Division of Eli Lilly and Co. The NADA provides for combining approved monensin and virginiamycin Type A medicated articles to make combination drug Type C medicated growing turkey feeds used for prevention of certain forms of coccidiosis and for increased rate of weight gain and improved feed efficiency.

EFFECTIVE DATE: March 17, 1999.

FOR FURTHER INFORMATION CONTACT: Charles J. Andres, Center for Veterinary Medicine (HFV–128), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–1600.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, a Division of Eli Lilly and Co., Lilly Corporate Center, Indianapolis, IN 46285, filed NADA 141–110 that provides for combining approved monensin and virginiamycin Type A medicated articles to make combination drug Type C medicated growing turkey feeds containing 54 to 90 grams per ton (g/t) monensin and 10 to 20 g/t virginiamycin. The Type C medicated growing turkey feed is used for the prevention of coccidiosis caused by *Eimeria meleagrimitis*, *E. adenoeides*, and *E. gallopavonis*, and for increased rate of weight gain and improved feed efficiency. The NADA is approved as of January 29, 1999, and the regulations are amended in 21 CFR 558.355 to reflect the approval.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

FDA has determined under 21 CFR 25.33(a)(2) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

2. Section 558.355 is amended by adding paragraph (f)(2)(iv) to read as follows:

§ 558.355 Monensin.

* * * * *

(f) * * *

(2) * * *

(iv) *Amount per ton*. Monensin, 54 to 90 grams, with virginiamycin, 10 to 20 grams.

(a) *Indications for use*. For the prevention of coccidiosis caused by *Eimeria adenoeides*, *E. meleagrimitis*, and *E. gallopavonis*, and for increased rate of weight gain and improved feed efficiency in growing turkeys.

(b) *Limitations*. For growing turkeys only. Feed continuously as sole ration. Do not allow horses, other equines, mature turkeys, or guinea fowl access to feed containing monensin. Ingestion of monensin by horses, mature turkeys, and guinea fowl has been fatal. Some strains of turkey coccidia may be monensin tolerant or resistant. Monensin may interfere with development of immunity to turkey coccidiosis. Virginiamycin as provided by No. 000069 in § 510.600(c) of this chapter.

* * * * *

Dated: February 26, 1999.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 99–6460 Filed 3–16–99; 8:45 am]

BILLING CODE 4160–01–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 52 and 81

[OH121–1a; FRL–6239–3]

Approval and Promulgation of Implementations; Ohio; Designation of Areas for Air Quality Planning Purposes; Ohio

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is approving two redesignation requests submitted by the State of Ohio. This action, which was requested on October 26, 1995, redesignates Lake and Jefferson Counties to attainment of National Ambient Air Quality Standard (NAAQS) for sulfur dioxide (SO_2). EPA is also approving the maintenance plans for Lake and Jefferson Counties, to ensure maintenance of the NAAQS, which were submitted with the redesignation requests. In conjunction with these actions, EPA is also approving State-adopted emission limits for the Eastlake Plant (currently operated by First Energy, formerly operated by Cleveland Electric Illuminating), and the Ohio Rubber Company Plant, replacing equivalent limits in the Federal Implementation Plan (FIP) for Lake County. In the proposed rules section of this **Federal Register**, EPA is proposing approval of, and soliciting comments on, this approval. If adverse written comments are received on this action, EPA will withdraw this final rule and address the comments received in response to this action in a final rule based on the related proposed rule. A second public comment period will not be held. Parties interested in commenting on this action should do so at this time.

DATES: This ''direct final'' rule is effective on May 17, 1999, unless EPA receives adverse written comments by April 16, 1999. If an adverse written comment is received, EPA will publish a timely withdrawal of the rule in the **Federal Register** and inform the public that rule will not take effect.

ADDRESSES: Written comments should be sent to: J. Elmer Bortzer, Chief, Regulation Development Section. Air Program Branch (AR–18J), Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604. Copies of the revision request are available for inspection at the following address: Environmental Protection Agency, Region 5, Air and Radiation Division, 77 West Jackson Boulevard, Chicago, Illinois 60604. (It is recommended that you telephone Phuong Nguyen at (312) 886–6708 before visiting the Region 5 office.)

FOR FURTHER INFORMATION CONTACT: Phuong Nguyen at (312) 886–6701.

SUPPLEMENTARY INFORMATION:

I. Background

The NAAQS for SO_2 consists of three standards: Two primary standards for the protection of public health and a secondary standard for protection of public welfare. The primary SO_2 standards address 24-hour average and annual average ambient SO_2 concentrations. The secondary standard addresses 3-hr average ambient SO_2 concentrations (See 40 CFR 50.2–50.5).

EPA promulgated the FIP regulations in 1976. These regulations required significant emission reductions at specific facilities throughout the State in order to attain and maintain the NAAQS for SO_2. On October 5, 1978, Lake and Jefferson Counties (among others) were designated nonattainment for the primary standards. The State adopted its own regulations in 1979, generally imposing limits similar to those promulgated in the FIP. The State submitted these regulations for EPA approval in 1980, including regulations for Jefferson and Lake Counties. The State withdrew its submittal with respect to specified Lake County sources, namely the Eastlake Plant (formerly operated by Cleveland Electric Illuminating company), the Ohio Rubber Company Plant, and the Painesville Municipal Plant boiler number 5. EPA approved these regulations on January 27, 1981 (for Jefferson County, 46 FR 8481) and on April 20, 1982 (for Lake County, 47 FR 16784). Revised regulations for Jefferson County were approved on December 9, 1996 (61 FR 52882). However, the federally promulgated FIP regulations have remained in effect for the above sources in Lake County.

On October 26, 1995, Governor Voinovich requested that EPA move forward with redesignation to attainment for all remaining SO_2 nonattainment areas within the State of Ohio including Lake and Jefferson Counties. On May 28, 1996, EPA Administrator Browner sent a letter to Governor Voinovich informing him that the redesignation request depended on approval of State adopted rules in place of FIP rules. On July 30, 1996, the Director of the Ohio Environmental Protection Agency replied by objecting to EPA's position that such further materials are a prerequisite for these redesignations and requesting that EPA reconsider its position regarding the need for Ohio to adopt State rules to replace Federal rules, prior to redesignating several areas in Ohio to attainment for sulfur dioxide. In a September 25, 1996 letter to the State, EPA reaffirmed its position. On August 20, 1998, Ohio submitted material requested by EPA, including State adopted limits, to support the State's requests to redesignate Lake and Jefferson Counties to attainment with respect to SO_2.

The criteria for redesignation to attainment are given in section 107 (d)(3)(E) of the Clean Air Act (Act). Of particular note is section 107 (d)(3)(E)(ii), requiring that EPA has fully approved the applicable plan. These criteria will be discussed in more detail below.

The sulfur dioxide nonattainment area in Lake County is described as the cities of Eastlake, Lakeline, Mentor (north of US 20 and west of SR 306), Timberlake and Willoughby (north of US 20). The only major sulfur dioxide source located within this area is the Eastlake Plant. The State adopted emission limits for sources at this facility are equivalent to those found in the FIP. Compliance with these limits was determined by examining information submitted in the facility's Title V permit application. The Ohio Rubber Company plant and Painesville Municipal Plant are located in the sulfur dioxide attainment portion of Lake county, and emissions of these sources are not expected to have a significant impact on air quality in the nonattainment portion of the county.

The sulfur dioxide nonattainment area in Jefferson county is described as the cities of Steubenville and Mingo Junction, and the townships of Steubenville, Island Creek, Cross Creek, Knox and Wells. The largest sulfur dioxide sources located within this area are the American Electric Power, Cardinal Power Plant and Tidd Plant, both in Brilliant; The First Energy, W.H. Sammis Plant in Stratton; The First Energy, Toronto Plant, in Toronto; The Wheeling-Pittsburgh Steel, Steubenville South Plant, in Mingo Junction; and the Wheeling-Pittsburgh Steel, Steubenville North Plant, in Steubenville. The state emission limits for sources at these facilities were approved by EPA as part of the State Implementation Plan (SIP), effective January 27, 1981. Revised limits for these sources were approved on December 9, 1996. Compliance with these limits was determined by examining information submitted in the sources' title V permit applications.

II. SIP Approval

On August 20, 1998, Ohio submitted material including State adopted limits for sources in Lake County. The State requested approval of SIP limits for the First Energy Eastlake Plant and the Ohio Rubber Plant in place of federally promulgated FIP limits.

Guidance relevant to the request at issue is provided in a September 28, 1994 memorandum from the Director, Air Quality Management Division, Office of Air Quality Planning and Standards, EPA, to the Director, Air and Radiation Division, Region 5, entitled, ''Response to Request for Guidance on Issues with Ohio Sulfur Dioxide Federal Implementation Plan''. This memo set forth three criteria to be met for the approval of State limits that are equivalent to existing FIP limits without new modeling. Under the first two criteria, there must be no known inadequacy in the original attainment demonstration. Under the third criteria, the State limits must reflect no relaxation of existing emission limits. All three of these criteria are met by the State promulgated SIP limits. Therefore, the revised limits can be considered to be adequate to assure attainment without further modeling. Consequently, EPA approves adopted revisions to rule OAC 3745–18–49(G) (the emission limitations for the First Energy, Eastlake plant) and rule OAC 3745–18–49(H) (the emission limitations for the Ohio Rubber Company plant). These emission limits are equivalent to the FIP limits for Lake County.

As a result of the limits just discussed, attainment in Lake County is assured on the basis of State-adopted, EPA-approved limits. Consequently, there is no further need for a federally promulgated limit, and the corresponding FIP limits for these sources in Lake County can be rescinded.

III. Maintenance Plan Approval

Ohio's attainment plan for sulfur dioxide provides for attainment even with major sources emitting their maximum allowable emissions. Therefore, maintenance is provided by assuring that minor source impacts do not increase significantly. The principal minor sources are distant point sources and diesel vehicles. Title IV reductions and the required national conversion to low sulfur diesel fuel were the identified maintenance provisions contained in the approved redesignation for Washington and Morgan counties in 1994 (59 FR 48403). These reductions will also be realized in the other nonattainment counties; therefore, this maintenance plan can also be applied for these counties. These reductions in minor source emissions, in combination with the limits on major source emissions, are expected to provide for continued attainment in Jefferson and Lake Counties. Therefore, EPA approves the maintenance plan for these two counties.

IV. Redesignation Evaluation Criteria

Section 107(d)(3)(E) of the Act, as amended in 1990, establishes requirements to be met before an area may be redesignated from nonattainment to attainment. The criteria used to review redesignation requests are derived from the Act. An area can be redesignated to attainment if the following conditions are met: (A) The area has attained the applicable NAAQS; (B) The area has a fully approved SIP under section 110(k) of the Act; (C) The EPA has determined that the improvement in air quality in the area is due to permanent and enforceable emission reductions; (D) EPA has determined that the maintenance plan for the area has met all of the requirements of the section 175A of the Act; and, (E) The state has met all requirements applicable to the area under section 110 and part D of the Act.

A. Demonstrated Attainment of the NAAQS

As explained in an April 21, 1983, memorandum ''Section 107 Designation Policy Summary'' from the Director of the Office of Air Quality Planning and Standards, eight consecutive quarters of data showing SO_2 NAAQS attainment are required for redesignation. A violation of NAAQS occurs when more than one exceedance of the SO_2 NAAQS is recorded in any year (40 CFR 50.4). Ohio's August 3, 1998, submittal provided ambient monitoring data showing that Lake and Jefferson Counties have met the NAAQS for the years 1992–1998, the most recent consecutive years with quality-assured monitoring data. There has not been a monitored violation of the NAAQS for sulfur dioxide within the state for over 15 years.

Dispersion modeling is commonly used to demonstrate attainment of the SO_2 NAAQS. A September 4, 1992 EPA policy memorandum on ''procedures for processing requests to redesignate areas to attainment'' explains that additional dispersion modeling is not required in support of an SO_2 redesignation request if an adequate modeled attainment demonstration is submitted and approved as part of the implemented SIP, and no indication of an existing air quality deficiency exists. Modeling was performed in 1976 to show that, under all allowed operating scenarios, the emission limit in these two counties' SO_2 SIPs would lead to attainment and maintenance of the SO_2 standards.

These approvals were based on modeling showing that compliance with the submitted limits would assure attainment of the standards. Therefore, an important part of Ohio's August 20, 1998 submittal was evidence that sources are complying with applicable limits. This evidence is in the form of certifications of compliance by the affected sources, pursuant to certification requirements of Title V. Based on this evidence, EPA concludes that emissions are sufficiently low as to assure attainment throughout the areas currently designated nonattainment.

B. Fully Approved SIP

The SIP for the area at issue must be fully approved under section 110(k) of the Act and must satisfy all requirements that apply to the area. EPA's guidance for implementing section 110 of the Act is discussed in the General Preamble to Title I (44 FR 20372, April 14, 1979, and 57 FR 13498, April 16, 1992). The SO_2 SIP for Jefferson County and for most of Lake County met the requirements of section 110 of the Act and were approved by EPA on January 27, 1981 (46 FR 8481) and on April 20, 1982 (47 FR 16784), respectively. Also on December 9, 1996, EPA approved a SIP revision submitted by State of Ohio which amends the SO_2 regulations applying to First Energy's Sammis and Toronto Plants in Jefferson County. This revision involves reverting to an emission limit option presented in the FIP for Jefferson County. State limits for the remainder of Lake County (except for the Painesville Municipal Plant) are being approved in this rulemaking. The SIP supplemented a set of general Statewide SO_2 limitations with a set of individual emission limits for specific sources in the respective counties.

C. Permanent and Enforceable Reductions in Emissions

Lake and Jefferson Counties' attainment of the SO_2 standards can be attributed to the implementation of the SO_2 SIP controls and other permanent emission reductions. On January 27, 1981 and also on April 20, 1982, EPA approved the control strategies and emissions limits in Ohio's SO_2 SIP for Jefferson and for Lake (except for Eastlake plant, Ohio Rubber Company plant, and Painesville Municipal plant boiler number 5) Counties respectively,

which rendered them federally enforceable. The regulations are permanent, and any future revisions to the rules must be submitted to and approved by EPA.

The major emissions of SO_2 in Jefferson County are due to power plants and steelmaking operations and the major emissions of SO_2 in Lake County are due to power plant and combustion sources. The reductions in SO_2 emissions are due primarily to the conversion of some fuel-burning sources to lower sulfur content fuels, and to the shutdown of various types of sources. The use of lower-sulfur ''cleaner'' fuels is reflected in the facilities'' air permits and federally enforceable SIP regulations.

D. Fully Approved Maintenance Plan

As discussed above, EPA has concluded that the combination of limitations on maximum allowable emissions from major point sources and implementation of programs that will yield reductions in minor source emissions will assure maintenance of the standards.

E. Part D and Other Section 110 Requirements

EPA approved the SO_2 SIPs for Jefferson County on January 27, 1981, and later on December 9, 1996, and for Lake County on April 20, 1982. Several of the section 110 requirements were revised in the 1990 amendments to the Act. These existing SIPs conform with the new provisions of the Act. The plans provide for the implementation of reasonably available control measures for SO_2 under Ohio's SIP rule. As required by part D of the Act, Ohio has a fully approved and implemented New Source Review Plan. The existing Prevention of Significant Deterioration program, which was federally delegated for all attainment areas, will apply in all of Lake and Jefferson Counties subsequent to redesignation.

V. Final Rulemaking Action

EPA has completed an analysis of the SIP revision request based on a review of material presented, and has determined that the revisions for the First Energy Eastlake plant and Ohio Rubber Company Plant are approvable. In addition, EPA is also approving the SO_2 maintenance plan for Lake and Jefferson Counties, which were submitted with the redesignation request, as adequately ensuring that attainment will be maintained. Finally, EPA is approving redesignation requests from the State of Ohio which were submitted on October 26, 1995 and is redesignating those portions of Lake and Jefferson counties currently designated nonattainment to attainment for SO_2.

EPA is publishing this action without prior proposal because EPA views this as a noncontroversial revision and anticipates no adverse comments. However, in a separate document in this **Federal Register** publication, EPA is proposing to approve the State Plan should adverse written comments be filed. This action will be effective without further notice unless EPA receives relevant adverse written comment by April 16, 1999. Should EPA receive such comments, it will publish a final rule informing the public that this action will not take effect. Any parties interested in commenting on this action should do so at this time. If no such comments are received, the public is advised that this action will be effective on May 17, 1999.

VI. Administration Requirements

A. Executive Order 12866

The office of Management and Budget (OMB) has exempted this regulatory action from Executive Order (E.O.) 12866, entitled ''Regulatory Planing and Review.''

B. Executive Order 12875: Enhancing Intergovernmental Partnerships

Under E.O. 12875, EPA may not issue a regulation that is not required by statute and that creates a mandate upon a state, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance cost incurred by those governments. If the mandate is unfunded , EPA must provide to the OMB a description of the extent of EPA's prior consultation with representatives of affected State, local and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, E.O. 12875 requires EPA to develop an effective process permitting elective official and other representatives of State, local and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.'' Today's rule does not create a mandate on State, local or tribal governments. The rule does not imposes any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of E.O. 12875 do not apply to this rule.

C. Executive Order 13084: Consultation and Coordination With Indian Tribal Governments

Under E.O. 13084, EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on these communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide to the OMB in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, E.O. 13084 requires EPA to develop an effective process permitting elected and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.'' Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. Accordingly, the requirements of section 3(b) of E.O. 13084 do not apply to this rule.

D. Executive Order 13045

Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997), applies to any rule that: (1) is determined to be ''economically significant'' as defined under E.O. 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternative considered by the Agency. EPA interprets E.O. 13045 as applying only to those regulatory actions that are based on health or safety risks, such that the analysis required under section 5–501 of the Order has the potential to influence the regulation. This action is not subject to E.O. 13045 because it approves a state rule implementing a previously promulgated health or safety-based Federal standard, and preserves the existing level of pollution control for the affected areas.

E. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and small governmental jurisdictions. This final rule will not have a significant impact on a substantial number of small entities because plan approvals under section 110 do not create any new requirements but simply approve requirements that the State is already imposing. Therefore, because the federal approval does not create any new requirements, I certify that this action will not have a significant economic impact on a substantial number of small entities. Moreover, due to the nature of the Federal-state relationship under the CAA preparation of a flexibility analysis would constitute Federal inquiry into the economic reasonableness of state action. The CAA forbids EPA to base its actions on such grounds. Union Electric Co., v. U.S. EPA, 427 U.S. 246, 255–66 (1976); 42 U.S.C. 7410(a)(2).

F. Unfunded Mandates

Under section 202 of the Unfunded Mandates Reform Act of 1995 (''Unfunded Mandates Act''), signed into law on March 22, 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a Federal mandate that may result in estimated annual cost to State, local, or tribal governments in the aggregate; or to private sector, of $100 million or more. Under Section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule.

The EPA has determined that the approval action promulgated does not include a Federal mandate that may result in estimated annual cost of $100 million or more to either State, local, or tribal governments in the aggregate, or to the private sector. This Federal action approves pre-existing requirements under State or local law, and imposes no new requirements. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, result from this action.

G. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 et seq., as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each house of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to the publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

H. Petitions for Judicial Review

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by May 17, 1999. Filing a petition for reconsideration by the administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects

40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Reporting and recordkeeping requirements, Sulfur dioxide.

40 CFR Part 81

Air pollution control, National parks, Wilderness areas.

Dated: February 26, 1999.

Jo Lynn Traub,

Acting Regional Administrator, Region 5.

For the reasons stated in the preamble, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

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

Authority: 42 U.S.C. 7401 et seq.

2. Section 52.1870 is amended by adding (c)(118) to read as follows:

§ 52.1870 Identification of plan.

* * * * *

(c) * * *

(118) On October 26, 1995, and August 20, 1998, Ohio submitted material including State adopted limits for Lake County, and requested approval of limits for the Ohio First Energy Eastlake Plant and the Ohio Rubber Company Plant.

(i) Incorporation by reference

(A) Rule 3745–18–49 (G) and (H) of the Ohio Administrative Code, effective May 11, 1987.

3. Section 52.1881 is amended by revising paragraphs (a)(4) and (a)(8) and adding paragraph (a)(13) to read as follows:

§ 52.1881 Control strategy; Sulfur oxide (sulfur dioxide).

(a) * * *

(4) Approval-EPA approves the sulfur dioxide emission limits for the following counties: Adams County (except Dayton Power & Light-Stuart), Allen County (except Cairo Chemical), Ashland County, Ashtabula County, Athens County, Auglaize County, Belmont County, Brown County, Carroll County, Champaign County, Clark County, Clermont County, (except Cincinnati Gas & Electric-Beckjord), Clinton County, Columbiana County, Coshocton County, (except Columbus & Southern Ohio Electric-Conesville), Crawford County, Darke County, Defiance County, Delaware County, Erie County, Fairfield County, Fayette County, Fulton County, Gallia County (except Ohio Valley Electric Company-Kyger Creek and Ohio Power-Gavin), Geauga County, Greene County, Guernsey County, Hamilton County, Hancock County, Hardin County, Harrison County, Henry County, Highland County, Hocking County, Holmes County, Huron County, Jackson County, Jefferson County, Knox County, Lake County (except Painesville Municipal Plant boiler number 5) , Lawrence County (except Allied Chemical-South Point), Licking County, Logan County, Lorain County (except Ohio Edison-Edgewater, Cleveland Electric Illuminating-Avon Lake, U.S. Steel-Lorain, and B.F. Goodrich), Lucas County (except Gulf Oil Company, Coulton Chemical Company, Phillips Chemical Company and Sun Oil Company), Madison County, Marion County, Medina County, Meigs County, Mercer County, Miami County, Monroe County, Morgan County, Montgomery County (except Bergstrom Paper, Miami Paper, Bergstrom Paper, Morrow County, Muskingum County, Noble County, Ottawa County, Paulding County, Perry County, Pickaway

County, Pike County (except Portsmouth Gaseous Diffusion Plant), Portage County, Preble County, Putnam County, Richland County, Ross County (except Mead Corporation), Sandusky County (except Martin Marietta Chemicals), Scioto County, Seneca County, Shelby County, Trumbull County, Tuscarawas County, Union County, Van Wert County, Vinton County, Warren County, Washington County (except Shell Chemical), Wayne County, Williams County, Wood County (except Libbey-Owens-Ford Plants Nos. 4 and 8 and No. 6), and Wyandot County.

* * * * *

(8) No Action-EPA is neither approving nor disapproving the emission limitations for the following counties on sources pending further review: Adams County (Dayton Power & Light-Stuart), Allen County (Cairo Chemical), Butler County, Clermont County (Cincinnati Gas & Electric-Beckjord), Coshocton County (Columbus & Southern Ohio Electric-Conesville), Cuyahoga County, Franklin County, Gallia County (Ohio Valley Electric Company-Kyger Creek, and Ohio Power-Gavin), Lake County (Painesville Municipal Plant boiler number 5), Lawrence County (Allied Chemical-South Point), Lorain County (Ohio Edison-Edgewater Plant, Cleveland Electric Illuminating Avon Lake, U.S. Steel-Lorain, and B.F. Goodrich), Lucas County (Gulf Oil Company, Coulton Chemical Company, Phillips Chemical Company and Sun Oil Company), Mahoning County, Montgomery County (Bergstrom Paper and Miami Paper), Pike County (Portsmouth Gaseous Diffusion Plant), Stark County, Washington County (Shell Chemical Company), and Wood County (Libbey-Owens-Ford Plants Nos. 4 and 8 and No. 6).

* * * * *

(13) In a letter dated October 26, 1995, Ohio submitted a maintenance plan for sulfur dioxide in Lake and Jefferson Counties.

* * * * *

PART 81—[AMENDED]

1. The authority citation for part 81 continues to read as follows:

Authority: 42 U.S.C. 7401 et seq.

Subpart K K—Ohio

2. In § 81.336 the table entitled ''Ohio SO_2'' is revised to read as follows:

§ 81.336 Ohio.

* * * * *

OHIO—SO_2

Designated area	Does not meet primary standards	Does not meet secondary standards	Cannot be classified	Better than national standards
Athens County	.....	.....	.....	X
Clermont County	.....	.....	.....	X
Columbiana County	.....	.....	.....	X
Coshocton County:				
Franklin Township	X[1]			
The remainder of Coshocton County	.....	.....	.....	X[1]
Cuyahoga County:				
The Cities of Bay Village, Westlake, North Olmsted, Olmsted Falls, Rock River, Fairview Park, Berea, Middleburg Hts., Strongsville, North Royalton, Broadview Hts., Brecksville and the Townships of Olmsted and Riveredge	.....	.....	.....	X
The remainder of Cuyahoga County	X			
Gallia County:				
Addison Township	.....	X[1]		
The remainder of Gallia County	.....	.....	.....	X[1]
Greene County	.....	.....	.....	X
Hamilton County:				
The City of Cincinnati bounded on the west by 175 and U.S. Route 127, and on the south by the Ohio and Little Miami Rivers; the Cities of Norwood, Fairfax, Silverton, Golf Manor, Amberly, Deer Park, Arlington Heights, Elwood Place, and St. Bernard	.....	.....	.....	X[1]
The remainder of Hamilton County	.....	.....	.....	X[1]
Jefferson County:				
Cities of Steubenville & Mingo Junction, Townships of Steubenville, Island Creek, Cross Creek, Knox and Wells	.....	.....	.....	X
The remainder of Jefferson County	.....	.....	.....	X[1]
Lake County:				
The Cities of Eastlake, Timberlake, Lakeline, Willoughby (north of U.S. 20), and Mentor (north of U.S. 20 west of S.R. 306)	.....	.....	.....	X
The remainder of Lake County	.....	.....	.....	X
Lorain County:				
Area bounded on the north by the Norfolk and Western Railroad Tracks, on the east by State Route 301 (Abbe Road), on the south by State Route 254, and on the west by Oberlin Road	X			
The remainder of Lorain County	.....	.....	.....	X
Lucas County:				
The area east of Rte. 23 & west of eastern boundary of Oregon Township	X[1]			
The remainder of Lucas County	.....	.....	.....	X[1]
Mahoning County	.....	.....	.....	X
Montgomery County	.....	.....	.....	X
Morgan County	.....	.....	.....	X
Center Township	.....	.....	.....	X[1]
The remainder of Morgan County	.....	.....	.....	X[1]
Summit County:				

OHIO—SO_2—Continued

Designated area	Does not meet primary standards	Does not meet secondary standards	Cannot be classified	Better than national standards
Area bounded by the following lines—North—Interstate 76, East—Route 93, South—Vanderhoof Road, West—Summit County Line	.....	.....	.....	X
Area bounded by the following lines—North—Bath Road (48 east to Route 8, Route 8 north to Barlow Road, Barlow Road east to county line, East—Summit/Portage County line, South Interstate 76 to Route 93, Route 93 south to Route 619, Route 619 east to County line, West-Summit/Medina County line	[2]	[2]	[2]	[2]
Entire area northwest of the following line Route 80 east to Route 91, Route 91 north to the County line	.....	.....	.....	X[3]
The remainder of Summit County	.....	.....	.....	X[4]
Trumbull County	.....	.....	.....	X
Washington County	.....	.....	.....	X
Waterford Township	.....	.....	.....	X
The remainder of Washington County	.....	.....	.....	X
All other counties in the State of Ohio	.....	.....	.....	X[1]

[1] EPA designation replaces State designation.
[2] This area remains undesignated at this time as a result of a court remand in PPG Industries, Inc. vs. Costle, 630 F.2d 462 (6th Cir. 1980).
[3] This area was affected by the Sixth Circuit Court remand but has since been designated.
[4] The area was not affected by the court remand in PPG Industries, Inc. vs. Costle, 630 F.2d 462 (6th Cir. 1980).

[FR Doc. 99–6256 Filed 3–16–99; 8:45 am]
BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 62

[PA–107–4066c; FRL–6311–3]

Approval and Promulgation of State Air Quality Plans for Designated Facilities and Pollutants; Allegheny County, Pennsylvania; Control of Landfill Gas Emissions from Existing Municipal Solid Waste Landfills

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is approving a municipal solid waste landfill (MSW) 111(d) plan submitted by the Commonwealth of Pennsylvania Department of Environmental Protection (PADEP) on behalf of the Allegheny County Health Department (ACHD) for the purpose of controlling MSW landfill gas emissions from existing facilities. The plan was submitted to fulfill requirements of the Clean Air Act (CAA). The Allegheny County plan establishes landfill gas emissions limits for existing MSW landfills, and provides for the implementation and enforcement of those limits.

EFFECTIVE DATE: This final rule is effective on April 16, 1999.

ADDRESSES: Copies of the documents relevant to this action are available for public inspection during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103; and Allegheny County Health Department, Bureau of Environmental Quality, Division of Air Quality, 301 39th Street, Pittsburgh, Pennsylvania 15201.

FOR FURTHER INFORMATION CONTACT: James B. Topsale, P.E., at (215) 814–2190, or by e-mail at topsale.jim@.epa.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On April 10, 1998 (63 FR 17683), EPA published a direct final rule for approval of the MSW landfill 111(d) plan submitted by the PADEP on behalf of ACHD. EPA concurrently published a proposed rule on April 10, 1998 (63 FR 17793) to allow interested parties to submit comments. During the public comment period, EPA received one adverse comment from Browning-Ferrris Industries, Inc. As a result, EPA withdrew the direct final rule granting approval of the MSW landfill 111(d) plan for Allegheny County on June 18, 1998 (63 FR 33250).

On June 16, 1998, EPA published in the **Federal Register** (63 FR 32743) a direct final action which amends, corrects errors, and clarifies the regulatory text of the ''Standards of Performance for New Stationary Sources and Guidelines for Control of Existing Sources: Municipal Solid Waste Landfills,'' which was promulgated on March 12, 1996. The Background section of the amended rule (63 FR 32744) states, ''These changes do not significantly modify the requirements of the regulation.'' No adverse comments were received on the amended landfill rule, and as a result, it became effective on August 17, 1998.

II. Response to Public Comments

During the public comment period offered on the approval of the Allegheny County MSW landfill 111(d) plan, EPA received an adverse comment from Browing-Ferris Industries, Inc. opposing approval of the Allegheny County portion of the Commonwealth of Pennsylvania's plan. The following paragraphs present the commenter's remarks and EPA's responses.

Comment: On May 12, 1998, the commenter noted that the effective date specified in ''Section G. Compliance Schedule'' of the direct final rule can be no sooner than the date of **Federal Register** publication, April 10, 1998. The direct final rule states: ''The final compliance date and enforceable increments of progress under the 111(d) plans are tied to the effective date of the County's MSW landfill regulation (Article XXI, section 2105.73).'' The table ''Reporting and Required Increments of Progress,'' which appears in Section G, indicates that the first compliance/reporting deadline pursuant to the emission guidelines (EG) is ''Within 90 days of the effective date of Article XXI Regulation*.'' The footnote (*) states that ''The regulation became effective on August 15, 1997.'' According to the commenter, use of the state/county effective date to trigger subsequent requirements is inconsistent with previous EPA approvals under 40 CFR Part 60, Subpart Cc, and with proposed revisions to the landfill new source performance standards/emission guidelines (NSPS/EG). Also, the Pennsylvania Air Pollution Control Act

(Section 4004.2(b)) prohibits the state from establishing more stringent requirements than the federal government. The commenter identified four EPA 111(d) plan approvals, excluding Allegheny County, to support his argument that the EG ''effective date'' is not established by the effective date of the state/local regulation. Furthermore, the commenter noted that a Title V application should not be due until one year plus 90 days from April 10, 1998, and that installation/operation of an EG compliant gas collection/control system should not be required until three years plus ninety days from April 10, 1998. To support his position, the commenter referenced the pending amended EG provision, 40 CFR 60.32c(c), relating to Title V permits, that was negotiated under the lawsuit settlement over the MSW Landfill NSPS/EG [*National Solid Waste Management Association* v. *Browner* No. 96–1152 (D.C. Cir)].

EPA's Response: It appears the commenter has misinterpreted the requirements of the EG, as amended, and EPA's approval with respect to compliance schedule requirements for Allegheny County's 111(d) plan landfills. Any ambiguity in the text of the direct final rule published on April 10, 1998 that may have caused confusion should now be clarified with the discussion below.

A state's 111(d) plan must include a compliance schedule that landfill owners/operators must meet. Most states have proposed that the initial design capacity and NMOC emissions rate report must be submitted 90 days after EPA approval of their 111(d) plans. The promulgated landfill EG require the same reporting and record keeping as the related NSPS. However, the EG do not stipulate when the initial NMOC emissions and design capacity reports are due for existing landfills. Even if a date were clearly specified in the EG, states can exercise their own judgement as to when the initial reporting requirement must be met, providing the requirement is no less stringent than that in the EG. EPA has no documentation that the Allegheny County landfill regulation violates any of the requirements of the Pennsylvania Air Pollution Control Act (Section 4004.2(b)). Based on our review of the public participation documents submitted with Allegheny County's 111(d) plan, the issues now raised by the commenter in his May 12, 1998 comments to EPA were not raised by that commenter, or anyone else, during the 111(d) plan public comment period. Furthermore, none of these comments or concerns were identified in the PADEP submittal of the Allegheny County MSW landfill 111(d) plan to EPA.

Although the 111(d) plan increments of progress are tied to the effective date of the County's MSW landfill regulation, the controlling date that triggers and defines the required increments of progress dates, from the time of submittal of the design plan to final source compliance, is the date when the NMOC emissions rate is first calculated to exceed 50 Mg/yr. This is clearly noted in ''Section G. Compliance Schedule'' of the direct final rule. Nevertheless, the design capacity and initial NMOC emission rate reports were due within 90 days of the effective date (i.e., August 15, 1997) of the Article XXI Regulation.

EPA has been involved in litigation over the requirements of the MSW landfill EG and NSPS since the summer of 1996. On November 13, 1997, EPA issued a notice of proposed settlement in *National Solid Wastes Management Association* v. *Browner* No. 96–1152 (D.C. Cir), in accordance with Section 113(g) of the Act. (See 62 FR 60898.) It is important to note that the proposed settlement did not vacate or void the March 12, 1996 MSW landfill EG or NSPS. Pursuant to the proposed settlement agreement, EPA published a direct final rulemaking on June 16, 1998, in which EPA amends 40 CFR Part 60, Subparts Cc and WWW, to add clarifying language, make editorial amendments, and to correct typographical errors. One particular clarification addresses the commenters concern regarding the date when Title V applications are due. Specifically, 60.32c(c), as amended, makes it clear that EG sources will not become subject to the requirement to apply for a Title V permit until 90 days after the effective date of EPA's approval of a state's 111(d) plan. (See 63 FR 32743–32753, 32783–32784.) EPA regulations at 40 CFR 60.23(a)(2) provide that a state has nine months to adopt and submit any necessary state plan revisions after publication of a final revised emission guideline document. Thus, states are not yet required to submit state plan revisions to address the June 16, 1998 direct final amendments in the EG. In addition, as stated in the June 16, 1998 rule's preamble, the changes to 40 CFR Part 60, Subparts Cc and WWW, do not significantly modify the requirements of those subparts. (See 63 FR 32744.) Accordingly, the MSW landfill EG published on March 12, 1996, was used as a basis by EPA for review of state 111(d) plan submittals.

III. Final Action

Based upon the rationale discussed in the proposed and related direct final rulemaking (63 FR 17793 and 17683, April 10, 1998), EPA is approving the Allegheny County portion of the Pennsylvania MSW landfill 111(d) plan. As provided by 40 CFR 60.28(c), any revisions to the Allegheny County portion of the plan or associated regulations will not be considered part of the applicable plan until submitted by PADEP in accordance with 40 CFR 60.28(a) or (b), as applicable, and until approved by EPA .

IV. Administrative Requirements

A. Executive Orders 12866

The Office of Management and Budget (OMB) has exempted this regulatory action from review under Executive Order (E.O.) 12866, entitled ''Regulatory Planning and Review.''

B. Executive Order 12875

Under E.O. 12875, EPA may not issue a regulation that is not required by statute and that creates a mandate upon a state, local, or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If EPA complies by consulting, E.O. 12875 requires EPA to provide to the Office of Management and Budget a description of the extent of EPA's prior consultation with representatives of affected state, local, and tribal governments, the nature of their concerns, copies of written communications from the governments, and a statement supporting the need to issue the regulation. In addition, E.O. 12875 requires EPA to develop an effective process permitting elected officials and other representatives of state, local, and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.'' Today's rule does not create a mandate on state, local or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of Section 1(a) of E.O. 12875 do not apply to this rule.

C. Executive Order 13045

E.O. 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), applies to any rule that the EPA determines (1) is ''economically significant,'' as defined under E.O. 12866, and (2) the environmental health or safety risk addressed by the rule has a disproportionate effect on children. If

the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency. This final rule is not subject to E.O. 13045 because it is not an economically significant regulatory action as defined by E.O. 12866, and it does not address an environmental health or safety risk that would have a disproportionate effect on children.

D. Executive Order 13084

Under E.O. 13084, EPA may not issue a regulation that is not required by statute, that significantly affects or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If EPA complies by consulting, E.O. 13084 requires EPA to provide to the Office of Management and Budget, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, E.O. 13084 requires EPA to develop an effective process permitting elected and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.'' Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of section 3(b) of E.O. 13084 do not apply to this rule.

E. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and small governmental jurisdictions. Pursuant to section 605 (b) of the RFA I certify that this rule will not have a significant economic impact on a substantial number of small entities. This Federal action approves pre-existing requirements under Federal, State, or Local law and imposes no new requirements on any entity affected by this rule, including small entities. Therefore, these amendments will not have a significant impact on a substantial number of small entities.

F. Unfunded Mandates

Under Section 202 of the Unfunded Mandates Reform Act of 1995 (''Unfunded Mandates Act''), signed into law on March 22, 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a Federal mandate that may result in estimated annual costs to State, local, or tribal governments in the aggregate; or to a private sector, of $100 million or more. Under Section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule. EPA has determined that the approval action promulgated does not include a Federal mandate that may result in estimated annual costs of $100 million or more to either State, local, or tribal governments in the aggregate, or to the private sector. This Federal action approves pre-existing requirements under State or local law, and imposes no new requirements. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, result from this action.

G. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

H. Petitions for Judicial Review

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action to approve the Allegheny County portion of the Pennsylvania MSW landfill 111(d) plan must be filed in the United States Court of Appeals for the appropriate circuit by May 17, 1999. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 62

Environmental protection, Administrative practice and procedure, Air pollution control, Intergovernmental relations, Non-methane organic compounds, Methane, Municipal solid waste landfills, Hydrocarbons, Reporting and record keeping requirement.

Dated: March 9, 1999.

Thomas Voltaggio,

Acting, Regional Administratopr, Region III.

40 CFR Part 62, Subpart NN, is amended as follows:

PART 62—[AMENDED]

1. The authority citation for Part 62 continues to read as follows:

Authority: 42 U.S.C. 7401–7671q.

Subpart NN—Pennsylvania

2. Subpart NN is amended by adding a new center heading and §§ 62.9630, 62.9631, and 62.9632 to read as follows:

Landfill Gas Emissions From Existing Municipal Solid Waste Landfills (Section 111(d) Plan)

§ 62.9630 Identification of plan.

Section 111(d) plan for municipal solid waste landfills and the associated Allegheny County Health Department Regulation in Article XXI, § 2105.73, as submitted on October 23, 1997, by the Commonwealth of Pennsylvania.

§ 62.9631 Identification of sources.

The plan applies to all Allegheny County, Pennsylvania, existing municipal solid waste landfills for which construction, reconstruction, or modification was commenced before May 30, 1991 and that has accepted waste at any time since November 8, 1987 or that has additional capacity available for future waste deposition, as described in 40 CFR part 60, subpart Cc.

§ 62.9632 Effective date.

The effective date of the plan for municipal solid waste landfills is April 16, 1999.

[FR Doc. 99–6500 Filed 3–16–99; 8:45 am]
BILLING CODE 6560–50–U

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300530A; FRL–6052–3]

RIN 2070–AB78

Potato Leaf Roll Virus Resistance Gene (also known as orf1/orf2 gene); Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; Technical amendment.

SUMMARY: EPA is issuing a technical amendment to a tolerance exemption it published in the **Federal Register** on August 15, 1997 (62 FR 43650). This technical amendment changes the name of the active ingredient from ''Replicase Protein of Potato Leaf Roll Virus and the genetic material necessary for it's production'' to ''Potato Leaf Roll Virus Resistance Gene (also known as orf1/orf2 gene) and the genetic material necessary for it's production.'' This action is requested by Monsanto Company, who originally filed the pesticide petition requesting an exemption from the requirement of a tolerance for residues of the biological pest control agent under the name ''Replicase Protein of Potato Leaf Roll Virus and the genetic material necessary for it's production.'' The change was suggested by the Agency as a result of the review of data which indicated that the former active ingredient, Replicase Protein of Potato Leaf Roll Virus and the genetic material necessary for it's production, was not solely responsible for providing the plant product with its' pesticidal properties (i.e., resistance to infection by the Potato Leaf Roll Virus). Changing the active ingredient name in no way changes the findings, determinations, or effects of the originally issued final rule published in the **Federal Register** of August 15, 1997 (62 FR 43650).

DATES: This regulation is effective March 17, 1999. Objections and requests for hearings must be received by EPA on or before May 17, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number [OPP–300530A], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees) and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–00530A], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of electronic objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 file format or ASCII file format. All copies of electronic objections and hearing requests must be identified by the docket number [OPP–300530A]. No Confidential Business Information (CBI) should be submitted through e-mail. Copies of electronic objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Linda Hollis, Product Manager (PM) 90, Biopesticides and Pollution Prevention Division (7511C), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number and e-mail address: 9th fl., Crystal Mall #2 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703)308-8733. e-mail: hollis.linda@epamail.epa.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 25, 1997 (62 FR 34283-34286) (FRL–5728–4), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) announcing the filing of a pesticide tolerance petition by Monsanto Company, St. Louis, Missouri. This notice included a summary of the petition prepared by the petitioner and this summary contained conclusions and arguments to support its conclusion that the petition complied with the Food Quality Protection Act (FQPA) of 1996. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of the biological pest control agent Replicase Protein of Potato Leaf Roll Virus and the genetic material necessary for it's production in or on all food commodities. EPA published a final rule establishing a tolerance exemption in the **Federal Register** on August 15, 1997 (62 FR 43650) (FRL–5738–3) amending 40 CFR 180.1183. An amendment to this petition and thus the final rule establishing a tolerance exemption, was requested by Monsanto Company to change the name of the active ingredient from the above to Potato Leaf Roll Virus Resistance Gene (also known as orf1/orf2 gene) and the genetic material necessary for it's production. This request came at the suggestion of the Agency as a result of the review of data which indicated that the former active ingredient, ''Replicase Protein of Potato leaf Roll Virus and the genetic material necessary for it's production,'' was not solely responsible for providing the plant with it's pesticidal properties (i.e., resistance to infection by the Potato Leaf Roll Virus). A change in the name of the active ingredient will in no way amend the text of the original petition or EPA's findings, conclusions or determinations as described in the August 15, 1997 Final Rule (62 FR 43650). Additionally, a change in the name of the active ingredient does not affect and/or compromise the Agency's original dietary risk exposure assessment which concluded that the active ingredient posed no dietary risk of concern under normal conditions. Therefore, this technical amendment only changes in the name of the active ingredient. All other text remains the same as in the final rule of August 15, 1997 (62 FR 43650) which amended 40 CFR 180.1183. For the reasons set forth above, EPA believes that it is approprate to issue this rule as a technical amendment. Because this amendment makes a minor corrective change to an existing regulation and has no substantive impact, EPA has determined that good cause exists to dispense with the notice and comment provisions of the Administrative Procedure Act (APA)

pursuant to 5 U.S.C. 553(b)(B). Section 408 of the FFDCA provides that the Administrator, before issuing a comment unless the Administrator for good cause finds that it would be in the public interest to provide a shorter period. EPA has determined that there is good cause for making today's rule final without prior proposal and opportunity for comment because EPA is merely correcting the name of a chemical for which a tolerance exemption has already been issued. Thus, notice and public procedure are unnecessary. The Agency finds that this constitutes good cause under section 408(e)(2). Under section 408(g)(1) of the FFDCA, today's rule is effective upon publication.

II. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d)and as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which governs the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by May 17, 1999, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given under the ''ADDRESSES'' section (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the hearing clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

III. Public Record and Electronic Submissions

EPA has established a record for this rulemaking under docket control number [OPP-300530A]. A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202.

Electronic comments can be sent directly to EPA at:

opp-docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this rulemaking, as well as the public version, as described above, is kept in paper form. Accordingly, in the event there are objections and hearing request, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record. The official rulemaking record is the paper record maintained at the Virginia address in ''ADDRESSES'' at the beginning of this document.

IV. Regulatory Assessment Requirements

This final rule does not impose any new requirements. It only implements a technical correction to the Code of Federal Regulations (CFR). As such, this action does not require review by the Office of Management and Budget (OMB) under Executive order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993), the Paperwork Reduction Act (PRA), 44 U.S.C. 3501., or Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1991). This action does not impose any enforceable duty, contain any unfunded mandate, or impose any significant or unique impact on small governments as described in the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4). Nor does it require prior consultation with State, local, and tribal government officials as specified by Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993) and Executive Order 13084, entitled Consultation and Coordination with Indian Tribal Governments (63 FR 27655, May 19, 1998), or special consideration of environmental justice related issues under Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Pub. L. 104-113, section 12(d) (15 U.S.C. 272 note). In addition, since this action is not subject to notice-and-comment requirements under the Administrative Procedure Act (APA) or any other statute, it is not subject to the regulatory flexibility provisions of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.)

V. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. Section 808 allows the issuing agency to make a good cause finding that notice and public determinations must be supported by a brief statement 5 U.S.C. 808(2). EPA has made such a good cause finding for this final rule, and established an effective date of March 17, 1999. Pursuant to 5 U.S.C 808(2), this determination is

supported by the brief statement in Unit I. of this preamble. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, pesticides and pests, Reporting and recordkeeping requirements.

Dated: March 2, 1999.

Janet L. Andersen,

Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180— [AMENDED]

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

Authority: 21 U.S.C. 321(q), 346a and 371.

2. Section 180.1183 is revised to read as follows:

§ 180.1183 Potato Leaf Roll Virus Resistance Gene (also known as orf1/orf2 gene) and the genetic material necessary for it's production; Exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of the biological plant pesticide Potato Leaf Roll Virus Resistance Gene (also known as orf1/orf2 gene) and the genetic material necessary for its production.

[FR Doc. 99–6176 Filed 3–16–99; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300810; FRL–6068–4]

RIN 2070–AB78

Propiconazole; Establishment of Time-Limited Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for combined residues of propiconazole, 1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1*H*-1,2,4-triazole, and its metabolites determined as 2,4-dichlorobenzoic acid and expressed as parent compound in or on corn, peanuts and pineapples. Novartis Crop Protection, Inc. requested these tolerances under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. The tolerances will expire on December 31, 2000.

DATES: This regulation is effective March 17, 1999. Objections and requests for hearings must be received by EPA on or before May 17, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number [OPP–300810], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300810, must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epa.gov. Copies of electronic objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 or ASCII file format. All copies of electronic objections and hearing requests must be identified by the docket control number [OPP–300810]. No Confidential Business Information (CBI) should be submitted through e-mail. Copies of electronic objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Mary L. Waller, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 249, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 308–9354, waller.mary@epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 20, 1998 (63 FR 64498) (FRL–6042–1), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, as amended by the Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104–170) announcing the filing of pesticide petitions (PP) for tolerances by Novartis Crop Protection, Inc., P.O. Box 18300, Greensboro, NC 27419. This notice included a summary of the petitions prepared by Novartis Crop Protection, Inc., the registrant. There were no comments received in response to the notice of filing.

The petitions requested that 40 CFR 180.434 be amended by establishing time-limited tolerances for combined residues of the fungicide propiconazole, 1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1*H*-1,2,4-triazole and its metabolites determined as 2,4-dichlorobenzoic acid and expressed as parent compound on corn, fodder at 12 parts per million (ppm); corn, forage at 12 ppm; corn, grain at 0.1 ppm; corn, sweet (kernels plus cobs with husks removed) at 0.1 ppm; peanuts at 0.2 ppm; peanuts, hay at 20 ppm; pineapple at 0.1 ppm and pineapple, fodder at 0.1 ppm. These proposed tolerances will expire on December 31, 2000 and will replace previously established tolerances which expired on December 31, 1998.

I. Background and Statutory Findings

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

EPA performs a number of analyses to determine the risks from aggregate

exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

II. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of propiconazole and to make a determination on aggregate exposure, consistent with section 408(b)(2), for time-limited tolerances for combined residues of propiconazole, 1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1*H*-1,2,4-triazole and its metabolites determined as 2,4-dichlorobenzoic acid and expressed as parent compound on corn, fodder at 12 parts per million (ppm); corn, forage at 12 ppm; corn, grain at 0.1 ppm; corn, sweet (kernels plus cobs with husks removed) at 0.1 ppm; peanuts at 0.2 ppm; peanuts, hay at 20 ppm; pineapple at 0.1 ppm and pineapple, fodder at 0.1 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerances follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by propiconazole are discussed in this unit.

1. Acute toxicity data were as follows: acute oral LD_{50} = 1,517 m/kg (toxicity category III); acute dermal LD_{50} > 4,000 mg/kg (toxicity category III); acute inhalation LC_{50} = 1.26 mg/L; primary eye irritation - clear by 72 hours (toxicity category III); primary skin irritation - slight irritation (toxicity category IV); and dermal sensitization - negative.

2. A developmental toxicity study with rats which were gavaged with doses of 0, 30, 90 or 360/300 mg/kg/day. The developmental no observed adverse effect level (NOAEL) was 30 mg/kg/day. Evidence of developmental toxicity observed at the 90 mg/kg/day level lowest observed adverse effect level (LOAEL) included statistically significant increased incidence of unossified sternebrae, and nominally increased rudimentary ribs, and shortened or absent renal papillae. The maternal NOAEL was 30 mg/kg/day and the maternal LOAEL was 90 mg/kg/day based on reduced body weight gain and occurrence of rales in 1/24 females.

3. A developmental toxicity study with rabbits which were gavaged with doses of 0, 30, 90, or 180 mg/kg/day with no evidence of maternal or developmental toxicity observed under the conditions of the study.

4. A developmental toxicity study with rabbits which were gavaged with doses of 0, 100, 250, or 400 mg/kg/day on gestation days 7 through 19 with no developmental toxicity observed under the conditions of the study. The maternal NOAEL was 100 mg/kg/day and the maternal LOAEL was 250 mg/kg/day based on decreased food consumption, weight gain, and an increase in the number of resorptions at the higher dose levels. The developmental NOAEL was 400 mg/kg/day.

5. A 2-generation reproduction study with rats fed diets containing 0, 1, 100, 500 or 2,500 ppm showed no reproductive effects under the conditions of the study. The developmental NOAEL was 500 ppm (equivalent to 25 mg/kg/day), and the developmental LOAEL was 2,500 ppm (equivalent to 125 mg/kg/day) based on decreased offspring survival, body weight depression, and increased incidence of hepatic lesions in rats. The parental NOAEL was 100 ppm (equivalent to 5 mg/kg/day) and the parental LOAEL was 500 ppm (equivalent to 25 mg/kg/day) based on increased incidence of hepatic cell change.

6. A 1–year feeding study with dogs fed diets containing 0, 5, 50, or 250 ppm with a NOAEL of 50 ppm (equivalent to 1.25 mg/kg/day). The LOAEL was 250 ppm (equivalent to 6.25 mg/kg/day based on mild irritation of stomach mucosa.

7. A 2–year chronic feeding/carcinogenicity study with rats fed diets containing 0, 100, 500, or 2,500 ppm with a systemic NOAEL of 100 ppm (equivalent to 5 mg/kg/day) based on hepatocyte changes in males at the 500 ppm level and in both sexes at the 2,500 ppm level. There were no carcinogenic effects observed under the conditions of the study.

8. A 2–year chronic feeding/carcinogenicity study with mice fed diets containing 0, 100, 500, or 2,500 ppm with a systemic NOAEL of 100 ppm (equivalent to 15 mg/kg/day) based on decreased body weight, and increased liver lesions and liver weight in males. There was a statistically significant increase in combined adenomas and carcinomas of the liver in male mice at the 2,500 ppm level (equivalent to 375 mg/kg/day).

9. A battery of mutagenicity studies to determine the potential of propiconazole to induce gene mutation, chromosomal aberrations, and other genotoxic effects were all negative.

B. Toxicological Endpoints

1. *Acute toxicity*. The acute reference dose (RfD) is 0.3 mg/kg/day based on the NOAEL of 30 mg/kg/day from a developmental toxicity study in rats and using an uncertainty factor (UF) of 100.

2. *Short- and intermediate-term toxicity*. For short- and intermediate-term dermal margin of exposure (MOE) calculations, the developmental NOAEL of 30 mg/kg/day from a developmental toxicity study in rats was selected. For short- and intermediate-term inhalation MOE calculations the NOAEL of 92.8 mg/kg/day (0.5 mg/L), the highest dose tested, from a 5–day inhalation toxicity study was selected.

3. *Chronic toxicity*. EPA has established the RfD for propiconazole at 0.013 milligrams/kilogram/day (mg/kg/day). This RfD is based on a 1–year feeding study in dogs with a NOAEL of 1.25 mg/kg/day and an uncertainty factor of 100. The LOAEL of 6.25 mg/kg/day was based on mild irritation of the gastric mucosa.

4. *Carcinogenicity*. Propiconazole has been classified as a Group C, ''possible human carcinogen'', chemical. The Cancer Peer Review Committee recommended using the RfD approach for quantification of human risk.

C. Exposures and Risks

1. *From food and feed uses*. Tolerances have been established (40 CFR 180.434) for the combined residues of propiconazole, 1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1*H*-1,2,4-triazole and its metabolites determined as 2,4-dichlorobenzoic acid and expressed as parent compound, in or on a variety of raw agricultural commodities. Among these tolerances are stone fruits, various grain crops, grass, bananas, celery, mushrooms and pecans. Tolerances have also been established for meat, milk, poultry and eggs. Risk assessments were conducted by EPA to assess dietary exposure from propiconazole as follows:

Section 408(b)(2)(E) authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide chemicals that have been measured in food. If EPA relies on

such information, EPA must require that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. Following the initial data submission, EPA is authorized to require similar data on a time frame it deems appropriate. As required by section 408(b)(2)(E), EPA will issue a data call-in for information relating to anticipated residues to be submitted no later than 5 years from the date of issuance of this tolerance.

Section 408(b)(2)(F) states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if the Agency can make the following findings: That the data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide residue; that the exposure estimate does not underestimate exposure for any significant population subgroup; and if data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area. In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of percent of crop treated as required by the section 408(b)(2)(F), EPA may require registrants to submit data on percent of crop treated.

Percent of crop treated estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. Typically, a range of estimates are supplied and the upper end of this range is assumed for exposure assessment. By using this upper end estimate of percent of crop treated, the Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimated. Regional consumption information and consumption information for significant population subgroups is taken into account through EPA's computer-based model for evaluating the exposure of significant population subgroups including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available information on the regional consumption of food to which propiconazole may be applied in a particular area.

The Agency used percent of crop treated (PCT) information as follows: The percent crop treated data used in the risk estimates for propiconazole for the crops for which tolerances are being established are: corn, 6%; pineapples, 100%; and peanuts, 1%. Percent crop treated data was used in determinations for several crops for which tolerances are already established (pecans, peaches, rice, rye and wheat).

i. *Acute exposure and risk*. Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1–day or single exposure. The acute dietary (food only) risk assessment used the theoretical maximum residue contribution (TMRC), individual food consumption data as reported in the USDA Nationwide Food Consumption Survey (NFCS) which accumulates exposure to propiconazole from each commodity, and the assumption that 100% of the crops were treated with propiconazole. This risk assessment used high-end exposure estimates and should be viewed as a conservative risk assessment which overestimates the risk. The acute dietary exposure for the only population subgroup of concern, females 13 years and older, used 3.3% of the acute RfD of 0.3 mg/kg/day. The acute dietary risk (food only) does not exceed the Agency's level of concern.

ii. *Chronic exposure and risk*. The chronic dietary risk assessment used the RfD of 0.013 mg/kg/day. EPA used data from the USDA NFCS, and made partial refinements to the exposure assumptions. Tolerance level residues were used for corn, pineapples and peanuts. Percent of crop treated estimates were made for corn (6%), pineapple (100%) and peanuts (1%). For some of the other crops included in the analysis, anticipated residue levels and percent crop treated estimates were used. The existing propiconazole tolerances (published and pending, including tolerances for emergency exemptions) resulted in exposure estimates that are equivalent to the following percentages of the RfD: U.S. population (48 states), 7%; non-nursing infants less than 1 year old, 20%; children 1-6 years old, 13%; children 7-12 years old, 9%; all other subgroups, 6-9%. EPA generally has no concern for exposures below 100% of the chronic RfD (when the FQPA factor has been removed) because this RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Therefore, the chronic dietary risk (food only) does not exceed the Agency's level of concern.

2. *From drinking water*. In the absence of reliable, available monitoring data, EPA uses models to estimate concentrations of pesticides in ground and surface water. For propiconazole, modeling data were used to estimate surface water concentrations because very limited surface water monitoring data were available. EPA does not use these model estimates to quantify risk. Currently, EPA uses drinking water levels of comparison (DWLOCs) to estimate risk associated with exposure to pesticides in drinking water. A DWLOC is the concentration of a pesticide in drinking water that would be acceptable as an upper limit in light of total aggregate exposure to that pesticide from food, water, and residential uses. A DWLOC will vary depending on the residue level in foods, the toxicity endpoint and with drinking water consumption patterns and body weights for specific population subgroups. EPA believes model estimates to be overestimations of concentrations of propiconazole expected in drinking water. Propiconazole is moderately persistent and moderately mobile to immobile in soil and aqueous environments. It has the potential to be transported with water, particularly in coarse-textured soils low in organic matter. Propiconazole's persistence indicates the potential to reach surface water with run-off or adsorb to soil particles. There is no established Maximum Contaminant Level for residues of propiconazole in drinking water. No health advisory levels for propiconazole in drinking water have been established.

i. *Acute exposure and risk*. The acute DWLOC is 8,700 µg/L for the only population subgroup of concern, females 13 years old or older. The estimated environmental concentration (EEC) in surface water (0.11 µg/L, peak value) is much lower than EPA's DWLOC of 8,700 µg/L for the population subgroup, females 13 years old or older. Therefore, EPA concludes with reasonable certainty that exposure to propiconazole in drinking water will result in no harm.

ii. *Chronic exposure and risk*. The chronic DWLOC is 100 µg/L for the population subgroup with the lowest chronic DWLOC (non-nursing infants < 1 year old). The lowest chronic DWLOC is substantially higher than the Generic Expected Environmental Concentration (GENEEC) 56-day EEC of 0.09 µg/L. Therefore, EPA concludes with reasonable certainty that exposure of propiconazole in drinking water is less than EPA's level of concern.

3. *From non-dietary exposure.* Propiconazole is currently registered for use on the following residential non-food sites: wood preservative. Under current Agency guidelines, this use does not present an acute or chronic exposure scenario, but may constitute a short- and/or intermediate-term dermal and inhalation exposure scenario for applicators. The Agency calculated short- and intermediate-term dermal and inhalation margins of exposure (MOEs) of 200 and 200,000 respectively for the wood preservative use of propiconazole. MOEs above 100 do not exceed the Agency's level of concern. For post application exposure, the Agency determined that propiconazole is volatile and not readily aerosolized. Therefore, post-application exposure from contact with treated wood is expected to be minimal and the Agency determined that a risk assessment for post-application exposure is not needed.

4. *Cumulative exposure to substances with common mechanism of toxicity.* Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA does not have, at this time, available data to determine whether propiconazole has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, propiconazole does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that propiconazole has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

D. Aggregate Risks and Determination of Safety for U.S. Population

1. *Acute risk.* The acute dietary (food only) risk does not exceed the Agency's level of concern. Using the TMRC, the population subgroup of concern, females 13 years old and older, utilizes 3.3% of the dietary (food only) acute RfD . For drinking water, the acute DWLOC for this population subgroup is 8,700 µg/L which is substantially higher that the peak EEC of 0.11 µg/L. Therefore, the risk from acute aggregate exposure to propiconazole does not exceed the Agency's level of concern.

2. *Chronic risk.* Using the exposure assumptions described in this unit, EPA has concluded that aggregate exposure to propiconazole from food will utilize 7% of the RfD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is discussed below. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to propiconazole in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD. EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to propiconazole residues.

3. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus short- and intermediate-term dermal and inhalation exposure from residential uses. The dermal and inhalation endpoints used for estimating short- and intermediate-term exposure via the two routes of exposure measured different toxic effects. Therefore, the dermal margin of exposure (MOE) and the inhalation MOE should not be aggregated. For residential uses, dermal exposure of applicators was considered to be the driving factor in the short- and intermediate-term risk assessment, and the contribution of inhalation exposure to the short- and intermediate-term risk assessment was negligible (inhalation MOE = 200,000). Therefore, the inhalation exposure was not calculated in the aggregate short-and intermediate-term risk assessment. The aggregate short- and intermediate-term risk assessment estimated the dietary MOE to be 33,000, the dermal MOE to be 200 and the DWLOC to be 4,500 µg/L which is higher than the EEC of 0.09 µg/L. Therefore, the short- and intermediate-term aggregate risk does not exceed the Agency's level of concern.

4. *Aggregate cancer risk for U.S. population.* EPA classified propiconazole as a Group C, possible human carcinogen and determined that the RfD approach be used to estimate the carcinogenic risk to humans. Risk concerns for carcinogenicity due to long-term consumption of propiconazole residues are adequately addressed by the aggregate chronic exposure analysis using the chronic RfD. Therefore, EPA concludes that there is reasonable certainty that no harm will result from aggregate exposure to propiconazole residue.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to residues of propiconazole.

E. Aggregate Risks and Determination of Safety for Infants and Children

1. *Safety factor for infants and children—i. In general.* In assessing the potential for additional sensitivity of infants and children to residues of propiconazole, EPA considered data from developmental toxicity studies in the rat and rabbit and a 2-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure gestation. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for pre-and post-natal toxicity and the completeness of the database unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard uncertainty factor (usually 100 for combined inter- and intra-species variability) and not the additional tenfold MOE/uncertainty factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

ii. *Pre- and post-natal sensitivity.* The pre- and post-natal toxicology data base for propiconazole is complete with respect to current FQPA-relevant toxicological data requirements. Propiconazole is not developmentally toxic in the rabbit. There is evidence that propiconazole is developmentally toxic in the rat at doses that are toxic to the parents. In the developmental toxicity study in rats, the toxicity noted

at the maternal LOAEL of 90 mg/kg/day consisted of rales and decreased weight gain on gestation days 6–8 whereas the toxicity noted at the developmental LOAEL of 90 mg/kg/day consisted of statistically significant increased incidences of unossified sternebrae, and nominally increased incidences of rudimentary ribs and shortened or absent renal papillae. Where fetotoxic effects occur at the maternally toxic dose levels, they generally are of less concern than those occurring at non-maternally toxic dose levels because of the influence of toxicity in the mothers on the fetal toxicity expressed. However, where the fetal effects are judged to be qualitatively more severe than the effects in the maternal animals, there may be greater sensitivity in the fetus and thus of greater concern. Here, the effects in the fetus (delayed development) were not judged to be more sever than the effects in the maternal animals (decreased weight gain).

iii. *Conclusion*. There is a complete toxicity database for propiconazole and exposure data is complete or is estimated based on data that reasonably accounts for potential exposures. Based on the completeness of the data base and the lack of any data indicating increased pre- or post-natal sensitivity, EPA concludes that an additional safety factor is not necessary to protect the safety of infants and children.

2. *Acute risk*. The available studies suggest the only acute risk infants and children face from propiconazole is through exposure to the developing fetus as a result of exposure to the mother. As shown in Unit II. D.1. of this preamble, the acute risk to the developing fetus from this exposure is not above the Agency's level of concern.

3. *Chronic risk*. Using the conservative exposure assumptions described in this unit, EPA has concluded that aggregate exposure to propiconazole from food will utilize 50% of the RfD for infants and children. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to propiconazole in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD. EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to propiconazole residues.

4. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to propiconazole residues.

III. Other Considerations

A. Metabolism In Plants and Animals

The nature of the residues in plants and animals is adequately understood. The residues of concern are propiconazole and its metabolites determined as 2,4-dichlorobenzoic acid and expressed as parent compound.

B. Analytical Enforcement Methodology

Adequate enforcement methodology (GC/ECD) is available to enforce the tolerance expression. The method may be requested from: Calvin Furlow, PRRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm 101FF, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–5229.

C. Magnitude of Residues

The currently established time-limited tolerances for corn, peanuts, and pineapple commodities are appropriate for these crops.

D. International Residue Limits

There are no CODEX, Canadian, or Mexican Maximum Residue Limits (MRL) for propiconazole on corn, peanuts, or pineapple. Thus, harmonization of tolerances is not an issue for the extension of these tolerances.

E. Rotational Crop Restrictions

Soybeans may be planted as a double crop following a cereal crop which has been treated with propiconazole. Crops intended for food, grazing, or any component of animal feed or bedding may not be rotated within 105 days of propiconazole application unless the crop appears on the product label.

IV. Conclusion

Therefore, the time-limited tolerances are extended for combined residues of propiconazole, 1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2- yl]methyl]-1*H*-1,2,4-triazole and its metabolites determined as 2,4-dichlorobenzoic acid and expressed as parent compound on corn, fodder at 12 ppm; corn, forage at 12 ppm; corn, grain at 0.1 ppm; corn, sweet (kernels, plus cobs with husks removed) at 0.1 ppm; peanuts at 0.2 ppm; peanuts, hay at 20 ppm; pineapple at 0.1 ppm and pineapple, fodder at 0.1 ppm. These tolerances will expire on December 31, 2000 and will replace previously established tolerances which expired on December 31, 1998. These tolerances are time-limited because the Agency has not completed the review of a modified carcinogenicity study in mice which required testing at a mid-dose level. This study was requested to confirm or supplement findings in an Agency reviewed carcinogenicity study in mice in which testing was conducted at low and high dose levels.

V. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a tolerance regulation issued by EPA as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which govern the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by May 17, 1999, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given under ''ADDRESSES'' section (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i) or a request for a fee waiver. EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding tolerance objection fee waivers, contact James Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 239, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–5697, tompkins.jim@epa.gov. Requests for waiver of tolerance objection fees should be sent to James Hollins, Information Resources and Services

Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

VI. Public Record and Electronic Submissions

EPA has established a record for this regulation under docket control number [OPP–300810] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

Objections and hearing requests may be sent by e-mail directly to EPA at:

opp-docket@epa.gov.

E-mailed objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this regulation, as well as the public version, as described in this unit will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official record which will also include all comments submitted directly in writing. The official record is the paper record maintained at the Virginia address in ''ADDRESSES'' at the beginning of this document.

VII. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

This final rule establishes time-limited tolerances under section 408(d) of the FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 et seq., or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997).

In addition, since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.) do not apply. Nevertheless, the Agency previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

B. Executive Order 12875

Under Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to OMB a description of the extent of EPA's prior consultation with representatives of affected State, local, and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local, and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

Today's rule does not create an unfunded Federal mandate on State, local, or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

C. Executive Order 13084

Under Executive Order 13084, entitled Consultation and Coordination with Indian Tribal Governments (63 FR 27655, May 19, 1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments ''to provide

meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

VIII. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 et seq., as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the Agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: March 4, 1999.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

Authority: 21 U.S.C. 321(q), 346a and 371.

§ 180.434 [Amended]

2. In § 180.434, in the table to paragraph (a), by changing the expiration dates for corn, fodder; corn, forage; corn, grain; corn, sweet (kernels plus cobs with husks removed); peanuts; peanuts, hay; pineapple; and pineapple, fodder, to read ''12/31/00''.

[FR Doc. 99–6388 Filed 3–16–99; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300804; FRL–6063–9]

RIN 2070–AB78

Pendimethalin; Extension of Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation extends time-limited tolerances for the combined residues of the herbicide pendimethalin and its metabolites in or on fresh mint hay and mint oil at 0.1 and 5.0 parts per million (ppm), respectively, for an additional 1-year period. These tolerances will expire and are revoked on May 31, 2000. This action is in response to EPA's granting of emergency exemptions under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on mint. Section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under FIFRA section 18.

DATES: This regulation becomes effective March 17, 1999. Objections and requests for hearings must be received by EPA, on or before May 17, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number [OPP–300804], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300804], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epa.gov. Copies of electronic objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 or ASCII file format. All copies of electronic objections and hearing requests must be identified by the docket control number [OPP–300804]. No Confidential Business Information (CBI) should be submitted through e-mail. Copies of electronic objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Stephen Schaible, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 271, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, 703–308–9362, schaible.stephen@epa.gov.

SUPPLEMENTARY INFORMATION: EPA issued a final rule, published in the **Federal Register** of May 23, 1997 (62 FR 28355) (FRL–5718–5), which announced that on its own initiative under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a and (l)(6), as amended by the Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104–170) it established time-limited tolerances for the combined residues of pendimethalin and its metabolites in or on fresh mint hay and mint oil at 0.1 ppm and 5.0 ppm, respectively, with an expiration date of May 31, 1998. EPA extended the expiration date of these tolerances to May 31, 1999 in a **Federal Register** notice published March 4, 1998 (63 FR 10545–10547) (FRL–5772–9). EPA established the tolerances because section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under FIFRA section 18. Such tolerances can be established without providing notice or period for public comment.

EPA received a request to extend the use of pendimethalin on mint for this year growing season due to the continued emergency situation for Idaho, Oregon and Washington mint

growers. Due to the potential spread of Verticillium wilt by tillage equipment, mechanical control of kochia and redroot pigweed is no longer considered a viable option. The continuous use of terbacil in past years has resulted in development of resistance to this chemical in kochia and pigweed, resulting in inadequate control of this pest by registered alternatives. After having reviewed the submissions, EPA concurs that emergency conditions exist. EPA has authorized under FIFRA section 18 the use of pendimethalin on mint for control of kochia and redroot pigweed in mint.

EPA assessed the potential risks presented by residues of pendimethalin in or on fresh mint hay and mint oil. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and decided that the necessary tolerances under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. The data and other relevant material have been evaluated and discussed in the final rule of May 23, 1997. Based on that data and information considered, the Agency reaffirms that extension of the time-limited tolerances will continue to meet the requirements of section 408(l)(6). Therefore, the time-limited tolerances are extended for an additional 1-year period. EPA will publish a document in the **Federal Register** to remove the revoked tolerances from the Code of Federal Regulations (CFR). Although these tolerances will expire and are revoked on May 31, 2000, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerances remaining in or on fresh mint hay and mint oil after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA and the application occurred prior to the revocation of the tolerances. EPA will take action to revoke these tolerances earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

I. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a tolerance regulation as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which govern the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by May 17, 1999, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given under the ''ADDRESSES'' section (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding tolerance objection fee waivers, contact James Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 239, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–5697, tompkins.jim@epa.gov. Requests for waiver of tolerance objection fees should be sent to James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

II. Public Record and Electronic Submissions

EPA has established a record for this regulation under docket control number [OPP–300804] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

Objections and hearing requests may be sent by e-mail directly to EPA at: opp-docket@epa.gov.

E-mailed objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this regulation, as well as the public version, as described in this unit will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official record which will also include all comments submitted directly in writing. The official record is the paper record maintained at the Virginia address in ''ADDRESSES'' at the beginning of this document.

III. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

This final rule establishes a tolerance under section 408 of the FFDCA. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any

unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4). Nor does it require any prior consultation as specficed by Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997).

In addition, since tolerances and exemptions that are established under section 408(l)(6) of FFDCA, such as the tolerance/exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. Nevertheless, the Agency previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

B. Executive Order 12875

Under Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to OMB a description of the extent of EPA's prior consultation with representatives of affected State, local, and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local, and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

Today's rule does not create an unfunded Federal mandate on State, local, or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

C. Executive Order 13084

Under Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

IV. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the Agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: March 3, 1999.

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180–[AMENDED]

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

Authority: 21 U.S.C. 321(q), 346a and 371.

§ 180.361 [Amended]

2. In § 180.361, by amending paragraph (b) in the table, for the commodities ''Mint hay, fresh'' and ''Mint oil'' by changing the date ''5/31/99'' to read ''5/31/00''.

[FR Doc. 99–6386 Filed 3–16–99; 8:45 am]
BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300799; FRL–6065–2]

RIN 2070–AB78

Tebufenozide; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for residues of tebufenozide in or on lychee and longan. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide tebufenozide on lychee and longan. This regulation establishes a maximum permissible level for residues of benzoic acid, 3,5-dimethyl-1–(1,1-dimethylethyl)-2–(4-ethylbenzoyl)hydrazide in these food commodities pursuant to section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. The tolerances will expire and are revoked on December 31, 2001.

DATES: This regulation is effective March 17, 1999. Objections and requests for hearings must be received by EPA on or before May 17, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number [OPP–300799], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300799], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, Crystal Mall 2 (CM #2), 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epa.gov. Copies of electronic objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 or ASCII file format. All copies of electronic objections and hearing requests must be identified by the docket control number [OPP–300799]. No Confidential Business Information (CBI) should be submitted through e-mail. Copies of electronic objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Barbara Madden, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 284, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–6463, Madden.Barbara@epa.gov.

SUPPLEMENTARY INFORMATION: EPA, on its own initiative, pursuant to sections 408 and (l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a and (l)(6), is establishing tolerances for residues of the insecticide tebufenozide, in or on lychee and longan at 1.0 part per million (ppm). These tolerances will expire and are revoked on December 31, 2001. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations.

I. Background and Statutory Findings

The Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104–170) was signed into law August 3, 1996. FQPA amends both the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 301 *et seq.*, and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.* The FQPA amendments went into effect immediately. Among other things, FQPA amends FFDCA to bring all EPA pesticide tolerance-setting activities under a new section 408 with a new safety standard and new procedures. These activities are described in this preamble and discussed in greater detail in the final rule establishing the time-limited tolerance associated with the emergency exemption for use of propiconazole on sorghum (61 FR 58135, November 13, 1996) (FRL–5572–9).

New section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

Section 18 of FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that ''emergency conditions exist which require such exemption.'' This provision was not amended by FQPA. EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

Section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment.

Because decisions on section 18-related tolerances must proceed before EPA reaches closure on several policy issues relating to interpretation and implementation of the FQPA, EPA does not intend for its actions on such tolerances to set binding precedents for the application of section 408 and the new safety standard to other tolerances and exemptions.

II. Emergency Exemption for Tebufenozide on Lychee and Longan and FFDCA Tolerances

There are approximately 611 and 410 acres of commercial lychee and longan grown in Florida, respectively. Lychee and longan have been relatively pest-free in Florida up until 1998. However, during the mid-1990's lychee webworm was introduced into Florida. During the 1998 growing season up to 80–90% of the lychee trees and 50–60% of the longan trees beared little to no marketable fruit due to lychee webworm infestation. There are very few pesticides registered for use on lychee and longan and none have proven effective in controlling the lychee webworm. Therefore, growers are left with no viable measures to control the lychee webworm. EPA has authorized under FIFRA section 18 the use of tebufenozide on lychee and longan for control of lychee webworms in Florida. After having reviewed the submission, EPA concurs that emergency conditions exist for this state.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of tebufenozide in or on lychee and longan. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment under section 408(e), as provided in section 408(l)(6). Although this tolerance will expire and is revoked on December 31, 2001, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts

specified in the tolerance remaining in or on lychee and longan after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by this tolerance at the time of that application. EPA will take action to revoke this tolerance earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because this tolerance is being approved under emergency conditions EPA has not made any decisions about whether tebufenozide meets EPA's registration requirements for use on lychee and longan or whether a permanent tolerance for this use would be appropriate. Under these circumstances, EPA does not believe that this tolerance serves as a basis for registration of tebufenozide by a State for special local needs under FIFRA section 24(c). Nor does this tolerance serve as the basis for any State other than Florida to use this pesticide on this crop under section 18 of FIFRA without following all provisions of EPA's regulations implementing section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for tebufenozide, contact the Agency's Registration Division at the address provided under the ''ADDRESSES'' section.

III. Aggregate Risk Assessment and Determination of Safety

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7) .

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of tebufenozide and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a time-limited tolerance for residues of tebufenozide on lychee and longan at 1.0 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by tebufenozide are discussed in this unit.

B. Toxicological Endpoint

1. *Acute toxicity*. No toxicological endpoint has been identified for acute toxicity. Toxicity observed in oral toxicity studies were not attributable to a single dose (exposure). No neurological or systemic toxicity was observed in rats given a single oral administration of tebufenozide at 0, 500, 1,000 or 2,000 milligrams/kilogram/day (mg/kg/day). No maternal or developmental toxicity was observed following oral administration of tebufenozide at 1,000 mg/kg/day (limit-dose) during gestation to pregnant rats or rabbits.

2. *Short - and intermediate - term toxicity.* No toxicological endpoints have been identified for short- and intermediate-term toxicity. No dermal or systemic toxicity was seen in rats administered 15 dermal applications at 1,000 mg/kg/day (limit dose) over 21 days with either technical tebufenozide or 23% active ingredient formulation. Despite hematological effects seen in the dog study, similar effects were not seen in these rats receiving the compound via the dermal route indicating poor dermal absorption. Also, no developmental endpoints of concern were evident due to the lack of developmental toxicity in either rat or rabbit studies.

3. *Chronic toxicity*. EPA has established the RfD for tebufenozide at 0.018 mg/kg/day. This RfD is based on the no observable adverse effect level (NOAEL) of 1.8 mg/kg/day based on growth retardation, alterations in hematology parameters, changes in organ weights, and histopathological lesions in the bone, spleen and liver at the lowest observable adverse effect level (LOAEL) of 8.7 mg/kg/day. An uncertainty factor of 100 (10X for inter-species extrapolation and 10X for intra-species variability) was applied to the NOAEL of 1.8 mg/kg/day to calculate the RfD of 0.018 mg/kg/day. EPA has determined that the 10X factor to account for enhanced susceptibility of infants and children (as required by FQPA) can be removed. This determination is based on the results of reproductive and developmental toxicity studies. No evidence of additional sensitivity to young rats or rabbits was observed following pre- or postnatal exposure to tebufenozide.

4. *Carcinogenicity*. Tebufenozide is classified as Group E (no evidence of carcinogenicity in humans).

C. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.482) for the residues of tebufenozide, in or on a variety of raw agricultural commodities. Tolerances, in support of registrations, currently exist for residues of tebufenozide on apples and walnuts. Additionally, time-limited tolerances associated with emergency exemptions have been established for cotton, eggs, leafy vegetables, milk, pears, peanuts, pecans, peppers, rice, sugar beet, sugarcane, sweet potatoes, turnip tops and livestock commodities of cattle, goats, hogs, horses, poultry and sheep. Risk assessments were conducted by EPA to assess dietary exposures and risks from tebufenozide as follows:

i. *Acute exposure and risk.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. Toxicity observed in oral toxicity studies were not attributable to a single dose or one day exposure. Therefore, no toxicological endpoint was identified for acute toxicity and no acute dietary risk assessment is needed.

ii. *Chronic exposure and risk.* The Agency conducted a chronic dietary exposure analysis and risk assessment. The chronic analysis for tebufenozide used a RfD of 0.018 mg/kg/day. The analysis evaluated individual food consumption as reported by respondents in the USDA 1989-92 Continuing Surveys of Food Intake by Individuals and accumulates exposure to the chemical for each commodity. Tolerance level residues and some percent crop treated (%CT) assumptions were made for the proposed commodities to estimate the Anticipated Residue Concentration (ARC) for the general population and subgroups of interest. Since the FQPA safety factor has been removed for all population subgroups, the percent RfD that would exceed the Agency level of concern would be 100%. The existing tebufenozide tolerances (published, pending, and including the necessary Section 18 tolerance(s)) result in a ARC that is equivalent to percentages of the RfD below 100% for all subgroups i.e., U.S. population, 12% and non-nursing infants (<1 year old), the most highly exposed subgroup, 25%.

Section 408(b)(2)(F) states that the Agency may use data on the actual percent of food treated (PCT) for assessing chronic dietary risk only if the

Agency can make the following findings: That the data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide residue; that the exposure estimate does not underestimate exposure for any significant subpopulation group; and if data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area. In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of percent crop treated as required by the section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency used PCT information as follows: almonds, <1%; apples, 2%; dry beans and peas, 1%; fresh cabbage, 3%; cole crops, 2%; cotton, 4%; pears, <5; fresh spinach, 3%; processed spinach, 29%; sugarcane, 5%; and walnuts, 16%.

The Agency believes that the three conditions, discussed in section 408 (b)(2)(F) in this unit concerning the Agency's responsibilities in assessing chronic dietary risk findings, have been met. The PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. Typically, a range of estimates are supplied and the upper end of this range is assumed for the exposure assessment. By using this upper end estimate of the PCT, the Agency is reasonably certain that the percentage of the food treated is not likely to be underestimated. The regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available information on the regional consumption of food to which tebufenozide may be applied in a particular area.

2. *From drinking water.* The Agency lacks sufficient water-related exposure data to complete a comprehensive drinking water exposure analysis and risk assessment for tebufenozide. Because the Agency does not have comprehensive and reliable monitoring data, drinking water concentration estimates must be made by reliance on some sort of simulation or modeling. To date, there are no validated modeling approaches for reliably predicting pesticide levels in drinking water. The Agency is currently relying on GENEEC and PRZM/EXAMS for surface water, which are used to produce estimates of pesticide concentrations in a farm pond and SCI-GROW, which predicts pesticide concentrations in groundwater. None of these models include consideration of the impact processing of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern. For the proposed uses, based on the GENEEC and SCI-GROW models the chronic drinking water concentration value are estimated to be 29 parts per billion (ppb) for surface water and 1 pbb for ground water.

In the absence of monitoring data for pesticides, drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, drinking water, and residential uses. A DWLOC will vary depending on the toxic endpoint, with drinking water consumption, and body weights. Different populations will have different DWLOCs. DWLOCs are used in the risk assessment process as a surrogate measure of potential exposure associated with pesticide exposure through drinking water. DWLOC values are not regulatory standards for drinking water. Since DWLOCs address total aggregate exposure to tebufenozide they are further discussed in the aggregate risk sections below.

3. *From non-dietary exposure.* Tebufenozide is not registered on any use sites which would result in non-dietary, non-occupational exposure. Therefore, EPA expects only dietary and occupational exposure from the use of tebufenozide.

4. *Cumulative exposure to substances with common mechanism of toxicity.* Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA does not have, at this time, available data to determine whether tebufenozide has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, tebufenozide does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that tebufenozide has a common mechanism of toxicity with other substances. For more information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

D. Aggregate Risks and Determination of Safety for U.S. Population

1. *Acute risk.* As discussed above, no toxicological endpoint was identified for acute toxicity. Therefore, no acute aggregate risk assessment is needed.

2. *Chronic risk.* Using the ARC exposure assumptions described above, EPA has concluded that aggregate exposure to tebufenozide from food will utilize 12% of the RfD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure, non-nursing infants (<1 year old) (discussed below) will utilize 25% of the RfD. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to tebufenozide in drinking water, after calculating DWLOCs (560 ppb) and comparing them to conservative model estimates of concentrations of tebufenozide in surface and ground water (29 ppb and 1 ppb, respectively), EPA does not expect the aggregate exposure to exceed 100% of the RfD.

3. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential exposure. Tebufenozide is not registered on any use sites which would result in non-dietary, non-occupational exposure. Therefore no short- and intermediate-

term aggregate risk assessments are needed.

4. *Aggregate cancer risk for U.S. population*. Tebufenozide is classified as Group E (no evidence of carcinogenicity in humans).

5. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to tebufenozide residues.

E. Aggregate Risks and Determination of Safety for Infants and Children

1. *Safety factor for infants and children* i. *In general*. In assessing the potential for additional sensitivity of infants and children to residues of tebufenozide, EPA considered data from developmental toxicity studies in the rat and rabbit and a 2-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure during gestation. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for pre-and post-natal toxicity and the completeness of the database unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard MOE and uncertainty factor (usually 100 for combined inter- and intra-species variability) and not the additional tenfold MOE/uncertainty factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

ii. *Developmental toxicity studies*. In prenatal developmental toxicity studies in rats and rabbits, there was no evidence of maternal or developmental toxicity; the maternal and developmental NOAELS were 1,000 mg/kg/day (highest dose tested).

iii. *Reproductive toxicity study*. In 2-generation reproduction studies in rats, toxicity to the fetuses/offspring, when observed, occurred at equivalent or higher doses than in the maternal/parental animals.

iv. *Pre- and post-natal sensitivity*. The data provided no indication of increased sensitivity of rats or rabbits to in utero and/or postnatal exposure to tebufenozide. No maternal or developmental findings were observed in the prenatal developmental toxicity studies at doses up to 1,000 mg/kg/day in rats and rabbits. In the 2-generation reproduction studies in rats, effects occurred at the same or lower treatment levels in the adults as in the offspring.

v. *Conclusion*. There is a complete toxicity database for tebufenozide and exposure data is complete or is estimated based on data that reasonably accounts for potential exposures. Data provided no indication of increased sensitivity of rats or rabbits to in utero and/or postnatal exposure to tebufenozide. Based on this, EPA concludes that reliable data support the use of the standard 100-fold uncertainty factor, and that an additional uncertainty factor is not needed to protect the safety of infants and children.

2. *Acute risk*. No toxicological endpoint was identified for acute toxicity. Therefore, no acute aggregate risk assessment is needed.

3. *Chronic risk*. Using the exposure assumptions described above, EPA has concluded that aggregate exposure to tebufenozide from food will utilize 25% of the RfD for infants and 19% of the RfD for children. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to tebufenozide in drinking water, after calculating DWLOCs (140 ppb) and comparing them to conservative model estimates of concentrations of tebufenozide in surface and ground water (29 ppb and 1 ppb, respectively), EPA does not expect the aggregate exposure to exceed 100% of the RfD.

4. *Short- or intermediate-term risk*. Tebufenozide is not registered on any use sites which would result in non-dietary, non-occupational exposure. Therefore no short- and intermediate-term aggregate risk assessments are needed.

5. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to tebufenozide residues.

IV. Other Considerations

A. Metabolism In Plants and Animals

Residue of concern in plants is adequately understood and is tebufenozide per se. Residues of concern in animals are not adequately understood. Studies to address residues of concern for animals are currently under Agency review. For the purpose of these section 18 actions only, the Agency has assumed the residue of concern is tebufenozide per se.

B. Analytical Enforcement Methodology

Adequate enforcement methodology (example - gas chromatography) is available to enforce the tolerance expression. The method may be requested from: Calvin Furlow, PRRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm 101FF, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–5229.

C. Magnitude of Residues

Residues of tebufenozide per se are not expected to exceed 1.0 ppm on lychee and longan as a result of these section 18 uses.

D. International Residue Limits

There are currently no Canadian, or Mexican listings for tebufenozide residues. Codex maximum residue levels (MRLs) have been set for tebufenozide at 0.1 ppm for rice (husked), 0.05 ppm for walnuts, and 1 ppm for pome fruits.

E. Rotational Crop Restrictions

Rotational crop restrictions do not apply to lychee and longan since they are tree crops.

V. Conclusion

Therefore, the tolerance is established for residues of tebufenozide in lychee and longan at 1.0 ppm.

VI. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a tolerance regulation as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which govern the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by May 17, 1999, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given under the ''ADDRESSES'' section (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding tolerance objection fee waivers, contact James Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 239, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305-5697, tompkins.jim@epa.gov. Requests for waiver of tolerance objection fees should be sent to James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

VII. Public Record and Electronic Submissions

EPA has established a record for this regulation under docket control number [OPP–300799] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Rm. 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

Objections and hearing requests may be sent by e-mail directly to EPA at:
opp-docket@epa.gov.

E-mailed objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this regulation, as well as the public version, as described in this unit will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official record which will also include all comments submitted directly in writing. The official record is the paper record maintained at the Virginia address in ''ADDRESSES'' at the beginning of this document.

VIII. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

This final rule establishes a tolerance under section 408 of the FFDCA. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4). Nor does it require any special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997).

In addition, since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(l)(6), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. Nevertheless, the Agency previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

B. Executive Order 12875

Under Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to OMB a description of the extent of EPA's prior consultation with representatives of affected State, local, and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local, and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

Today's rule does not create an unfunded Federal mandate on State, local, or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

C. Executive Order 13084

Under Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

IX. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the Agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: March 3, 1999.

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In § 180.482, add the following commodities to the table in paragraph (b) to read as follows:

§ 180.482 Tebufenozide; tolerances for residues.

* * * * *

(b) * * *

Commodity	Parts per million	Expiration/revocation date
* * * *	*	* *
Longan	1.0	12/31/01
Lychee	1.0	12/31/01
* * * *	*	* *

* * * * *

[FR Doc. 99–6385 Filed 3–16–99; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300806; FRL 6065–6]

RIN 2070–AB78

Dicloran; Extension of Tolerance for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation extends time-limited tolerances for residues of the fungicide 2,6-dichloro-4-nitroaniline (dicloran) in or on peanuts at 3.0 parts per million (ppm) and peanut oil at 6.0 ppm for an additional 2–year period. This tolerance will expire and is revoked on October 31, 2001. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on peanuts. Section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under FIFRA section 18.

DATES: This regulation becomes effective March 17, 1999. Objections and requests for hearings must be received by EPA, on or before May 17, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number [OPP–300806], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300806], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epa.gov. Copies of electronic objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 or ASCII file format. All copies of electronic objections and hearing requests must be identified by the docket control number [OPP–300806]. No Confidential Business Information (CBI) should be submitted through e-mail. Copies of electronic objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Barbara Madden, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 284, Crystal Mall #2, 1921 Jefferson Davis

Hwy., Arlington, VA, (703) 305–6463; e-mail: madden.barbara@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA issued a final rule, published in the **Federal Register** of January 5, 1998 (63 FR 162) (FRL–5762–4), which announced that on its own initiative under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a and (l)(6), as amended by the Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104–170) it established time-limited tolerances for the residues of dicloran in or on peanuts at 3.0 ppm and peanut oil at 6.0 with an expiration date of October 31, 1999. EPA established the tolerances because section 408(l)(6) of the FFDCA requires EPA to establish time-limited tolerances or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under FIFRA section 18. Such tolerances can be established without providing notice or period for public comment.

EPA received a request to extend the use of dicloran on peanuts for the 1999 growing season since environmental conditions conducive for disease outbreaks of *Sclerotinia blight* have developed every year and are likely to develop this growing season. The disease is favored by high humidity and cool to warm temperatures. The disease is expected to be most severe in the late summer when the prevailing temperatures are cooler and the peanut plant canopy shades the soil and cools soil temperatures. After having reviewed the submission, EPA concurs that emergency conditions exist. EPA has authorized under FIFRA section 18 the use of dicloran on peanuts for control of *Sclerotinia blight* in peanuts.

EPA assessed the potential risks presented by residues of dicloran in or on peanuts and peanut oil. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. The data and other relevant material have been evaluated and discussed in the final rule of January 5, 1998 (63 FR 162) (FRL–5762–4). Based on that data and information considered, the Agency reaffirms that extension of the time-limited tolerances will continue to meet the requirements of section 408(l)(6). Therefore, the time-limited tolerances are extended for an additional 2–year period. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations (CFR). Although this tolerance will expire and is revoked on October 31, 2001, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on peanuts and peanut oil after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA and the application occurred prior to the revocation of the tolerance. EPA will take action to revoke this tolerance earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

I. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a tolerance regulation as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which govern the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by May 17, 1999, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given under the ''ADDRESSES'' section (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding tolerance objection fee waivers, contact James Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 239, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–5697, tompkins.jim@epa.gov. Requests for waiver of tolerance objection fees should be sent to James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

II. Public Record and Electronic Submissions

EPA has established a record for this regulation under docket control number [OPP–300806] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

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E-mailed objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this regulation, as well as the public version, as described in this unit will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official record which will also include all comments submitted directly in writing. The official record is the paper record maintained at the Virginia address in ''ADDRESSES'' at the beginning of this document.

III. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

This final rule establishes a tolerance under section 408 of the FFDCA. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 et seq., or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4). Nor does it require any prior consultation as specficed by Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997).

In addition, since tolerances and exemptions that are established under section 408(l)(6) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq*.) do not apply. Nevertheless, the Agency previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

B. Executive Order 12875

Under Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to OMB a description of the extent of EPA's prior consultation with representatives of affected State, local, and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local, and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

Today's rule does not create an unfunded Federal mandate on State, local, or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

C. Executive Order 13084

Under Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

IV. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq*., as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the Agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: March 5, 1999.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180 — [AMENDED]

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

Authority: 21 U.S.C. 346a and 371.

§180.200 [Amended]

2. In §180.200, by amending the table in paragraph (b) for the following commodities ''Peanut, oil '' and '' Peanuts'' by changing the date ''10/31/99'' to read ''10/31/01.''

[FR Doc. 99–6384 Filed 3–16–99; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300809; FRL–6067–9]

RIN 2070–AB78

Maneb (manganous ethylenebisdithiocarbamate); Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues of maneb (manganous ethylenebisdithiocarbamate), calculated as zinc ethylenebisdithiocarbamate and its metabolite ethylenethiourea in or on walnuts . This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on walnuts.This regulation establishes a maximum permissible level for residues of maneb (manganous ethylenebisdithiocarbamate) in this food commodity pursuant to section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. The tolerance will expire and is revoked on December 31, 2000.

DATES: This regulation is effective March 17, 1999. Objections and requests for hearings must be received by EPA on or before May 17, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number [OPP–300809], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300809], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, Crystal Mall 2 (CM #2), 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epa.gov. Copies of electronic objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 or ASCII file format. All copies of electronic objections and hearing requests must be identified by the docket control number [OPP–300809]. No Confidential Business Information (CBI) should be submitted through e-mail. Copies of electronic objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Meredith Laws, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 282, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 308–9366, laws.meredith@epa.gov.

SUPPLEMENTARY INFORMATION: EPA, on its own initiative, pursuant to sections 408 and (l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a and (l)(6), is establishing a tolerance for residues of the fungicide maneb (manganous ethylenebisdithiocarbamate), calculated as zinc ethylenebisdithiocarbamate and its metabolite ethylenethiourea, in or on walnuts at 0.05 part per million (ppm). This tolerance will expire and is revoked on December 31, 2000. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations.

I. Background and Statutory Findings

The Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104–170) was signed into law August 3, 1996. FQPA amends both the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 301 *et seq.*, and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.* The FQPA amendments went into effect immediately. Among other things, FQPA amends FFDCA to bring all EPA pesticide tolerance-setting activities under a new section 408 with a new safety standard and new procedures. These activities are described in this preeamble and discussed in greater detail in the final rule establishing the time-limited tolerance associated with the emergency exemption for use of propiconazole on sorghum (61 FR 58135, November 13, 1996) (FRL–5572–9).

New section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

Section 18 of FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that ''emergency conditions exist which require such exemption.'' This provision was not amended by FQPA. EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

Section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment.

Because decisions on section 18-related tolerances must proceed before EPA reaches closure on several policy issues relating to interpretation and implementation of the FQPA, EPA does not intend for its actions on such tolerances to set binding precedents for the application of section 408 and the new safety standard to other tolerances and exemptions.

II. Emergency Exemption for Maneb (manganous ethylenebisdithiocarbamate) on Walnuts and FFDCA Tolerances

The California Department of Pesticide Regulation has requested an emergency exemption under FIFRA section 18 to use maneb on walnuts to control bacterial blight. Currently,

copper based bactericides are the only registered products for control of this disease. The increase of walnut blight since 1992 is attributed to the development of a tolerance to copper based bactericides. The state has demonstrated that copper resistant bacteria have become economically important, with a potential 55,000 acres affected. EPA has authorized under FIFRA section 18 the use of maneb (manganous ethylenebisdithiocarbamate) on walnuts for control of bacterial blight in California. After having reviewed the submission, EPA concurs that emergency conditions exist for this state.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of maneb (manganous ethylenebisdithiocarbamate) in or on walnuts. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment under section 408(e), as provided in section 408(l)(6). Although this tolerance will expire and is revoked on December 31, 2000, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on walnuts after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by this tolerance at the time of that application. EPA will take action to revoke this tolerance earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because this tolerance is being approved under emergency conditions EPA has not made any decisions about whether maneb (manganous ethylenebisdithiocarbamate) meets EPA's registration requirements for use on walnuts or whether a permanent tolerance for this use would be appropriate. Under these circumstances, EPA does not believe that this tolerance serves as abasis for registration of maneb (manganous ethylenebisdithiocarbamate) by a State for special local needs under FIFRA section 24(c). Nor does this tolerance serve as the basis for any State other than to use this pesticide on this crop under section 18 of FIFRA without following all provisions of EPA's regulations implementing section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for maneb (manganous ethylenebisdithiocarbamate), contact the Agency's Registration Division at the address provided under the ''ADDRESSES'' section.

III. Aggregate Risk Assessment and Determination of Safety

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7) .

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of maneb (manganous ethylenebisdithiocarbamate) and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a time-limited tolerance for residues of maneb (manganous ethylenebisdithiocarbamate), calculated as zinc ethylenebisdithiocarbamate and its metabolite ethylenethiourea on walnuts at 0.05 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by maneb (based on calculations on its metabolite, ethylenethiourea) are discussed in this unit.

B. Toxicological Endpoint

1. *Acute toxicity*. The acute dietary risk assessment is being conducted for ethylenethiourea (ETU) rather than maneb, since the no observed adverse effect level (NOAEL) for acute dietary risk for ETU is 4 times lower (5 milligrams/kilogram/day (mg/kg/day)) than the NOAEL for acute dietary risk for maneb (20 mg/kg/day). Therefore, an acceptable margin of exposure (MOE) for ETU will also be protective of exposure to maneb. The oral developmental NOAEL in rats for ETU is 5 mg/kg/day, based on a threshold finding of delayed ossification in the fetal skeletal structures at the NOAEL. The NOAEL is more correctly identified as a slightly lower dose level which is close to a threshold NOAEL in the developmental study. The EBDC PD-4 stated that MOEs could be calculated from the 5 mg/kg/day NOAEL, which was close to the NOAEL, and was the lowest dose tested.

2. *Short - and intermediate - term toxicity*. EPA recommends use of the systemic NOAEL of 100 mg/kg/day from the 3-week dermal toxicity study in rabbits. At the lowest observed adverse effect level (LOAEL) of 300 mg/kg/day, there were slightly increased thyroid weights and follicular cell hypertrophy of the thyroid.

3. *Chronic toxicity*. EPA has established the Reference Dose (RfD) for ETU at 0.00008 mg/kg/day. This RfD is based on the LOAEL of 0.25 mg/kg/day due to thyroid hyperplasia in a 2-year rat feeding study, with an uncertainty factor of 3,000. The uncertainty factor of 3,000 was based on a factor of 3 for absence of a NOAEL for ETU, a factor of 10 for data gaps for ETU, and a factor of 100 to take into account inter- and intra-species variability.

4. *Carcinogenicity*. Maneb has been classified as a Group B2, probable human carcinogen, based on evidence of thyroid tumors in rats and liver tumors. The Q1* for quantitation of human oral risk is 0.0601 $(mg/kg/day)^{-1}$ for the carcinogenic metabolite, ETU.

C. Exposures and Risks

1. *From food and feed uses*. Tolerances have been established (40 CFR 180.110) for the residues of maneb (manganous ethylenebisdithiocarbamate), calculated as zinc ethylenebisdithiocarbamate and its metabolite ethylenethiourea, in or on a variety of raw agricultural commodities including almonds at 0.1 ppm. Risk assessments were conducted by EPA to assess dietary exposures and risks from maneb (manganous ethylenebisdithiocarbamate) as follows:

i. *Acute exposure and risk*. Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. The high end dietary exposure for the population subgroup of concern, females 13+ years

old, is 0.000036 mg/kg/day, which results in an MOE of 5,000. Maximum field trial residue values were used to calculate the MOE. This is considered a partially refined risk estimate.

ii. *Chronic exposure and risk*. The chronic exposure estimate for the general population is 0.000020 mg/kg/day and the anticipated residue contribution (ARC) as percentage of the RfD is 24.4%.

Section 408(b)(2)(E) authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide chemicals that have been measured in food. If EPA relies on such information, EPA must require that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. Following the initial data submission, EPA is authorized to require similar data on a time frame it deems appropriate. As required by section 408(b)(2)(E), EPA will issue a data call-in for information relating to anticipated residues to be submitted no later than 5 years from the date of issuance of this tolerance.

Section 408(b)(2)(F) states that the Agency may use data on the actual percent of food treated (PCT) for assessing chronic dietary risk only if the Agency can make the following findings: That the data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide residue; that the exposure estimate does not underestimate exposure for any significant subpopulation group; and if data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area. In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of percent crop treated as required by the section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency used PCT information as follows:

In the Dietary Risk Evaluation Model (DEEM), it was assumed that 100% of the walnut crop would be treated under this emergency exemption. Refined percent crop treated values were used for some commodities such as 10% for cranberries, 50% for apples, 15% for pears, and 10% for almonds. The DEEM run did not use refined percent crop treated values for all registered uses, however, 100% crop treated was used for a number of commodities such as tomatoes, cucurbits, peppers, broccoli, onions, potatoes, and corn.

The Agency believes that the three conditions, discussed in section 408 (b)(2)(F) in this unit concerning the Agency's responsibilities in assessing chronic dietary risk findings, have been met. The PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. Typically, a range of estimates are supplied and the upper end of this range is assumed for the exposure assessment. By using this upper end estimate of the PCT, the Agency is reasonably certain that that the percentage of the food treated is not likely to be underestimated. The regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available information on the regional consumption of food to which maneb may be applied in a particular area.

2. *From drinking water.* Submitted environmental fate studies suggest that maneb has moderate potential to leach into ground water; thus maneb could potentially leach to ground water and runoff to surface water under certain environmental conditions. There are no established Maximum Contaminant Levels (MCLs) for residues of maneb in drinking water. No Health Advisories (HA) for maneb in drinking water have been established. However, EPA has considered the carcinogenic risk resulting from a maximum theoretical drinking water residue of 1.0 parts per billion (ppb) for ETU. ETU, which is highly soluble in water, is assumed to be persistent and highly mobile.

Chronic exposure and risk. Because the Agency lacks sufficient water-related exposure data to complete a comprehensive drinking water risk assessment for many pesticides, EPA has commenced and nearly completed a process to identify a reasonable yet conservative bounding figure for the potential contribution of water-related exposure to the aggregate risk posed by a pesticide. In developing the bounding figure, EPA estimated residue levels in water for a number of specific pesticides using various data sources. The Agency then applied the estimated residue levels, in conjunction with appropriate toxicological endpoints (RfD's or acute dietary no observed adverse effect levels (NOAEL's)) and assumptions about body weight and consumption, to calculate, for each pesticide, the increment of aggregate risk contributed by consumption of contaminated water. While EPA has not yet pinpointed the appropriate bounding figure for exposure from contaminated water, the ranges the Agency is continuing to examine are all below the level that would cause maneb (manganous ethylenebisdithiocarbamate) to exceed the RfD if the tolerance being considered in this document were granted. The Agency has therefore concluded that the potential exposures associated with maneb (manganous ethylenebisdithiocarbamate) in water, even at the higher levels the Agency is considering as a conservative upper bound, would not prevent the Agency from determining that there is a reasonable certainty of no harm if the tolerance is granted.

3. *From non-dietary exposure.* Maneb (manganous ethylenebisdithiocarbamate) is currently registered for use on the following residential non-food sites: turf, lawn, trees, and shrubs. Maneb is not registered for indoor uses. While EPA does not consider that these types of outdoor residential uses constitute a chronic residential exposure scenario, EPA acknowledges that there may be short- and intermediate-term non-occupational exposure scenarios. The Agency has identified toxicity endpoints for short- and intermediate-term residential risk assessments. For this action, the risk to public health from the use of maneb is calculated based on it's metabolite/degradate ETU. However, no acceptable reliable exposure data to assess these potential risks are available at this time. Given the time-limited nature of this request, the need to make emergency exemption decisions quickly, the significant scientific uncertainty at this time about how to aggregate non-occupational exposure with dietary exposure, the Agency will make it's safety determination for these tolerances based on those factors which it can reasonably integrate into a risk assessment.

i. *Chronic exposure and risk.* The Agency has concluded that a chronic residential exposure scenario does not exist for non-occupational uses of maneb.

ii. *Short- and intermediate-term exposure and risk*. The amortized ETU cancer risk for the U.S. population for short- and intermediate-term exposure to the turf use of maneb has been calculated to be 2.2 x 10^{-7}.

4. *Cumulative exposure to substances with common mechanism of toxicity*. Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA does not have, at this time, available data to determine whether maneb (manganous ethylenebisdithiocarbamate) has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, maneb (manganous ethylenebisdithiocarbamate) does not appear to produce a toxic metabolite produced by other substances, other than ETU, a metabolite common to the EBDC pesticides. For more information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

D. Aggregate Risks and Determination of Safety for U.S. Population

1. *Acute risk*. The MOE for females 13+ years was calculated to be 5,000. Therefore, aggregate acute risk estimates do not exceed the Agency's level of concern.

2. *Chronic risk*. Using the ARC exposure assumptions described in this unit, EPA has concluded that aggregate exposure to maneb (manganous ethylenebisdithiocarbamate) from food will utilize 24.4% of the RfD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is non-nursing infants (<1 year old) discussed below. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to maneb (manganous ethylenebisdithiocarbamate) in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD.

3. *Short- and intermediate-term risk*. Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential exposure.

Although surface and ground water monitoring data are limited, maneb does have the potential to leach into groundwater and run off to surface water. California monitoring programs have picked up one detect of .725 ppb, in three years of sampling (1986–89). Subsequent sampling 4 - 5 months later showed no residues. California has not found ETU when surveying high EBDC use areas. There were two detections in the U.S. EPA's National Pesticide Survey. The MOE for the U.S. population exceeds the desired MOE, therefore, EPA has no short- or intermediate-term aggregate risk concerns.

4. *Aggregate cancer risk for U.S. population*. The aggregate dietary cancer risk for maneb is based on ETU. The dietary cancer risk is calculated using the Q* for ETU, 0.601 mg/kg/day^{-1}. EPA calculated that the dietary cancer risk for the EBDC pesticides, including this use on walnuts is 1.2 x 10^{-6}. This risk assessment is partially refined; incorporation of percent crop treated information for all commodities would result in a lower dietary exposure estimate. The cancer risk from the residential uses of EBDC pesticides is approximately 10^{-7}. The aggregate cancer risk estimate would not exceed EPA's acceptable level unless the drinking water concentration exceeds 1 ppb. The availability of surface-water and ground-water monitoring data for maneb and ETU is limited. EPA is not aware of any surface-water monitoring data for either maneb or ETU, and it does not have any ground-water monitoring data for maneb. However, EPA has ground-water monitoring data which indicates that ETU has leached into the ground water; some of which are direct drinking water sources.

In California from 1986 to 1989, 65 wells were monitored for ETU. One well in San Joaquin County during March 1988 had an ETU concentration of 0.725 ppb. The remainder of the samples had no ETU detections (limit of detection (LOD) of 0.5 ppb). The California Department of Food and Agriculture concluded that this ETU concentration in the ground water did not represent a legal agriculture use based upon another sampling event where this well and five nearby wells in a predominantly walnut orchard use area were sampled 125 days or more subsequent to the March sampling event. ETU was not detected in any of these ground-water samples at that later date.

There were two ETU detections in the ground water in the U.S. EPA's statistically designed National Pesticide Survey (NPS). The NPS analyzed a statistically representative sample of wells to provide a national assessment of the presence of pesticides in drinking water wells. On the basis of this study, EPA estimated that nationally, 8,470 rural domestic wells could contain ETU over the NPS reporting limit of 4.5 ppb. The 95% confidence interval ranged from 1 to 111,000 wells. One quantified ETU detection of 16.0 ppb was obtained from a rural well in Warren County, Illinois. A second detection, described as a ''trace'' detection, was reported in Iowa. For this compound in the NPS, samples containing ETU at concentrations greater than 9.0 ppb were quantified; samples containing concentrations between 4.5 and 9.0 ppb were reported as ''trace''; and no detections were reported if concentrations were below 4.5 ppb. The source of the ETU was not determined; however, both agricultural and industrial practices may contribute to ETU contamination of the ground water.

These limited sampling results indicate some potential for ETU to be found in ground water. However, there are significant uncertainties associated with using these data in quantitative carcinogenic risk assessment for purposes of national tolerance-setting. EPA is uncertain as to whether a significant subpopulation would be exposed to high enough concentrations of ETU (greater than 1 ppb) for a long enough period of time to pose a significant carcinogenic risk. For example, in the ground-water sampling conducted in San Joaquin County between 1986–1989, the single contaminated well (out of 65 tested) subsequently was found 4 months later to have no detectable levels of ETU. Additionally, although the NPS results show two detections of ETU in ground water, it is not clear whether agricultural or industrial practices were the source of the ETU. If the source of the ETU was industrial and not agricultural use, it is likely that contamination of ground water with ETU would be less widespread than is suggested by the statistical analysis of the NPS results. EPA does not believe that the available data demonstrate that a significant subpopulation would be exposed to residues of ETU in drinking water greater than 1 ppb; therefore, EPA does not believe that the aggregate cancer risk associated with the granting

of this tolerance would exceed acceptable levels.

5. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to maneb (manganous ethylenebisdithiocarbamate) residues.

E. Aggregate Risks and Determination of Safety for Infants and Children

1. *Safety factor for infants and children* —i. *In general.* In assessing the potential for additional sensitivity of infants and children to residues of maneb (manganous ethylenebisdithiocarbamate), EPA considered data from developmental toxicity studies in the rat and a 2-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure during gestation. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for pre-and post-natal toxicity and the completeness of the database unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard MOE and uncertainty factor (usually 100 for combined inter- and intra-species variability) and not the additional tenfold MOE/uncertainty factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

ii. *Developmental toxicity studies*. From the rat developmental study for ETU, the oral developmental NOAEL is 5 mg/kg/day, based on a threshold finding of delayed ossification in the fetal skeletal structures at the NOAEL.

iii. *Reproductive toxicity study*. There is no reproduction study with ETU available. In the rat reproduction study for maneb, the parental (systemic) NOAEL was 6.0 mg/kg/day, based on decreased body weight and food consumption at the LOAEL of 25 mg/kg/day. The developmental (pup) NOAEL was 6.0 mg/kg/day, based on increased startle response at the LOAEL of 25 mg/kg/day.

iv. *Pre- and post-natal sensitivity*. The rat developmental study with ETU demonstrated a special prenatal sensitivity for infants and children. The results of the rat reproduction study with maneb do not demonstrate any additional special post-natal sensitivity for infants and children, since the NOAEL and LOAEL for parental toxicity and pup toxicity occur at the same doses and the pup effects are not of unusual concern.

v. *Conclusion*. In the absence of a complete data base for ETU, EPA is assuming an additional tenfold safety factor to account for the possibility of special prenatal sensitivity for infants and children.

2. *Acute risk*. The acute dietary risk assessment for ETU residues demonstrated an MOE of 5,000 based on the NOAEL of 5 mg/kg/day in the rat developmental study. Therefore, this calculated MOE for ETU for females 13+ years of age shows that the MOEs for this population subgroup are far in excess of the required dietary MOE of 1,000 due to ETU data gaps. Therefore, the acute dietary risks for ETU to females 13+ years of age are below EPA's level of concern. The RfD for ETU incorporates an uncertainty factor of 3,000. The uncertainty factor was based on a factor of 3 for absence of a NOAEL for ETU, a factor of 10 for data gaps needed to assess extra sensitivity to infants and children for ETU, and the normal factor of 100 for converting between and within species (EBDC PD/4, 3/2/92).

3. *Chronic risk*. Using the exposure assumptions described in this unit, EPA has concluded that aggregate exposure to maneb (manganous ethylenebisdithiocarbamate) from food will utilize 78.4% of the RfD for nonnursing infants (<1 year old). EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to maneb (manganous ethylenebisdithiocarbamate) in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD.

4. *Short- or intermediate-term risk*. The MOEs for infants and children exceed the desired MOE, therefore, EPA has no short- and intermediate-term aggregate risk concerns.

5. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to maneb (manganous ethylenebisdithiocarbamate) residues.

IV. Other Considerations

A. Metabolism In Plants and Animals

The nature of the residue in plants is adequately understood. The residues of concern are the fungicide maneb, calculated as zinc ethylenebisdithiocarbamate, and its metabolite ethylenthiourea. Secondary residues are not expected in animal commodities as no feed items are associated with this use.

B. Analytical Enforcement Methodology

Adequate enforcement methodology is available for maneb in the Pesticide Analytical Manual (PAM) II Method III.

C. Magnitude of Residues

Residues of maneb (manganous ethylenebisdithiocarbamate) calculated as zinc ethylenebisdithiocarbamate and its metabolite ethylenethiourea are not expected to exceed 0.05 ppm in or on walnuts as a result of this proposed use. Secondary residues are not expected in animal commodities as no feed items are associated with this use.

D. International Residue Limits

No Codex, Canadian, or Mexican maximum residue levels have been established for residues of maneb in/on walnuts.

V. Conclusion

Therefore, the tolerance is established for residues of maneb (manganous ethylenebisdithiocarbamate), calculated as zinc ethylenebisdithiocarbamate and its metabolite ethylenethiourea in walnuts at 0.05 ppm.

VI. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a tolerance regulation issued by EPA under new section 408 and (l)(6) as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which govern the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by May 17, 1999, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given under the ''ADDRESSES'' section (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding tolerance objection fee waivers, contact James Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 239, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–5697, tompkins.jim@epa.gov. Requests for waiver of tolerance objection fees should be sent to James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

VII. Public Record and Electronic Submissions

EPA has established a record for this regulation under docket control number [OPP–300809] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Rm. 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

Objections and hearing requests may be sent by e-mail directly to EPA at:
opp-docket@epa.gov.

E-mailed objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this regulation, as well as the public version, as described in this unit will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official record which will also include all comments submitted directly in writing. The official record is the paper record maintained at the Virginia address in ''ADDRESSES'' at the beginning of this document.

VIII. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

This final rule establishes a tolerance under section 408 of the FFDCA. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4). Nor does it require any special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997).

In addition, since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(l)(6), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. Nevertheless, the Agency previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

B. Executive Order 12875

Under Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to OMB a description of the extent of EPA's prior consultation with representatives of affected State, local, and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local, and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

Today's rule does not create an unfunded Federal mandate on State, local, or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of

Executive Order 12875 do not apply to this rule.

C. Executive Order 13084

Under Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

IX. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the Agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: March 5, 1999.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In § 180.110, by revising paragraph (b) to read as follows:

§ 180.110 Maneb; tolerances for residues.

* * * * *

(b) *Section 18 emergency exemptions.* A time-limited tolerance is established for residues of the fungicide maneb (manganous ethylenebisdithiocarbamate), calculated as zinc ethylenebisdithiocarbamate, and its metabolite ethylenethiourea in connection with use of the pesticide under a section 18 emergency exemption granted by EPA. The tolerance will expire and is revoked on the date specified in the following table:

Commodity	Parts per million	Expiration/revocation date
Walnuts	0.05	12/31/00

* * * * *

[FR Doc. 99–6383 Filed 3–16–99; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300797; FRL–6064–2]

RIN 2070–AB78

Propiconazole; Extension of Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation extends time-limited tolerances for combined residues of the fungicide propiconazole and its metabolites in or on almond nutmeats at 0.1 parts per million (ppm), and in or on almond hulls at 2.5 ppm, for an additional 1–year period. These tolerances will expire and are revoked on July 31, 2000. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on almonds. Section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under FIFRA section 18.

DATES: This regulation becomes effective March 17, 1999. Objections and requests for hearings must be received by EPA, on or before May 17, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number [OPP–300797], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300797], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, Crystal Mall 2 (CM #2), 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epa.gov. Copies of electronic objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 or ASCII file format. All copies of electronic objections and hearing requests must be identified by the docket control number [OPP–300797]. No Confidential Business Information (CBI) should be submitted through e-mail. Copies of electronic objections and hearing requests on this rule may be

filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Stephen Schaible, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 271, Crystal Mall 2 (CM #2), 1921 Jefferson Davis Hwy., Arlington, VA, 703 308–9362, schaible.stephen@epa.gov.

SUPPLEMENTARY INFORMATION: EPA issued a final rule, published in the **Federal Register** of April 11, 1997 (62 FR 17710) (FRL–5600–5), which announced that on its own initiative under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a and (l)(6), as amended by the Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104–170) it established time-limited tolerances for the combined residues of propiconazole and its metabolites in or on almond nutmeat and almond hulls at 0.1 ppm and 2.5 ppm, respectively, with an expiration date of July 31, 1998. EPA extended the expiration date of these tolerances to July 31, 1999 in a **Federal Register** notice published April 3, 1998 (63 FR 16437) (FRL–5781–7). EPA established the tolerances because section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under FIFRA section 18. Such tolerances can be established without providing notice or period for public comment.

EPA received a request to extend the use of propiconazole on almonds for this year growing season due to the lack of available effective alternative fungicides, and wetter-than-normal conditions. After having reviewed the submission, EPA concurs that emergency conditions exist. EPA has authorized under FIFRA section 18 the use of propiconazole on almonds for control of anthracnose in almonds.

EPA assessed the potential risks presented by residues of propiconazole in or on almonds. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. The data and other relevant material have been evaluated and discussed in the final rule of April 11, 1997 (62 FR 17710) (FRL–5600–5). Based on that data and information considered, the Agency reaffirms that extension of the time-limited tolerances will continue to meet the requirements of section 408(l)(6). Therefore, the time-limited tolerances are extended for an additional 1–year period. EPA will publish a document in the **Federal Register** to remove the revoked tolerances from the Code of Federal Regulations (CFR). Although these tolerances will expire and are revoked on July 31, 2000, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerances remaining in or on almond nutmeats and almond hulls after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA and the application occurred prior to the revocation of the tolerances. EPA will take action to revoke these tolerances earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

I. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a tolerance regulation as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which govern the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by May 17, 1999, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given under the ''ADDRESSES'' section (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding tolerance objection fee waivers, contact James Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 239, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–5697, tompkins.jim@epa.gov. Requests for waiver of tolerance objection fees should be sent to James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

II. Public Record and Electronic Submissions

EPA has established a record for this regulation under docket control number [OPP–300797] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Rm. 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

Objections and hearing requests may be sent by e-mail directly to EPA at:
opp-docket@epa.gov.

E-mailed objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this regulation, as well as the public version, as described in this unit will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official record which will also include all comments submitted directly in writing. The official record is the paper record maintained at the Virginia address in ''ADDRESSES'' at the beginning of this document.

III. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

This final rule establishes a tolerance under section 408 of the FFDCA. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4). Nor does it require any special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997).

In addition, since tolerances and exemptions that are established under section 408(l)(6) of FFDCA, such as the tolerance/exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. Nevertheless, the Agency previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

B. Executive Order 12875

Under Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to OMB a description of the extent of EPA's prior consultation with representatives of affected State, local, and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local, and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

Today's rule does not create an unfunded Federal mandate on State, local, or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

C. Executive Order 13084

Under Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

IV. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the Agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: March 3, 1999.

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

Authority: 21 U.S.C. 321(q), 346a and 371.

§ 180.434 Amended

2. In § 180.434, by amending paragraph (b) by changing the date for the commodities ''almond hull'' and ''almond nutmeat'' from ''7/31/99'' to ''7/31/00''.

[FR Doc. 99–6382 Filed 3–16–99; 8:45 am]
BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300801; FRL–6064–6]

RIN 2070–AB78

Azoxystrobin; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of azoxystrobin (methyl(*E*)-2-(2-(6-(2-cyanophenoxy)pyrimidin-4-yloxy)phenyl)-3-methoxyacrylate and its Z isomer (methyl(*Z*)-2-(2-(6-(2-cyanophenoxy)pyrimidin-4-yloxy)phenyl)-3-methoxyacrylate) in or on almond hulls, aspirated grain fractions, bananas (postharvest), canola, cucurbits, peanut hay, pistachios, potatoes, rice, stone fruits, and wheat; and residues of azoxystrobin (only) on fat of cattle, goats, hogs, horses, and sheep; meat of cattle, goats, hogs, horses, and sheep; meat byproducts of cattle, goats, hogs, horses, and sheep; and milk. Zeneca Ag Products requested these tolerances under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective March 17, 1999. Objections and requests for hearings must be received by EPA on or before May 17, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300801], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300801], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300801]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Cynthia Giles-Parker, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 249, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, 703–305–7740, giles-parker.cynthia@epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 8, 1997 (62 FR 52544)(FRL–5746–9) and December 11, 1998 (63 FR 68458)(FRL–6043–3), EPA issued notices pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a as amended by the Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104–170) announcing the filing of two pesticide petitions (PP) 8F4995 and 7F4864, for tolerances by Zeneca Ag Products, 1800 Concord Pike, P.O. Box 15458, Wilmington, DE 19850–5458. This notice included a summary of the petition prepared by Zeneca Ag Products, the registrant. There were no comments received in response to the notices of filing.

The petitions requested that 40 CFR part 180 be amended by establishing tolerances for combined residues of the fungicide azoxystrobin (methyl(*E*)-2-(2-(6-(2-cyanophenoxy)pyrimidin-4-yloxy)phenyl)-3-methoxyacrylate) and its Z isomer (methyl(*Z*)-2-(2-(6-(2-cyanophenoxy)pyrimidin-4-yloxy)phenyl)-3-methoxyacrylate) in or on almond hulls at 4.0 parts per million (ppm), bananas (postharvest) at 2.0 ppm, canola at 1.0 ppm, cucurbits at 0.3 ppm, peanut hay at 1.5 ppm, pistachios at 0.01 ppm, potatoes at 0.03 ppm, rice grain at 4.0 ppm, rice straw at 11 ppm, rice hulls at 20 ppm, stone fruits at 1.5 ppm, tree nuts at 0.01 ppm; wheat grain at 0.04 ppm, wheat bran at 0.12 ppm, wheat hay at 13.0 ppm, wheat straw at 4.0 ppm; wheat aspirated grain fractions at 15.0 ppm, and for the residues of azoxystrobin (only) in eggs at 0.4 ppm; fat of cattle, goats, hogs, horses, poultry, and sheep at 0.01 ppm; kidney of cattle at 0.06 ppm; liver of cattle, goats, horses, and sheep at 0.3 ppm; liver of hogs at 0.2 ppm; liver of poultry at 0.4 ppm; meat of cattle, goats, hogs, horses, poultry, and sheep at 0.01 ppm; and milk at 0.006 ppm.

I. Background and Statutory Findings

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal upper limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

II. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of the FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of azoxystrobin and to make a determination on aggregate exposure, consistent with section 408(b)(2), for establishment of permanent tolerances for combined residues of azoxystrobin (methyl(*E*)-2-(2-(6-(2-cyanophenoxy)pyrimidin-4-yloxy)phenyl)-3-methoxyacrylate) and its Z isomer (methyl(*E*)-2-(2-(6-(2-cyanophenoxy)pyrimidin-4-yloxy)phenyl)-3-methoxyacrylate) in or on almond hulls at 4.0 ppm, aspirated grain fractions at 10 ppm, bananas (pre-harvest and postharvest) at 2.0 ppm (of which not more than 0.1 ppm is

contained in the pulp), canola at 1.0 ppm, cucurbits at 0.3 ppm, peanut hay at 2.0 ppm, pistachios at 0.01 ppm, potatoes at 0.03 ppm, rice grain at 5.0 ppm, rice straw at 12 ppm, rice hulls at 20 ppm, stone fruits at 1.5 ppm, tree nuts at 0.010 ppm, wheat grain at 0.10 ppm, wheat bran at 0.20 ppm, wheat hay at 15 ppm, wheat straw at 4.0 ppm, and for the residues of azoxystrobin (only) in fat of cattle, goats, hogs, horses, and sheep at 0.010 ppm; meat of cattle, goats, hogs, horses, and sheep at 0.01 ppm; meat byproducts of cattle, goats, hogs, horses, and sheep at 0.010 ppm; and milk at 0.006 ppm. A permanent domestic tolerance of 0.5 ppm already exists for bananas and will be amended by this rule. Temporary tolerances already exist for fat of cattle, goats, hogs, horses, and sheep at 0.01 ppm; kidney of cattle, goats, hogs, and sheep at 0.06 ppm; liver of cattle, goats, horses, and sheep at 0.3 ppm; liver of hogs at 0.2 ppm; meat of cattle, goats, hogs, horses, and sheep at 0.01 ppm; cucurbits at 1.0 ppm; milk at 0.006 ppm; potatoes at 0.03 ppm; rice grain at 4 ppm; rice hulls at 20 ppm; and rice straw at 10 ppm. A tolerance of 0.8 ppm already exists for peaches; this will be superseded by the stone fruits tolerance of 1.5 ppm that is being established in this rule. Several of the tolerances that are being established by this rule are different from (often higher than) those proposed by Zeneca Ag Products. EPA review of the data submitted by the company lead to an Agency decision to modify the proposed tolerances. During these reviews it was also determined that azoxystrobin uses that have been registered so far do not lead to a need to establish tolerances for poultry commodities (including eggs). EPA's assessment of the exposures and risks associated with establishment of the above tolerances follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by azoxystrobin is discussed in this unit.

1. *Acute toxicity.* The acute oral toxicity study in rats of technical azoxystrobin resulted in an LD_{50} of > 5,000 milligrams/kilogram (mg/kg) (limit test) for both males and females. The acute dermal toxicity study in rats of technical azoxystrobin resulted in an LD_{50} of > 2,000 mg/kg (limit dose). The acute inhalation study of technical azoxystrobin in rats resulted in an LC_{50} of 0.962 mg/liter (mg/L) in males and 0.698 mg/L in females. In an acute oral neurotoxicity study in rats dosed once by gavage with 0, 200, 600, or 2,000 mg/kg azoxystrobin, the systemic toxicity no observable adverse effect level (NOAEL) was < 200 mg/kg and the systemic toxicity lowest observed adverse effect level (LOAEL) was 200 mg/kg, based on the occurrence of transient diarrhea in both sexes. There was no indication of neurotoxicity at the doses tested.

2. *Mutagenicity.* Azoxystrobin was negative for mutagenicity in the salmonella/mammalian activation gene mutation assay, the mouse micronucleus test, and the unscheduled DNA synthesis in rat hepatocytes/mammalian cells (*in vivo*/*in vitro* procedure study). In the forward mutation study using L5178 mouse lymphoma cells in culture, azoxystrobin tested positive for forward gene mutation at the TK locus. In the *in vitro* human lymphocytes cytogenetics assay of azoxystrobin, there was evidence of a concentration related induction of chromosomal aberrations over background in the presence of moderate to severe cytotoxicity.

3. *Rat metabolism*. In this study, azoxystrobin--unlabeled or with a pyrimidinyl, phenylacrylate, or cyanophenyl label--was administered to rats by gavage as a single dose or as 14–day repeated doses. Less than 0.5% of the administered dose was detected in the tissues and carcass up to 7 days post-dosing and most of it was in excretion-related organs. There was no evidence of potential for bioaccumulation. The primary route of excretion was via the feces, though 9- to 18% was detected in the urine of the various dose groups. Absorbed azoxystrobin appeared to be extensively metabolized. A metabolic pathway was proposed showing hydrolysis and subsequent glucuronide conjugation as the major biotransformation process. This study was classified as supplementary but upgradeable; the company has submitted data intended to upgrade the study to acceptable and these data have been scheduled for review.

4. *Sub-chronic toxicity*. i. In a 90–day rat feeding study the NOAEL was 20.4 mg/kg/day for males and females. The LOAEL was 211.0 mg/kg/day based on decreased weight gain in both sexes, clinical observations of distended abdomens and reduced body size, and clinical pathology findings attributable to reduced nutritional status.

ii. In a subchronic toxicity study in which azoxystrobin was administered to dogs by capsule for 92 or 93 days, the NOAEL for both males and females was 50 mg/kg/day. The LOAEL was 250 mg/kg/day, based on treatment-related clinical observations and clinical chemistry alterations at this dose.

iii. In a 21–day repeated-dose dermal rat study using azoxystrobin, the NOAEL for both males and females was greater than or equal to 1,000 mg/kg/day (the highest dosing regimen); a LOAEL was therefore not determined.

5. *Chronic feeding toxicity and carcinogenicity*. i. In a 2–year feeding study in rats fed diets containing 0, 60, 300, and 750/1,500 ppm (males/females), the systemic toxicity NOAEL was 18.2 mg/kg/day for males and 22.3 mg/kg/day for females. The systemic toxicity LOAEL for males was 34 mg/kg/day, based on reduced body weights, food consumption, and food efficiency; and bile duct lesions. The systemic toxicity LOAEL for females was 117.1 mg/kg/day, based on reduced body weights. There was no evidence of carcinogenic activity in this study.

ii. In a 1–year feeding study in dogs to which azoxystrobin was fed by capsule at doses of 0, 3, 25, or 200 mg/kg/day, the NOAEL for both males and females was 25 mg/kg/day and the LOAEL was 200 mg/kg/day for both sexes, based on clinical observations, clinical chemistry changes, and liver weight increases that were observed in both sexes.

iii. In a 2–year carcinogenicity feeding study in mice using dosing concentrations of 0, 50, 300, or 2,000 ppm, the systemic toxicity NOAEL was 37.5 mg/kg/day for both males and females. The systemic toxicity LOAEL was 272.4 mg/kg/day for both sexes, based on reduced body weights in both sexes at this dose. There was no evidence of carcinogenicity at the dose levels tested.

According to the new proposed guidelines for Carcinogen Risk Assessment (April, 1996), the appropriate descriptor for human carcinogenic potential of azoxystrobin is ''Not Likely.'' The appropriate subdescriptor is ''has been evaluated in at least two well conducted studies in two appropriate species without demonstrating carcinogenic effects.''

6. *Developmental and reproductive toxicity*. i. In a prenatal development study in rats gavaged with azoxystrobin at dose levels of 0, 25, 100, or 300 mg/kg/day during days 7 through 16 of gestation, lethality at the highest dose caused the discontinuation of dosing at that level. The developmental NOAEL was greater than or equal to 100 mg/kg/

day and the developmental LOAEL was > 100 mg/kg/day because no significant adverse developmental effects were observed. In this same study, the maternal NOAEL was not established; the maternal LOAEL was 25 mg/kg/day, based on increased salivation.

ii. In a prenatal developmental study in rabbits gavaged with 0, 50, 150, or 500 mg/kg/day during days 8 through 20 of gestation, the developmental NOAEL was 500 mg/kg/day and the developmental LOAEL was > 500 mg/kg/day because no treatment-related adverse effects on development were seen. The maternal NOAEL was 150 mg/kg/day and the maternal LOAEL was 500 mg/kg/day, based on decreased body weight gain.

iii. In a two-generation reproduction study, rats were fed 0, 60, 300, or 1,500 ppm of azoxystrobin. The reproductive NOAEL was 32.2 mg/kg/day. The reproductive LOAEL was 165.4 mg/kg/day; reproductive toxicity was demonstrated as treatment-related reductions in adjusted pup body weights as observed in the F1a and F2a pups dosed at 1,500 ppm (165.4 mg/kg/day).

B. Toxicological Endpoints

1. *Acute toxicity*. The Agency evaluated the existing toxicology database for azoxystrobin and did not identify any acute dietary endpoint because there were no effects of concern attributable to a single dose (exposure) in oral toxicology studies including developmental toxicity studies in the rat and rabbit and acute neurotoxicity study in the rat. Therefore, this risk assessment is not required.

2. *Short- and intermediate-term toxicity*. The Agency evaluated the existing toxicology database for short-term and intermediate-term dermal and inhalation exposure and determined that this risk assessment is not required because no dermal or systemic effects were seen in the repeated dose dermal study at the limit dose. The only registered residential use for azoxystrobin is residential turf.

3. *Chronic toxicity*. EPA has established the Reference Dose (RfD) for azoxystrobin at 0.18 mg/kg/day. This RfD is based on a NOAEL of 18.2 mg/kg/day from the rat chronic toxicity/carcinogenicity feeding study. Effects observed at the LOAEL's (34 mg/kg/day for males, 117.1 mg/kg/day for females) included reduced body weights, food consumption and efficiency. Males also had bile duct lesions. An uncertainty factor of 100 was used to allow for interspecies sensitivity and intraspecies variability. There was no evidence of increased susceptibility of infants or children to azoxystrobin. Therefore, no additional uncertainty factor to protect infants and children is needed at this time.

4. *Carcinogenicity*. The Agency determined that azoxystrobin should be classified as ''Not Likely'' to be a human carcinogen according to the proposed revised Cancer Guidelines. This classification is based on the lack of evidence of carcinogenicity in long-term rat and mouse feeding studies.

C. Exposures and Risks

1. *From food and feed uses.* Permanent tolerances have been established (40 CFR 180. 507(a)) for the combined residues of azoxystrobin (methyl(*E*)-2(2-(6-(2-cyanophenoxy)pyrimidin-4-yloxy)phenyl)-3-methoxyacrylate) and its Z isomer (methyl (*Z*)-2-(2-(6-(2-cyanophenoxy)pyrimidin-4-yloxy)phenyl)-3-methoxyacrylate)), in or on the following raw agricultural commodities: pecans at 0.01 ppm, peanuts at 0.01 ppm, peanut oil at 0.03 ppm, grapes at 1.0 ppm, bananas at 0.5 ppm, peaches at 0.80 ppm, tomatoes at 0.2 ppm, and tomato paste at 0.6 ppm. In addition, time-limited tolerances have been established for crops, processed foods and animal commodities (40 CFR 180.507(b)) at levels ranging from 0.006 ppm in milk to 20 ppm in rice hulls and including cucurbits at 1.0 ppm, rice grain at 4 ppm, rice hulls at 20 ppm, rice straw at 10 ppm, and potatoes at 0.03 ppm. Risk assessments were conducted by EPA to assess dietary exposures from azoxystrobin as follows:

i. *Acute exposure and risk*. The Agency did not conduct an acute risk assessment because no toxicological endpoint of concern was identified during review of available data.

ii. *Chronic exposure and risk*. The Dietary Exposure Evaluation Model (DEEM), a chronic exposure analysis, was used in conducting this chronic dietary risk assessment. EPA has made very conservative assumptions -- 100% of all commodities having azoxystrobin residues at the level of the tolerance with the exception of raisins and grape juice which are expected to result in an over estimation of human dietary exposure. Thus, in making a safety determination for this tolerance, the Agency is taking into account these conservative exposure assessments. The following percentages of the RfD from dietary exposure were calculated: U.S. population (48 states, all seasons), 2%; all infants (< 1 year old), 7%; nursing infants (< 1 year old), 2%; non-nursing infants (< 1 year old), 9%; children (1–6 years old), 5%; children (7–12 years old), 3% and non-Hispanic (other than black or white), 4%. The subgroups listed are infants/children and other subgroups for which the percentage of the RfD occupied is greater than the group U.S. population (48 states).

2. *From drinking water.* In the absence of reliable, available monitoring data, EPA uses models to estimate concentrations of pesticides in ground and surface water. For azoxystrobin, modeling was used to estimate surface water concentrations because of very limited surface water monitoring data. However, EPA does not use these model estimates to quantify risk. Currently, EPA uses drinking water levels of comparison (DWLOC's) as a surrogate to capture risk associated with exposure to pesticides in drinking water. A DWLOC is the concentration of a pesticide in drinking water that would be acceptable as an upper limit in light of total aggregate exposure to that pesticide from food, water, and residential uses. A DWLOC will vary depending on the residue level in foods, the toxicity endpoint and with drinking water consumption patterns and body weight for specific subpopulations. EPA believes model estimates to be overestimations of concentrations of azoxystrobin expected in drinking water. Azoxystrobin is moderately persistent in soil in the absence of light and one of its metabolites is potentially moderately mobile in coarse textured soils. The potential mobility and persistence of some degradates based on batch equilibrium studies, aerobic soil metabolism and some field dissipation studies are similar to pesticides with a potential to leach into ground water under some conditions. There is no established Maximum Contaminant Level for residues of azoxystrobin in drinking water. No health advisory levels for azoxystrobin in drinking water have been established.

i. *Acute exposure and risk*. An assessment was not conducted because no toxicological end-point of concern was identified.

ii. *Chronic exposure and risk*. Based on the chronic dietary (food) exposure estimates, chronic DWLOC's for azoxystrobin were calculated and are summarized as follows: U. S. Population (48 states) 6,200 µg/L; females (13+) (using the highest TMRC for the 5 subgroups of females), 5,200 µg/L; infants/children (using the highest TMRC for the 5 subgroups of infants/children) 1,600 µg/L and non-Hispanic (other than black or white), 6,100 µg/L. The highest EEC for azoxystrobin in surface water is from the application of azoxystrobin on grapes (39 µg/L) and is substantially lower than the DWLOCs

calculated. Therefore, chronic exposure to azoxystrobin residues in drinking water does not exceed EPA's level of concern.

3. *From non-dietary exposure.* The only registered indoor/outdoor residential use for azoxystrobin is residential turf. The Agency evaluated the existing toxicology database and determined that there are no toxicological end points of concern.

4. *Cumulative exposure to substances with common mechanism of toxicity.* Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA does not have, at this time, available data to determine whether azoxystrobin has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, azoxystrobin does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that azoxystrobin has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

D. Aggregate Risks and Determination of Safety for U.S. Population

1. *Acute risk.* There were no effects of concern attributable to a single dose (exposure) in oral toxicological studies including developmental toxicity studies in rat and rabbit and an acute neurotoxicity study in rats. Accordingly, EPA concludes that azoxystrobin does not pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit, EPA has concluded that aggregate exposure to azoxystrobin from food will utilize from 2% to 9% of the RfD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is non-nursing infants (<1 year old). EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Based on the chronic (food only) exposure, chronic DWLOC's were calculated. The lowest DWLOC of 1,600 µg/L was for infants/children (using the highest TMRC for the five subgroups of infants/children listed in the DEEM analysis). The highest Estimated Environmental Concentration (EEC) in surface water is from application to grapes (39 µg/L) and is substantially lower than the calculated DWLOC. The EEC's as a result of application to the proposed uses are no higher than those calculated for grapes. Therefore chronic exposure in drinking water does not exceed the Agency's level of concern.

3. *Short- and intermediate-term risk.* Short- and intermediate-term risk. No dermal or systemic effects were seen in the repeated dose dermal study at the limit dose. The only indoor or outdoor residential use currently registered for azoxystrobin is residential turf. EPA concluded that azoxystrobin does not pose a short- or intermediate-term risk.

4. *Aggregate cancer risk for U.S. population.* The Agency determined that azoxystrobin should be classified as ''Not Likely'' to be a human carcinogen according to the proposed revised Cancer Guidelines because there was no evidence of carcinogenicity in valid chronic toxicity studies using two species of mammals. The Agency has therefore concluded that azoxystrobin does not pose a cancer risk.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to azoxystrobin residues as a result of current use patterns.

E. Aggregate Risks and Determination of Safety for Infants and Children

1. *Safety factor for infants and children*—i. *In general.* In assessing the potential for additional sensitivity of infants and children to residues of azoxystrobin, EPA considered data from developmental toxicity studies in the rat and rabbit and a 2-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure during gestation. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and the completeness of the database unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard MOE and uncertainty factor (usually 100 for combined inter- and intra species variability) and not the additional tenfold MOE/uncertainty factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

ii. *Developmental toxicity studies*— a. *Rabbit.* In the developmental toxicity study in rabbits, developmental NOAEL was 500 mg/kg/day, at the highest dose tested (HDT). Because there were no treatment-related effects, the developmental LOAEL was greater than 500 mg/kg/day. The maternal NOAEL was 150 mg/kg/day. The maternal LOAEL of 500 mg/kg/day was based on decreased body weight gain during dosing.

b. *Rat.* In the developmental toxicity study in rats, the maternal (systemic) NOAEL was not established. The maternal LOAEL of 25 mg/kg/day at the lowest dose tested (LDT) was based on increased salivation. The developmental (fetal) NOAEL was 100 mg/kg/day (HDT).

iii. *Reproductive toxicity study. Rat.* In the 2-generation reproductive toxicity study in rats, the parental (systemic) NOAEL was 32.3 mg/kg/day. The parental LOAEL of 165.4 mg/kg/day was based on decreased body weights in males and females, decreased food consumption and increased adjusted liver weights in females, and cholangitis. The reproductive NOAEL was 32.3 mg/kg/day. The reproductive LOAEL of 165.4 mg/kg/day was based on increased weanling liver weights and decreased body weights for pups of both generations.

iv. *Pre- and post-natal sensitivity.* The pre- and post-natal toxicology data base for azoxystrobin is complete with respect to current toxicological data requirements. The results of these studies indicate that infants and children are no more sensitive to exposure than adults, based on the results of the rat and rabbit developmental toxicity studies and the 2-generation reproductive toxicity study in rats. There are no developmental effects in the rat and rabbit developmental studies and the effects

observed in the offspring in the reproduction study occur at the same dose levels in which toxicity was observed in the parents. The effects in the young are not more severe than those observed with the parents (decreased body weights in both parents and pups).

v. *Conclusion*. There is a complete toxicity database for azoxystrobin and exposure data are complete or are estimated based on data that reasonably account for potential exposures. Accordingly, EPA has determined that the standard margin of safety of infants and children and the additional tenfold safety factor can be removed.

2. *Chronic risk*. Using the exposure assumptions described in this unit, EPA has concluded that aggregate exposure to azoxystrobin from food will utilize from 2% to 9% of the RfD for infants and children. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to azoxystrobin in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD.

3. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to azoxystrobin residues.

III. Other Considerations

A. Metabolism In Plants and Animals

The qualitative nature of the residue in plants is adequately understood. A grape metabolism study was evaluated by the Agency in December, 1995 and it was determined that the residues of concern in grapes were the parent and its Z isomer. In peanut and wheat metabolism studies the major residues were also azoxystrobin and its Z isomer. Azoxystrobin does not accumulate in crop seeds or fruits. Metabolism of azoxystrobin in plants is complex, with more than 15 metabolites identified. However, these metabolites are present at low levels, typically much less than 5% of the total radioactive residue level. Based on parent being the predominant residue in the grape, wheat and peanut metabolism studies, the Agency concludes that the residues of concern in all directly treated crops are the parent and its Z isomer.

The nature of the residue in animals is adequately understood. The Agency has determined that the residue of concern in livestock is parent azoxystrobin only. This determination was based on the results of metabolism studies performed on goats and poultry. The goat metabolism study was reviewed in conjunction with PP 5F4541. The poultry metabolism study was reviewed in conjunction with PP 6F4762. Azoxystrobin and one metabolite (compound 28) were identified in egg yolk and compound 28 alone was found in liver. Residues in extracts of egg whites, muscle, and skin with underlying peritoneal fat were less than 0.01 ppm. Residues of azoxystrobin were less than 0.01 ppm at a feeding level of 1.4x in the radiolabeled study and also less than 0.01 ppm in a feeding study at 60 ppm (about 7x). As a result, there is no reasonable expectation of finite residues of azoxystrobin in poultry commodities.

The registrant submitted three analytical methods for the analysis of the subject commodities.

1. The first method, RAM 243, is a gas chromatography with nitrogen-phosphorus detection (GC/NPD) method which can be used for the analysis of cereals, processed cereals, dried beans, peas, leafy crops, bananas, soft fruits, processed soft fruits, citrus, fruiting vegetables, root crops, stone fruits, wine, and citrus juice. This method has been reviewed and validated by the Agency, and will be submitted to the Food and Drug Administration (FDA) for inclusion in PAM II.

2. The second method, RAM 260, is a GC/NPD method for the analysis of azoxystrobin and its Z isomer in crops of high lipid content. The registrant has used it for analysis of peanut kernel and hull, processed peanut, pecan kernel, coffee bean, citrus skin, and canola oil. This method has been validated by the Agency and will be submitted to the FDA for inclusion in PAM II.

3. The third method, RAM 255, uses gas chromatography with thermionic detection, nitrogen mode, for analysis of animal commodities. It has been validated by the Agency for analysis of milk and animal tissues. The laboratory will issue a written report shortly and the method will be submitted to FDA for inclusion in PAM II.

Therefore, adequate analytical methodology is available to enforce the tolerance expression. The method may be requested from: Calvin Furlow, PIRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office and telephone number: Rm. 101FF, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–5229.

B. Magnitude of Residues

Azoxystrobin has been subjected to FDA's multiresidue protocols. It could not be recovered through application of any protocol. Residues of azoxystrobin and its Z isomer are not expected to exceed the proposed tolerance levels and the submitted data support tolerance levels for combined residues of azoxystrobin (methyl(*E*)-2-(2-(6-(2-cyanophenoxy)pyrimidin-4-yloxy)phenyl)-3-methoxyacrylate) and its Z isomer (methyl(*Z*)-2-(2-(6-(2-cyanophenoxy)pyrimidin-4-yloxy)phenyl)-3-methoxyacrylate) in or on almond hulls at 4.0 ppm, aspirated grain fractions at 10 ppm, bananas (pre-harvest and postharvest) at 2.0 ppm (of which not more than 0.1 ppm is contained in the pulp), canola at 1.0 ppm, cucurbits at 0.3 ppm, peanut hay at 2.0 ppm, pistachios at 0.01 ppm, potatoes at 0.03 ppm, rice grain at 5.0 ppm, rice straw at 12 ppm, rice hulls at 20 ppm, stone fruits at 1.5 ppm, tree nuts at 0.010 ppm, wheat grain at 0.10 ppm, wheat bran at 0.20 ppm, wheat hay at 15 ppm, wheat straw at 4.0 ppm, and for the residues of azoxystrobin (only) in fat of cattle, goats, hogs, horses, and sheep at 0.010 ppm; meat of cattle, goats, hogs, horses, and sheep at 0.01 ppm; meat byproducts of cattle, goats, hogs, horses, and sheep at 0.010 ppm; and milk at 0.006 ppm. The submitted residue data support a tolerance level of 2.0 ppm for residues of azoxystrobin in or on whole bananas and a tolerance level of 0.1 ppm in or on banana pulp. The tolerance for bananas must be listed as 2.0 ppm for the combined residues of azoxystrobin and its Z isomer in/on bananas (whole fruit) and residues in banana pulp must not exceed 0.1 ppm.

C. International Residue Limits

There are no Codex, Canadian or Mexican Maximum Residue Limits (MRL) established for azoxystrobin for bananas, curcurbits, potatoes, or stone fruits.

D. Rotational Crop Restrictions

Rotational crop data were previously submitted. Based on this information, a 45–day plantback interval is appropriate for all crops other than those having tolerances for azoxystrobin and its Z isomer.

IV. Conclusion

Therefore, tolerances are established for combined residues of azoxystrobin (methyl(*E*)-2-(2-(6-(2-cyanophenoxy)pyrimidin-4-yloxy)phenyl)-3-methoxyacrylate) and its Z isomer (methyl(*Z*)-2-(2-(6-(2-cyanophenoxy)pyrimidin-4-yloxy)phenyl)-3-methoxyacrylate) in or

on almond hulls at 4.0 ppm, aspirated grain fractions at 10 ppm, bananas (preharvest and postharvest) at 2.0 ppm (of which not more than 0.1 ppm is contained in the pulp), canola at 1.0 ppm, cucurbits at 0.3 ppm, peanut hay at 2.0 ppm, pistachios at 0.01 ppm, potatoes at 0.03 ppm, rice grain at 5.0 ppm, rice straw at 12 ppm, rice hulls at 20 ppm, stone fruits at 1.5 ppm, tree nuts at 0.010 ppm, wheat grain at 0.10 ppm, wheat bran at 0.20 ppm, wheat hay at 15 ppm, wheat straw at 4.0 ppm, and for the residues of azoxystrobin (only) in fat of cattle, goats, hogs, horses, and sheep at 0.010 ppm; meat of cattle, goats, hogs, horses, and sheep at 0.01 ppm; meat byproducts of cattle, goats, hogs, horses, and sheep at 0.010 ppm; and milk at 0.006 ppm.

V. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a tolerance regulation as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which govern the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by May 17, 1999, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given under the ''ADDRESSES'' section (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this regulation. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding tolerance objection fee waivers, contact James Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 239, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305-5697, tompkins.jim@epa.gov. Requests for waiver of tolerance objection fees should be sent to James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

VI. Public Record and Electronic Submissions

EPA has established a record for this regulation under docket control number [OPP–300801] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

Objections and hearing requests may be sent by e-mail directly to EPA at: opp-docket@epa.gov.

E-mailed objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this regulation, as well as the public version, as described in this unit will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official record which will also include all comments submitted directly in writing. The official record is the paper record maintained at the Virginia address in ''ADDRESSES'' at the beginning of this document.

VII. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

This final rule establishes a tolerance under section 408(d) of the FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997).

In addition, since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. Nevertheless, the Agency previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for

the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

B. Executive Order 12875

Under Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to OMB a description of the extent of EPA's prior consultation with representatives of affected State, local, and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local, and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

Today's rule does not create an unfunded Federal mandate on State, local, or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

C. Executive Order 13084

Under Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

VIII. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the Agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: March 5, 1999.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

Authority: 21 U.S.C. 321(q), 346a and 371.

§ 180.507 [Amended]

2. In § 180.507, paragraph (a)(1), by removing from the table the commodities ''Bananas'', and ''Peaches''.

3. Section 180.507 is further amended in paragraph (a)(1) by changing the words ''raw agricultural commodities'' to read ''food commodities'', by alphabetically adding the following commodities to the table in paragraph (a)(1), by redesignating paragraph (a)(2) as paragraph (a)(3), and by adding a new paragraph (a)(2) to read as follows:

§ 180.507 Azoxystrobin; tolerances for residues General.

(a) *General.* (1) * * *

Commodity	Parts per million
Almond hulls	4.0
Aspirated grain fractions.	10
Bananas (pre-harvest and post harvest).	2.0 (of which not more than 0.1 is contained in the pulp)
Canola	1.0
Cucurbits	0.3
* * * * *	
Peanut hay	2.0
Pistachios	0.010
Potatoes	0.03
Rice grain	5.0
Rice hulls	20
Rice straw	12
Stone fruits	1.5
* * * * *	
Tree nuts	0.010
Wheat bran	0.20
Wheat grain	0.10
Wheat hay	15
Wheat straw	4.0

(2) Tolerances are established for residues of the fungicide, azoxystrobin [methyl(*E*)-2-(2-(6-(2-cyanophenoxy)pyrimidin-4-yloxy)phenyl)-3-methoxyacrylate] in or on the following food commodities.

Commodity	Parts per million
Cattle, fat	0.010
Cattle, meat	0.01
Cattle, meat byproducts	0.010
Goats, fat	0.010
Goats, meat	0.01
Goats, meat byproducts	0.010
Hogs, fat	0.010
Hogs, meat	0.01
Hogs, meat byproducts	0.010
Horses, fat	0.010
Horses, meat	0.01
Horses, meat byproducts	0.010
Milk.	0.006
Sheep, fat	0.010
Sheep, meat	0.01
Sheep, meat byproducts	0.010

* * * * *

[FR Doc. 99–6387 Filed 3–16–99; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 302 and 355

[FRL–6309–3a]

Administrative Reporting Exemptions for Certain Radionuclide Releases

AGENCY: Environmental Protection Agency (EPA).

ACTION: Technical amendment of final rule.

SUMMARY: The Environmental Protection Agency today is issuing amended language to a final rule published on March 19, 1998, (63 FR 13460) that granted exemptions from certain reporting requirements under the Comprehensive Environmental Response, Compensation, and Liability Act and the Emergency Planning and Community Right-to-Know Act.

Among other reporting exemptions, the March 19, 1998, final rule exempted from certain reporting requirements releases of naturally occurring radionuclides associated with land disturbance incidental to extraction activities, except that which occurs at uranium, phosphate, tin, zircon, hafnium, vanadium, and rare earth mines. Today's technical amendment will clarify that land disturbance incidental to extraction includes replacing in mined-out areas coal ash, earthen materials from farming and construction, or overburden or other raw materials generated from the exempted mining activities. The clarification is intended to remove misunderstanding as to which radionuclide releases are subject to the final reporting exemptions.

EFFECTIVE DATE: March 17, 1999.

ADDRESSES:

Release Notification: The toll-free telephone number of the National Response Center is 800/424–8802; in the Washington, DC metropolitan area, the number is 202/267–2675. The facsimile number for the National Response Center is 202/267–2165 and the telex number is 892427.

Docket: Copies of materials relevant to the March 19, 1998, rulemaking are contained in the U.S. EPA CERCLA Docket Office, Crystal Gateway #1, 1st Floor, 1235 Jefferson Davis Highway, Arlington, VA 22202 [Docket Number 102RQ3–RN–2]. The docket is available for inspection, by appointment only, between the hours of 9:00 a.m. and 4:00 p.m., Monday through Friday, excluding Federal holidays. Appointments to review the docket can be made by calling 703/603–9232. The public may copy a maximum of 266 pages from any regulatory docket at no cost. If the number of pages copied exceeds 266, however, an administrative fee of $25 and a charge of $0.15 per page for each page after page 266 will be incurred. The Docket Office will mail copies of materials to requestors who are outside the Washington, DC metropolitan area. The docket for the March 19, 1998, rulemaking will be kept in paper form.

FOR FURTHER INFORMATION CONTACT: The RCRA/UST, Superfund, and EPCRA Hotline at 800/424–9346 (in the Washington, DC metropolitan area, contact 703/412–9810). The Telecommunications Device for the Deaf (TDD) Hotline number is 800/553–7672 (in the Washington, DC metropolitan area, contact 703/486–3323); or the Office of Emergency and Remedial Response (5202G), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460 (contact Elizabeth Zeller 703/603–8744).

SUPPLEMENTARY INFORMATION:

Potentially Affected Entities

Entities that may be affected by this technical amendment include: (1) persons in charge of vessels or facilities that may have naturally occurring radionuclide releases into the environment that are among those granted an administrative reporting exemption by the March 19, 1998, final rule; and (2) entities that plan for or respond to such releases.

The table below lists potentially affected entities. This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other entities not listed in the table could also be affected. To determine whether your organization is affected by this action, carefully examine the changes to 40 CFR parts 302 and 355. If you have questions regarding the applicability of this action to a particular entity, consult the contact names and phone numbers listed in the preceding **FOR FURTHER INFORMATION CONTACT** section of this preamble.

POTENTIALLY AFFECTED ENTITIES

Type of entity	Examples of affected entities
Industry	Mines and entities that backfill mined-out areas.
State, Local, or Tribal Governments	State Emergency Response Commissions, Local Emergency Planning Committees.
Federal Government	National Response Center, and any Federal agency that may have radionuclide releases granted a reporting exemption.

Reasons for Today's Amendment

The March 19, 1998, final rule broadened exemptions from the CERCLA section 103 and EPCRA section 304 release reporting requirements to include releases of naturally occurring radionuclides from land disturbance incidental to extraction activities at all mines except certain categories of mines that are likely to handle raw materials with elevated radionuclide concentrations. The final rule also broadened the reporting exemptions to include releases of naturally occurring radionuclides to and from coal and coal ash piles at all sites. EPA granted these exemptions to eliminate needless reporting burdens on persons responsible for certain mine sites and coal and coal ash piles. The reporting exemptions also allow the government to better focus its resources on the most serious releases, resulting in more effective protection of public health and welfare and the environment.

Sections 302.6(c)(2) and 355.40(a)(2)(vi)(B) of the final rule stated that land disturbance incidental to extraction includes: land clearing; overburden removal and stockpiling; excavating, handling, transporting, and storing ores and other raw materials; and replacing materials in mined-out areas so long as such materials have not been beneficiated or processed and do not contain elevated radionuclide concentrations (defined as greater than 7.6 picocuries per gram or pCi/g of Uranium-238, 6.8 pCi/g of Thorium-232, or 8.4 pCi/g of Radium-226, which equal two times the upper end of the concentration range reported in the literature for typical surface soil). One person involved with a mining operation has since commented that this language can be read to suggest that mines subject to the reporting exemption would have to test their raw materials or any other materials they use to backfill mined-out areas to determine

whether they are below the stated concentration thresholds. If so, such a requirement would in fact impose a new burden on those categories of mines that were supposed to be granted regulatory relief.

EPA did not intend for the reporting exemptions to be contingent on new measurements of radionuclide concentrations in materials handled at mines. Instead, the final rule itself distinguished between the exempt mines and those mines handling ores likely to have elevated radionuclide concentrations. The final rule granted the exemption for radionuclide releases from land disturbance incidental to extraction based on the Agency's review of available data showing that overburden and raw (not beneficiated or processed) ore generated at most types of mines have radionuclide concentrations that are at or near background. EPA intended to exempt all land disturbance in the exempt mines, including replacement, so long as the replacement materials originated from an exempt activity. Therefore, mines subject to the exemption do not need to test their raw materials when backfilling mined-out areas.

In summary, mines subject to the exemption do not need to report releases associated with the placement of raw materials that they generate into mined-out areas. Moreover, mines subject to the exemption do not need to report radionuclide releases associated with the placement of coal ash or earthen materials from farming or construction into mined-out areas, because these materials have also been found to have radionuclide concentrations that are at or near background. Today's technical amendment to the final regulatory language clarifies these points and removes confusing language from the regulation.

Today's notice does not create any new or any different regulatory requirement; rather, it clarifies which activities are covered by the administrative exemptions promulgated on March 19, 1998. For this reason, EPA finds that this rule falls under the good cause exemption in section 553(b) of the Administrative Procedure Act (APA), allowing the Agency to forego prior notice and opportunity for public comment before issuing this final rule. For the same reason, EPA finds that good cause exists to provide for an immediate effective date under section 553(d) of the APA.

Administrative Requirements

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a ''significant regulatory action'' and is therefore not subject to review by the Office of Management and Budget. In addition, this action does not impose any enforceable duty, contain any unfunded mandate, or impose any significant or unique impact on small governments as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). This rule also does not require prior consultation with State, local, and tribal government officials as specified by Executive Order 12875 (58 FR 58093, October 28, 1993) or Executive Order 13084 (63 FR 27655 (May 10, 1998), or involve special consideration of environmental justice related issues as required by Executive Order 12898 (59 FR 7629, February 16, 1994). Because this action is not subject to notice-and-comment requirements under the Administrative Procedure Act or any other statute, it is not subject to the regulatory flexibility provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). This rule also is not subject to Executive Order 13045 (62 F.R. 19885, April 23, 1997) because EPA interprets E.O. 13045 as applying only to those regulatory actions that are based on health or safety risks, such that the analysis required under section 5–501 of the Order has the potential to influence the regulation. This rule is not subject to E.O. 13045 because it does not establish an environmental standard intended to mitigate health or safety risks. EPA's compliance with these statutes and Executive Orders for the underlying rule is discussed in the March 19, 1998 **Federal Register** notice.

Submission to Congress and the General Accounting Office

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of Congress and to the Comptroller General of the United States. Section 808 allows the issuing agency to make a rule effective sooner than otherwise provided by the CRA if the agency makes a good cause finding that notice and public procedure is impracticable, unnecessary or contrary to the public interest. This determination must be supported by a brief statement. 5. U.S.C. § 808(2). As stated previously, EPA has made such a good cause finding, including the reasons therefor, and established an effective date of March 17, 1999. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register.** This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Parts 302 and 355

Environmental protection, Air pollution control, Chemicals, Hazardous materials, Hazardous wastes, Reporting and recordkeeping requirements, Superfund, Water pollution control, Water supply.

Dated: February 19, 1999.

Timothy Fields, Jr.,

Acting Assistant Administrator.

For the reasons set out above, title 40, chapter I of the Code of Federal Regulations is amended as follows:

PART 302—DESIGNATION, REPORTABLE QUANTITIES, AND NOTIFICATION

1. The authority citation for part 302 continues to read as follows:

Authority: 42 U.S.C. 9602, 9603, and 9604; 33 U.S.C. 1321 and 1361.

2. Section 302.6 is amended by revising paragraph (c)(2) to read as follows:

§ 302.6 Notification requirements.

* * * * *

(c) * * *

(2) Releases of naturally occurring radionuclides from land disturbance activities, including farming, construction, and land disturbance incidental to extraction during mining activities, except that which occurs at uranium, phosphate, tin, zircon, hafnium, vanadium, monazite, and rare earth mines. Land disturbance incidental to extraction includes: land clearing; overburden removal and stockpiling; excavating, handling, transporting, and storing ores and other raw (not beneficiated or processed) materials; and replacing in mined-out areas coal ash, earthen materials from farming or construction, or overburden or other raw materials generated from the exempted mining activities.

* * * * *

PART 355—EMERGENCY PLANNING AND NOTIFICATION

3. The authority citation for part 355 continues to read as follows:

Authority: 42 U.S.C. 11002, 11004, and 11048.

4. Section 355.40 is amended by revising paragraph (a)(2)(vi)(B) to read as follows:

§ 355.40 Emergency release notification.

(a) * * *

(2) * * *

(vi) * * *

(B) Naturally from land disturbance activities, including farming, construction, and land disturbance incidental to extraction during mining activities, except that which occurs at uranium, phosphate, tin, zircon, hafnium, vanadium, monazite, and rare earth mines. Land disturbance incidental to extraction includes: land clearing; overburden removal and stockpiling; excavating, handling, transporting, and storing ores and other raw (not beneficiated or processed) materials; and replacing in mined-out areas coal ash, earthen materials from farming or construction, or overburden or other raw materials generated from the exempted mining activities.

* * * * *

[FR Doc. 99–6512 Filed 3–16–99; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL EMERGENCY MANAGEMENT AGENCY

44 CFR Part 61

RIN 3067–AC96

National Flood Insurance Program (NFIP); Insurance Coverage and Rates

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Final rule.

SUMMARY: We (the Federal Insurance Administration) are increasing the amount of premium you (the flood insurance policyholder) pay for flood insurance coverage for ''pre-FIRM'' buildings in coastal areas subject to high velocity waters, such as storm surges, and wind-driven waves (''V'' zones). (''Pre-FIRM'' buildings are those whose construction was started before January 1, 1975, or the effective date of a community's Flood Insurance Rate Map (FIRM), whichever is later. Pre-FIRM buildings and their contents are eligible for subsidized rates.) We are increasing rates for pre-FIRM, V-zone properties to recognize the inherently greater flood risk of these properties.

EFFECTIVE DATE: This rule is effective on May 1, 1999.

FOR FURTHER INFORMATION CONTACT: Charles M. Plaxico, Jr., Federal Emergency Management Agency, Federal Insurance Administration, 500 C Street, SW., room 840, Washington, DC 20472, 202–646–3422, (facsimile) 202–646–4327, or (email) *charles.plaxico@fema.gov*. 202–646–4536, or (email) *rule@fema.gov*.

SUPPLEMENTARY INFORMATION: We proposed a rule at 64 FR 3909, January 26, 1999, that would increase the premium rates that we charge under the National Flood Insurance Program for pre-FIRM, V-zone properties. We received comments from: the Association of State Floodplain Managers, Inc., the Amite River Basin Drainage and Water Conservation District, and the Coast Alliance.

The *Association of State Floodplain Managers, Inc.* raised three issues. The first issue deals with the subsidy. The Association said that ''we believe that any rate increase, however justified, needs to be made in the context established by Congress—that owners of buildings constructed before the communities joined the NFIP are intended to be subsidized.'' This rule does not eliminate the subsidy for pre-FIRM, V-zone structures. It only reduces the subsidy. The change in rates for the pre-FIRM, V-zone policyholders, currently paying an average annual premium of $440, will result in an average increase of about seven percent. The rule remains consistent with the National Flood Insurance Program's enabling legislation and the discretionary authority granted to FEMA to administer the program.

The second issue the Association raised is that the National Flood Insurance Reform Act of 1994 requires FEMA to conduct a study ''of the impact of reducing the subsidy of pre-FIRM policies.'' The Association pointed out correctly that FEMA has not yet finished that study. However, the Association's comment incorrectly characterizes the nature of the study, which involves examining economic impacts of eliminating the subsidy by charging full actuarial premiums to pre-FIRM structures. Our current regulatory action calls for a modest rate increase for pre-FIRM, V-zone properties and does not need to await completion of the study.

The Association's third issue is that ''any rate increase must be part of an overall effort to evaluate all measures to reduce flood losses, and such measures must not be based solely on increasing income by increasing the cost of insurance, but needs to focus on mitigation measures to reduce claims against the NFIP.'' We have not forsaken nor do we intend to forsake mitigation efforts in favor of merely raising premiums for a small group of policyholders. Experience shows us that we can make small improvements to the program without jeopardizing or delaying larger initiatives such as the agency's repetitive for dealing with properties with multiple flood losses.

The *Amite River Basin Drainage and Water Conservation District* agreed with our overall objective of minimizing losses, but disagreed with the rule as proposed saying that ''we do not agree on the proposed rules to increase the subsidized rates for pre-FIRM properties in A and V zones.'' The District went on to say that any ''increase in subsidized insurance rates should be considered in the context of an overall strategy and program to reduce flood losses at this time, which FEMA has not done. The overall strategy and program should include a very critical and important 'phase-out' program that will lead us from a 'high loss' status to a 'low loss' status. This will require time (years) and funding at the federal, state, and local level.''

There are several misunderstandings by the District. First, the rule does not affect pre-FIRM, A-zone properties. The rule affects only the rates for pre-FIRM, V-zone properties. The affected properties currently constitute a little more than one percent of the National Flood Insurance Program's policies in force. Second, our action complements rather than stands apart from other initiatives that FEMA has undertaken or is currently developing, particularly with regard to structures with multiple flood losses. The agency is currently looking at permanent solutions, including funding, technical assistance, and insurance approaches, to the recurring problems of multiple-flood-loss structures. Taking this action now in no way diminishes any of those other initiatives. Third, we have phased in rate increases for pre-FIRM properties over time. The last time we increased subsidized premium rates was in 1996. So we believe we are consistent with the District's recommendation for a phased-in approach.

The *Coast Alliance* agreed with the proposed rule saying, ''We support the Federal Emergency Management Agency's proposed rule to increase the amount of premium paid by the policyholder for flood insurance for 'pre-FRM' buildings in coastal areas subject to high velocity waters and wind-driven waves ('V' zones).'' The Coast Alliance, however, expressed concern about any availability of subsidized or non-actuarial premium rates in coastal areas and recommended that ''FEMA must take the next logical step to deny new flood policies in high risk areas.'' We believe that this recommendation should be dealt with legislatively, as were the two precedents for denying flood insurance coverage in certain geographical areas at 42 U.S.C.

4028–4029. As required by the National Flood Insurance Reform Act of 1994, we are evaluating the impact of erosion hazards on the NFIP. Part of that study will explore the economic impact of denying insurance in areas subject to coastal erosion. It is premature for us to comment on the Alliance's recommendation before we complete that study and report to Congress.

In summary, we believe that targeting a particularly risky class of properties with higher premium rates supports FEMA's overall program of loss reduction. It more accurately reflects the loss exposure of pre-FIRM, V-zone properties, which are at a greater exposure to flood loss than pre-FIRM, A-zone properties. Also, it helps make policyholders aware of the danger of their V-zone properties.

National Environmental Policy Act

Under section 102(2)(C) of the National Environmental Policy Act of 1969, 42 U.S.C. 4371 *et seq.*, and the implementing regulations of the Council on Environmental Quality, 40 CFR parts 1500–1508, we conducted an environmental assessment of this rule. The assessment concludes that there will be no significant impact on the human environment as a result of the issuance of this final rule, and no Environmental Impact Statement will be prepared. Copies of the environmental assessment are on file for inspection through the Rules Docket Clerk, Federal Emergency Management Agency, room 840, 500 C Street SW., Washington, DC 20472.

Executive Order 12866, Regulatory Planning and Review

This rule is not a significant regulatory action within the meaning of § 2(f) of E.O. 12866 of September 30, 1993, 58 FR 51735, but attempts to adhere to the regulatory principles set forth in E.O. 12866. The rule has not been reviewed by the Office of Management and Budget under E.O. 12866.

Paperwork Reduction Act

This rule does not contain a collection of information and therefore is not subject to the provisions of the Paperwork Reduction Act of 1995.

Executive Order 12612, Federalism

This rule involves no policies that have federalism implications under E.O. 12612, Federalism, dated October 26, 1987.

Executive Order 12778, Civil Justice Reform

This rule meets the applicable standards of § 2(b)(2) of E.O. 12778.

List of Subjects in 44 CFR Part 61

Flood insurance.

Accordingly, we amend 44 CFR Part 61 as follows:

PART 61—INSURANCE COVERAGE AND RATES

1. The authority citation for Part 61 continues to read as follows:

Authority: 42 U.S.C. 4001 *et seq.*; Reorganization Plan No. 3 of 1978, 43 FR 41943, 3 CFR, 1978 Comp., p. 329; E.O. 12127 of Mar. 31, 1979, 44 FR 19367, 3 CFR, 1979 Comp., p. 376.

2. We are revising Section 61.9 to read as follows:

§ 61.9 Establishment of chargeable rates.

(a) Under section 1308 of the Act, we are establishing annual chargeable rates for each $100 of flood insurance coverage as follows for pre-FIRM, A zone properties, pre-FIRM, V zone properties, and emergency program properties.

Type of structure	A zone rates[1] per year per $100 coverage on:		V zone rates[2] per year per $100 coverage on:	
	Structure	Contents	Structure	Contents
1. Residential:				
No Basement or Enclosure	.68	.79	.82	.95
With Basement or Enclosure	.73	.79	.88	.95
2. All other including hotels and motels with normal occupancy of less than 6 months duration:				
No Basement or Enclosure	.79	1.58	.95	1.90
With Basement or Enclosure	.84	1.58	1.01	1.90

[1] A zones are zones A1–A30, AE, AO, AH, and unnumbered A zones.
[2] V zones are zones V1–V30, VE, and unnumbered V zones.

(b) We will charge rates for contents in pre-FIRM buildings according to the use of the building.

(c) A-zone rates for buildings without basements or enclosures apply uniformly to all buildings throughout emergency program communities.

(Catalog of Federal Domestic Assistance No. 83.100, ''Flood Insurance''; No. 83.516, ''Disaster Assistance'')

Dated: March 11, 1999.

Jo Ann Howard

Administrator,

Federal Insurance Administration.

[FR Doc. 99–6466 Filed 3–16–99; 8:45 am]

BILLING CODE 6718–03–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

RIN 1018–AE48

Endangered and Threatened Wildlife and Plants; Determination of Endangered Status for Catesbaea Melanocarpa

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: We, the U.S. Fish and Wildlife Service, determine *Catesbaea melanocarpa* (no common name) to be an endangered species under the Endangered Species Act of 1973, as amended (Act). *Catesbaea melanocarpa* is known from Puerto Rico, St. Croix in the U.S. Virgin Islands, Barbuda, Antigua, and Guadeloupe. In Puerto Rico, it is currently known from only one location in Cabo Rojo; in the U.S. Virgin Islands, it is known from one location near Christiansted, St. Croix. Both populations are located on privately-owned land subject to intense pressure for development for residential, tourist, and industrial purposes. This final rule implements the Federal protection and recovery provisions afforded by the Act for *C. melanocarpa*.

EFFECTIVE DATE: April 16, 1999.

ADDRESSES: The complete file for this rule is available for inspection, by appointment, during normal business

hours, at the U.S. Fish and Wildlife Service, Boquerón Field Office, P.O. Box 491, Boquerón, Puerto Rico 00622.

FOR FURTHER INFORMATION CONTACT: Ms. Susan Silander, Botanist, at the above address (telephone 787/851–7297; facsimile 787/851–7440).

SUPPLEMENTARY INFORMATION:

Background

The German collector Hienrich Rudolph Wullschlaegel first discovered *Catesbaea melanocarpa* (no common name) in the mid-nineteenth century on the British island of Antigua. In about 1881, the Danish collector Baron H. F. A. von Eggers found *C. melanocarpa* in St. Croix, U.S. Virgin Islands, and in 1886, the German collector Paul Sintenis found it in Guánica, Puerto Rico. Although other herbariums maintain duplicate specimens, bombing during World War II destroyed the original collections in the herbarium at Berlin-Dahlem, Germany.

Howard (1989) and Proctor (1991) reported the species from Barbuda and Guadeloupe, islands of the Lesser Antilles. Little is known about its status on these islands; the Center for Plant Conservation (1992) describes *C. melanocarpa* as rare on Antigua. It was not rediscovered in St. Croix until 1988 and, to date, it has not been relocated in the Gúnica, Puerto Rico, area. The St. Croix population, located near Christiansted, consists of about 24 individual plants (Breckon and Kolterman 1993). In 1995, a single plant was located in Cabo Rojo, Puerto Rico (Puerto Rico Planning Board 1995). One specimen, collected in 1974, located in the herbarium in San Juan, apparently originated from the Susúa Commonwealth Forest. However, this specimen is sterile and poorly developed; therefore, its identification cannot be confirmed.

Catesbaea melanocarpa, of the family Rubiaceae, belongs to a genus that consists of ten or more species of spiny shrubs. Most are confined to the Antilles, but some may extend into the Bahamas and the Florida Keys. In Puerto Rico, two species are known—*C. melanocarpa* and *C. parviflora*. These two species are differentiated by the size and color of the fruits; black and larger, 5 to 6 millimeters (mm) (.19 to .23 inches (in)) in diameter, in the former, and white and smaller, 2 to 4 mm (.07 to .15 in) in diameter in the latter (Breckon and Kolterman 1993, Britton and Wilson 1925). Some authors note that *C. melanocarpa* may be a synonym or variant of *C. parviflora* (Howard 1989, Proctor 1991) and recommend further review. However, Breckon and Kolterman (1993) and the Center for Plant Conservation (1992) recommend its protection due to the extremely small number of individuals currently known, the intense pressure for development in these areas, and the potential for an appreciable loss of the species' genetic diversity.

Catesbaea melanocarpa is a branching shrub that may reach approximately 3 meters (9.8 feet) in height. Spines, 1 to 2 centimeters (.39 to .78 in) long, occur on the stems between the leaves. Leaves are small, from 5 to 25 mm (.19 to 1.0 in) long and 2 to 15 mm (.07 to .58 in) wide, often in clusters, and the small stipules (appendages at the base of the leaf stalk) are deciduous (shed seasonally). The flowers are white, solitary or paired, and almost sessile (attached directly at the base) in the axils. The corolla (petals) is funnelform and from 8 to 10 mm (.31 to .39 in) long. The fruit is globe-shaped, 5 to 6 mm (.19 to .23 in) in diameter, and black with a brittle fruit wall. The 2-celled fruit contains five to seven seeds in each cell (Proctor 1991).

Previous Federal Action

We had identified *Catesbaea melanocarpa* as a Category 2 species in notices of review published in the **Federal Register** on February 21, 1990 (55 FR 6184), and September 30, 1993 (58 FR 51144). Prior to 1996, a Category 2 species was one that we were considering for possible addition to the Federal List of Endangered and Threatened Plants, but for which conclusive data on biological vulnerability and threat were not available to support a proposed rule. We discontinued designation of Category 2 species in the February 28, 1996, Notice of Review (61 FR 7596). We approved *Catesbaea melanocarpa* as a candidate species on September 6, 1995, and identified as such in the 1996 Notice of Review. A candidate species is now defined as a species for which we have on file sufficient information to propose it for protection under the Act. This small shrub is considered a ''critical'' plant species by the Natural Heritage Program of the Puerto Rico Department of Natural and Environmental Resources. The Center for Plant Conservation (1992) has assigned the species a Priority Status of A (a species which could possibly go extinct in the wild in the next 5 years). On December 16, 1997, we published a proposed rule to list *Catesbaea melanocarpa* (62 FR 65783).

On May 8, 1998, we published Listing Priority Guidance for Fiscal Years 1998 and 1999 (63 FR 25502). The guidance clarifies the order in which we will process rulemakings, giving highest priority (Tier 1) to processing emergency rules to add species to the Lists of Endangered and Threatened Wildlife and Plants (Lists); second priority (Tier 2) to processing final determinations on proposals to add species to the Lists, processing new proposals to add species to the Lists, processing administrative findings on petitions (to add species to the Lists, delist species, or reclassify listed species), and processing a limited number of proposed or final rules to delist or reclassify species; and third priority (Tier 3) to processing proposed or final rules designating critical habitat. Processing of this final rule is a Tier 2 action.

Summary of Comments and Recommendations

In the December 16, 1997, proposed rule and associated reports of information that might contribute to the development of a final rule. We contacted appropriate agencies of the Commonwealth of Puerto Rico and the Territory of the Virgin Islands, Federal agencies, scientific organizations and other interested parties and requested their comments. We published a newspaper notice inviting public comment in *El Nuevo Dia* on January 27, 1998, and in *The Daily News of the Virgin Islands* on January 31, 1998. We also solicited the expert opinions of four appropriate and independent specialists regarding the pertinent scientific or commercial data and assumptions relating to taxonomy, population models, and biological and ecological information for this species. We did not receive any comments from these experts. We received two letters of comment, neither of which opposed the listing. The Puerto Rican Planning Board did not have comments on the listing, but stated that they would use the information in the evaluation of projects that might affect the species. The U.S. Department of Housing and Urban Development did not have comments concerning the listing. A public hearing was neither requested nor held.

Summary of Factors Affecting the Species

After a thorough review and consideration of all information available, we have determined that *Catesbaea melanocarpa* should be classified as an endangered species. We followed procedures found at Section 4(a)(1) of the Act and regulations implementing the listing provisions of the Act (50 CFR part 424). We may determine a species to be endangered or

threatened due to one or more of the five factors described in section 4(a)(1). These factors and their application to *Catesbaea melanocarpa* Krug and Urban are as follows:

A. The Present or Threatened Destruction, Modification, or Curtailment of Its Habitat or Range

Catesbaea melanocarpa is known only from Puerto Rico, St. Croix, Barbuda, Antigua, and Guadeloupe. Available information indicates that it is rare on Antigua (Center for Plant Conservation 1992). In Puerto Rico, only a single plant is known to exist. This plant is located on privately owned land, in Cabo Rojo, currently proposed for a residential/tourist development, consisting of a hotel, condo-hotel, residential villas and lots, a golf course, and other associated facilities. In St. Croix, only one population consisting of about 24 plants is known to exist. This population is located on privately-owned land near Christiansted and is subject to pressure for development.

B. Overutilization for Commercial, Recreational, Scientific, or Educational Purposes

We have not received information documenting that the use of the species for such purposes is a factor in its decline. Although overcollection has not been documented, the extremely small population size and limited range make this species vulnerable to overcollection (see ''CRITICAL HABITAT'' below).

C. Disease or Predation

Disease and predation have not been documented as factors in the decline of this species.

D. The Inadequacy of Existing Regulatory Mechanisms

The Commonwealth of Puerto Rico's regulations recognize and provide protection for certain Commonwealth listed species. However, *Catesbaea melanocarpa* is not yet on the Commonwealth list and therefore receives no special protection. Federal listing will provide immediate protection under the Act and, by virtue of an existing section 6 cooperative agreement with the Commonwealth, it will also ensure the addition of this species to the Commonwealth list and enhance possibilities for funding needed research. The Territory of the U.S. Virgin Islands has amended an existing regulation to provide for protection of endangered and threatened wildlife and plants. The U.S. Virgin Islands consider *Catesbaea melanocarpa* to be endangered (see ''Available Conservation Measures'' for discussion of prohibitions). As with the Commonwealth, the existence of a section 6 cooperative agreement with the Service will increase possibilities for funding needed research with this plant.

E. Other Natural or Manmade Factors Affecting Its Continued Existence

One of the most important factors affecting the continued survival of this species is its limited distribution. Because so few individuals are known to occur in limited areas, the risk of extinction is extremely high. Catastrophic natural events, such as hurricanes, may dramatically affect forest species composition and structure, felling large trees and creating numerous canopy gaps. Breckon and Kolterman (1993) documented the loss of individuals in St. Croix following the passing of hurricane Hugo in 1989. In addition, the limited gene pool may depress reproductive vigor.

We have carefully assessed the best scientific and commercial information available regarding the past, present, and future threats faced by this species in determining to make this rule final. Based on this evaluation, the preferred action is to list *Catesbaea melanocarpa* as endangered. Within the United States, the species occurs in only one locality in Puerto Rico and one in St. Croix, U.S. Virgin Islands. Deforestation for residential and tourist development are imminent threats to the survival of the species. Because this species is in danger of extinction throughout all or significant portion of its range, it meets the definition of endangered under the Act. We discuss the reasons for not designating critical habitat for this species in the ''Critical Habitat'' section below.

Critical Habitat

Critical habitat is defined in section 3 of the Act as: (i) the specific areas within the geographical area occupied by a species, at the time it is listed in accordance with the Act, on which are found those physical or biological features (I) essential to the conservation of the species and (II) that may require special management considerations or protection; and (ii) specific areas outside the geographic area occupied by a species at the time it is listed, upon a determination that such areas are essential for the conservation of the species. ''Conservation'' means the use of all methods and procedures needed to bring the species to the point at which listing under the Act is no longer necessary.

Section 4(a)(3) of the Act, as amended, and implementing regulations (50 CFR 424.12) require that, to the maximum extent prudent and determinable, we designate critical habitat at the time the species is determined to be endangered or threatened. Our regulations (50 CFR 424.12(a)(1)) state that the designation of critical habitat is not prudent when one or both of the following situations exist—(1) the species is threatened by taking or other human activity, and identification of critical habitat can be expected to increase the degree of threat to the species, or (2) such designation of critical habitat would not be beneficial to the species. We find that designation of critical habitat for *Catesbaea melanocarpa* is not prudent because such designation would not be beneficial to the species and may increase the threats to the species.

Critical habitat designation, by definition, directly affects only Federal agency actions through consultation under section 7(a)(2) of the Act. Section 7(a)(2) requires Federal agencies to ensure that activities they authorize, fund, or carry out are not likely to jeopardize the continued existence of a listed species or destroy or adversely modify its critical habitat. Neither of the two known populations of *Catesbaea melanocarpa* occur on Federal land. However, Federal involvement with this species may occur through the use of Federal funding for rural housing and development on non-Federal lands. The use of such funding for projects affecting occupied habitat for this species would be subject to review under section 7(a)(2), whether or not critical habitat was designated. The precarious status of *C. melanocarpa* is such that any adverse modification or destruction of its occupied habitat would also jeopardize its continued existence. This would also hold true as the species recovers and its numbers increase. In addition, we believe that notification of Federal agencies of the areas where these plants occur can be accomplished without the designation of critical habitat. All involved parties and landowners have been notified of the location and importance of protecting this species' habitat. For these reasons, we believe that designation of currently occupied habitat of this species as critical habitat would not result in any additional benefit to the species and that such designation is not prudent.

Potential introduction sites within unoccupied lands occur on lands under Federal management (Cabo Rojo, Laguna Cartagena, and Sandy Point National Wildlife Refuges) and Commonwealth management (Guánica Commonwealth Forest). As managers of these

subtropical dry forest lands, the Service and the Puerto Rico Department of Natural and Environmental Resources are actively involved in conservation activities. Both agencies are committed to the protection of these forested areas and would minimize or avoid any impacts to such habitat. Any introduction would be closely coordinated with the area managers. Introduction of this species onto unoccupied private lands likely would not be pursued because suitable habitat under private ownership occurs only in very small patches which are interspersed among developed areas and are too small for development of viable populations. For these reasons, we believe that designation of currently unoccupied habitat of this species as critical habitat would not result in any additional benefit to the species and, therefore, such designation is not prudent.

To publish precise maps and descriptions of critical habitat in the **Federal Register**, as required in a proposal for critical habitat, would make this plant vulnerable to incidents of collection and vandalism and, therefore, could contribute to the decline of the species. The Center for Plant Conservation (1992) described *Catesbaea melanocarpa* as a ''handsome little shrub'' with good horticulture potential. The listing of this species as endangered publicizes its rarity and, thus, may make this plant more attractive to researchers, collectors, and those wishing to see rare plants. Additionally, designating critical habitat would not only provide specific location information to potential vandals, but the effects of a critical habitat designation on private property are often misunderstood. This misunderstanding can create a negative perception of the species' listing and could contribute to the threat of vandalism or intentional habitat destruction. Because of its few populations, *Catesbaea melanocarpa* is especially susceptible to adverse consequences resulting from the loss of individuals or habitat damage due to vandalism. We find that the increased degree of threat from vandalism outweighs any benefits that might derive from the designation of critical habitat.

Available Conservation Measures

Conservation measures provided to species listed as endangered or threatened under the Act include recognition, recovery actions, requirements for Federal protection, and prohibitions against certain practices. Recognition through listing encourages and results in conservation actions by Federal, Commonwealth, Territory, and private agencies, groups and individuals. The Act provides for possible land acquisition and cooperation with the Commonwealth and/or Territory, and requires that recovery actions be carried out for all listed species. We initiate such actions following listing. We discuss the protection required of Federal agencies and the prohibitions against certain activities involving listed plants, in part, below.

Section 7(a) of the Act, as amended, requires Federal agencies to evaluate their actions with respect to any species that is proposed or listed as endangered or threatened and with respect to its critical habitat, if any is being designated. Regulations implementing this interagency cooperation provision of the Act are codified at 50 CFR part 402. Section 7(a)(2) requires Federal agencies to ensure that activities they authorize, fund, or carry out are not likely to jeopardize the continued existence of the species or to destroy or adversely modify its critical habitat. If a Federal action may affect a listed species or its critical habitat, the responsible Federal agency must enter into formal consultation with us. We are not designating critical habitat for this species, as discussed above. Federal involvement may occur through the use of Federal funding for rural housing and development (for example, the Rural Development or Housing and Urban Development).

The Act and its implementing regulations set forth a series of general trade prohibitions and exceptions that apply to all endangered plants. All prohibitions of section 9(a)(2) of the Act, implemented by 50 CFR 17.61, apply. These prohibitions, in part, make it illegal for any person subject to the jurisdiction of the United States to import or export any endangered plant, transport it in interstate or foreign commerce in the course of commercial activity, sell or offer it for sale in interstate or foreign commerce, or remove and reduce to possession the species from areas under Federal jurisdiction. In addition, for plants listed as endangered, the Act prohibits the malicious damage or destruction on areas under Federal jurisdiction and the removal, cutting, digging up, or damaging or destroying of endangered plants in knowing violation of any Commonwealth or Territorial law or regulation, including Commonwealth or Territorial criminal trespass law. Certain exceptions can apply to agents of the Service and Commonwealth and Territorial conservation agencies.

The Act and 50 CFR 17.62 and 17.63 also provide for the issuance of permits to carry out otherwise prohibited activities involving endangered species under certain circumstances. Such permits are available for scientific purposes and to enhance the propagation and survival of the species. We anticipate that few trade permits for this species will ever be sought or issued, since the species is neither common in cultivation nor common in the wild.

It is our policy, published in the **Federal Register** on July 1, 1994 (59 FR 34272), to identify to the maximum extent practicable those activities that would or would not constitute a violation of section 9 of the Act at the time of listing. The intent of this policy is to increase public awareness of the effect of listing on proposed or ongoing activities. The only known populations of *Catesbaea melanocarpa* are located on privately-owned land. Since there is no Federal ownership, and the species is not currently in trade, the only potential section 9 involvement would relate to removing or damaging the plant in knowing violation of Commonwealth or Territorial law, or in knowing violation of Commonwealth or Territorial criminal trespass law. Section 15.01(b) of the Commonwealth ''Regulation to Govern the Management of Threatened and Endangered Species in the Commonwealth of Puerto Rico'' states: ''It is illegal to take, cut, mutilate, uproot, burn or excavate any endangered plant species or part thereof within the jurisdiction of the Commonwealth of Puerto Rico.'' The U.S. Virgin Islands' regulation states that ''no person may harass, injure or kill, or attempt to do the same, or sell or offer for sale any specimen, or parts or produce of such specimen, of an endangered or threatened species.'' We are not aware of any otherwise lawful activities being conducted or proposed by the public that will be affected by this listing and result in a violation of section 9.

You should direct questions regarding whether specific activities will constitute a violation of section 9 to the Field Supervisor of the Service's Boquerón Field Office (see ADDRESSES section). You may request copies of the regulations on listed species from and address inquiries regarding prohibitions and permits to the U.S. Fish and Wildlife Service, Ecological Services, 1875 Century Boulevard, Atlanta, Georgia 30345–3301 (telephone 404/679–7313).

National Environmental Policy Act

We have determined that an Environmental Assessment and Environmental Impact Statement, as defined under the authority of the National Environmental Policy Act of 1969, need not be prepared in connection with regulations adopted pursuant to section 4(a) of the Endangered Species Act of 1973, as amended. We published a notice outlining our reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244).

Required Determinations

This rule does not contain any new collections of information other than those already approved under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*, and assigned Office of Management and Budget clearance number 1018–0094. For additional information concerning permit and associated requirements for endangered plants, see 50 CFR 17.62 and 17.63.

References Cited

Breckon, G. and D. Kolterman. 1993. *Catesbaea melanocarpa* Krug & Urban [Rubiaceae]. Final Report under Cooperative Agreement No. 14–16–0004–92–970 between the U.S. Fish and Wildlife Service and the University of Puerto Rico, Mayaguez Campus.

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Center for Plant Conservation. 1992. Report on the Rare Plants of Puerto Rico. Missouri Botanical Garden, St. Louis, Missouri.

Howard, R.A. 1989. Flora of the Lesser Antilles. Leeward and Windward Islands. Volume 6. Dicotyledoneae—Part 3. Arnold Arboretum, Harvard University, Jamaica Plain, Massachusetts. 658 pp.

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Proctor, G. R. 1991. Puerto Rican plant species of special concern. Status and recommendations. Publicación Científica Miscelánea No. 2. Departamento de Recursos Naturales de Puerto Rico. San Juan, Puerto Rico. 197 pp.

Puerto Rico Planning Board. 1995. Draft Environmental Impact Statement for Monte Carlo Resort and Boqueron Bay Site. San Juan, Puerto Rico. 88 pp.

Author

The primary author of this final rule is Ms. Susan Silander (see **ADDRESSES** section).

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

Regulation Promulgation

Accordingly, we amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations as follows:

PART 17—[AMENDED]

1. The authority citation for Part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 16 U.S.C. 1531–1544; 16 U.S.C. 4201–4245; Pub. L. 99–625, 100 Stat. 3500, unless otherwise noted.

2. Amend Section 17.12(h) by adding the following, in alphabetical order under FLOWERING PLANTS, to the List of Endangered and Threatened Plants:

17.12 Endangered and threatened plants.

* * * * *

(h) * * *

Species		Historic range	Family	Status	When listed	Critical habitat	Special rules
Scientific name	Common name						
FLOWERING PLANTS							
*	*	*	*	*	*		*
Catesbaea melanocarpa	None.	U.S.A.(PR, VI), Antigua, Barbuda, Guadeloupe.	Rubiaceae	E	657	NA	NA
*	*	*	*	*	*		*

Dated: March 1, 1999.

Jamie Rappaport Clark,

Director, Fish and Wildlife Service.

[FR Doc. 99–6444 Filed 3–16–99; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 961204340–7087–02; I.D. 031299A]

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Coastal Migratory Pelagic Resources of the Gulf of Mexico and South Atlantic; Closure

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Closure.

SUMMARY: NMFS closes the commercial fishery for king mackerel in the exclusive economic zone (EEZ) in the Florida east coast subzone. This closure is necessary to protect the overfished Gulf king mackerel resource.

DATES: Effective 12:01 a.m., local time, March 13, 1999, through March 31, 1999.

FOR FURTHER INFORMATION CONTACT: Mark Godcharles, 727–570–5305.

SUPPLEMENTARY INFORMATION: The fishery for coastal migratory pelagic fish (king mackerel, Spanish mackerel, cero, cobia, little tunny, dolphin, and, in the Gulf of Mexico only, bluefish) is managed under the Fishery Management Plan for the Coastal Migratory Pelagic Resources of the Gulf of Mexico and South Atlantic (FMP).

The FMP was prepared by the Gulf of Mexico and by the South Atlantic Fishery Management Councils (Councils) and is implemented under the authority of the Magnuson-Stevens Fishery Conservation and Management Act by regulations at 50 CFR part 622.

Based on the Councils' recommended total allowable catch and the allocation ratios in the FMP, NMFS implemented a commercial quota for the Gulf of Mexico migratory group of king mackerel in the Florida east coast subzone of 1.17 million lb (0.53 million kg) (50 CFR 622.42(c)(1)(i)(A)(*1*). The Florida east coast subzone extends from 25°20.4' N. lat. (due east of the Dade/Monroe County, FL, boundary) to 29°25' N. lat. (due east of the Flagler/Volusia County, FL, boundary) through March 31, 1999.

Under 50 CFR 622.43(a)(3), NMFS is required to close any segment of the king mackerel commercial fishery when its quota has been reached, or is projected to be reached, by filing a notification at the Office of the Federal Register. NMFS has determined that the commercial quota of 1.17 million lb (0.53 million kg) for Gulf group king mackerel for vessels fishing in the Florida east coast subzone was reached on March 12, 1999. Accordingly, the commercial fishery for king mackerel for such vessels in the Florida east coast subzone is closed effective 12:01 a.m., local time, March 13, 1999, through March 31, 1999. The closure remains in effect until April 1, 1999, when the boundary separating the Gulf from the Atlantic migratory group of king mackerel shifts from the east coast to the west coast of Florida.

Except for a person aboard a charter vessel or headboat, during the closure, no person aboard a vessel for which a commercial permit for king mackerel has been issued may fish for Gulf group king mackerel in the EEZ in the closed zones or retain Gulf group king mackerel in or from the EEZ of the closed zones. A person aboard a vessel that has a valid charter vessel/headboat permit for coastal migratory pelagic fish may continue to retain king mackerel in or from the closed zones under the bag and possession limits set forth in 50 CFR 622.39(c)(1)(ii) and (c)(2), provided the vessel is operating as a charter vessel or headboat. A charter vessel or headboat that also has a commercial king mackerel permit is considered to be operating as a charter vessel or headboat when it carries a passenger who pays a fee or when there are more than three persons aboard, including operator and crew.

During the closure, king mackerel from the closed zones or subzones taken in the EEZ, including those harvested under the bag and possession limits, may not be purchased or sold. This prohibition does not apply to trade in king mackerel from the closed zones that were harvested, landed ashore, sold prior to the closure, and held in cold storage by a dealer or processor.

Classification

This action is taken under 50 CFR 622.43(a)(3) and is exempt from review under E.O. 12866.

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

Dated: March 12, 1999.

Bruce C. Morehead,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 99–6494 Filed 3–12–99; 3:28 pm]

BILLING CODE 3510–22–F

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[I.D. 030999C]

Fisheries of the Exclusive Economic Zone Off Alaska; Sablefish Managed Under the Individual Fishing Quota Program

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Fishing season dates.

SUMMARY: NMFS is opening directed fishing for sablefish with fixed gear managed under the Individual Fishing Quota (IFQ) program. The season will open on 1200 hrs, Alaska local time (A.l.t.), March 15, 1999, and will close 1200 hrs, A.l.t., November 15, 1999. This period is the same as the IFQ season for Pacific halibut announced by the International Pacific Halibut Commission (IPHC). The IFQ halibut season is announced by publication in the **Federal Register**.

DATES: Effective March 15, 1999, 1200 hrs, A.l.t., until 1200 hrs, A.l.t., November 15, 1999.

FOR FURTHER INFORMATION CONTACT: James Hale, 907–586-7228.

SUPPLEMENTARY INFORMATION: Since 1995, NMFS has managed fishing for Pacific halibut (*Hippoglossus stenolepis*) and sablefish (*Anoplopoma fimbria*) with fixed gear in the IFQ regulatory areas defined in § 679.2 under the IFQ Program. The IFQ Program is a regulatory regime designed to promote the conservation and management of these fisheries and to further the objectives of the Magnuson-Stevens Fishery Conservation and Management Act and the Northern Pacific Halibut Act. Persons holding quota share receive an annual allocation of IFQ. Persons receiving an annual allocation of IFQ are authorized to harvest IFQ species within specified limitations. Further information on the implementation of the IFQ Program, and the rationale supporting it, are contained in the preamble to the final rule implementing the IFQ Program published in the **Federal Register**, November 9, 1993 (58 FR 59375) and subsequent amendments.

This announcement is consistent with § 679.23(g)(1), which requires that the directed fishing season for sablefish managed under the IFQ program be specified by the Administrator, Alaska Region, and announced by publication in the **Federal Register**. This method of season announcement was selected to facilitate coordination between the sablefish season, chosen by the Administrator, Alaska Region, and the halibut season, chosen by the IPHC. The directed fishing season for sablefish with fixed gear managed under the IFQ program will open at 1200 hrs, A.l.t., March 15, 1999, and will close 1200 hrs, A.l.t., November 15, 1999. This period runs concurrently with the IFQ season for Pacific halibut announced by the IPHC. The IFQ halibut season is announced by publication in the **Federal Register**.

Classification

This action is taken under § 679.23(g)(1) and is exempt from review under E.O. 12866.

Authority: 16 U.S.C. 773 *et seq.* and 1801 *et seq.*

Dated: March 11, 1999.

Gary C. Matlock,

Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 99–6483 Filed 3–12–99; 3:28 pm]

BILLING CODE 3510–22–F

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 981222314–8321–02; I.D. 031199A]

Fisheries of the Exclusive Economic Zone Off Alaska; Pacific Cod by Vessels Catching Pacific Cod for Processing by the Inshore Component in the Central Regulatory Area of the Gulf of Alaska

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Closure.

SUMMARY: NMFS is prohibiting directed fishing for Pacific cod by vessels catching Pacific cod for processing by the inshore component in the Central Regulatory Area of the Gulf of Alaska (GOA). This action is necessary to prevent exceeding the amount of the Pacific cod total allowable catch (TAC) apportioned to vessels catching Pacific cod for processing by the inshore component of the Central Regulatory Area of the GOA.

DATES: Effective 1200 hrs, Alaska local time (A.l.t.), March 14, 1999, until 2400 hrs, A.l.t., December 31, 1999.

FOR FURTHER INFORMATION CONTACT: Mary Furuness, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the GOA exclusive economic zone according to the Fishery Management Plan for Groundfish of the Gulf of Alaska (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

The Final 1999 Harvest Specifications of Groundfish for the GOA (64 FR 12094, March 11, 1999) established the Pacific cod TAC apportioned to the inshore component in the Central Regulatory Area as 30,913 metric tons (mt) in accordance with § 679.20(c)(3)(ii).

In accordance with § 679.20(d)(1)(i), the Administrator, Alaska Region, NMFS (Regional Administrator), has determined that the amount of the interim 1999 harvest specification of Pacific cod for processing by the inshore component of the Central Regulatory Area of the GOA will be reached. Therefore, the Regional Administrator is establishing a directed fishing allowance of 30,613 mt, and is setting aside the remaining 300 mt as bycatch to support other anticipated groundfish fisheries. In accordance with § 679.20(d)(1)(iii), the Regional Administrator finds that this directed fishing allowance will soon be reached. Consequently, NMFS is prohibiting directed fishing for Pacific cod by vessels catching Pacific cod for processing by the inshore component in the Central Regulatory Area of the GOA.

Maximum retainable bycatch amounts may be found in the regulations at § 679.20(e) and (f).

Classification

This action responds to the final TAC limitations and other restrictions on the fisheries established in the final 1999 harvest specifications for groundfish in the GOA. It must be implemented immediately to prevent overharvesting the amount of the final 1999 Pacific cod TAC apportioned to vessels catching Pacific cod for processing by the inshore component in the Central Regulatory Area of the GOA. A delay in the effective date is impracticable and contrary to the public interest, and further delay would only result in overharvest. NMFS finds for good cause that the implementation of this action should not be delayed for 30 days. Accordingly, under 5 U.S.C. 553(d), a delay in the effective date is hereby waived.

This action is required by § 679.20 and is exempt from review under E.O. 12866.

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

Dated: March 11, 1999.

Bruce C. Morehead,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 99–6482 Filed 3–12–99; 3:28 pm]

BILLING CODE 3510–22–F

Proposed Rules

Federal Register
Vol. 64, No. 51
Wednesday, March 17, 1999

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

Agricultural Marketing Service

7 CFR Part 915

[Docket No. FV99–915–1 PR]

Avocados Grown in South Florida; Increased Assessment Rate

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: This proposed rule would increase the assessment rate from $0.08 to $0.16 per 55-pound bushel container or equivalent of avocados established for the Avocado Administrative Committee (Committee) under Marketing Order No. 915 for the 1999–2000 and subsequent fiscal years. The Committee is responsible for local administration of the marketing order which regulates the handling of avocados grown in South Florida. Authorization to assess avocado handlers enables the Committee to incur expenses that are reasonable and necessary to administer the program. The fiscal year begins April 1 and ends March 31. The assessment rate would remain in effect indefinitely unless modified, suspended, or terminated.

DATES: Comments must be received by April 16, 1999.

ADDRESSES: Interested persons are invited to submit written comments concerning this rule. Comments must be sent to the Docket Clerk, Fruit and Vegetable Programs, AMS, USDA, room 2525–S, P.O. Box 96456, Washington, DC 20090–6456; Fax: (202) 720–5698; or E-mail: moabdocket__clerk@usda.gov. Comments should reference the docket number and the date and page number of this issue of the **Federal Register** and will be available for public inspection in the Office of the Docket Clerk during regular business hours.

FOR FURTHER INFORMATION CONTACT: Doris Jamieson, Southeast Marketing Field Office, Fruit and Vegetable Programs, AMS, USDA, P.O. Box 2276; Winter Haven, FL 33883–2276; telephone: (941) 299–4770, Fax: (941) 299–5169; or George Kelhart, Technical Advisor, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, room 2525–S, P.O. Box 96456, Washington, DC 20090–6456; telephone: (202) 720–2491, Fax: (202) 720–5698. Small businesses may request information on complying with this regulation, or obtain a guide on complying with fruit, vegetable, and specialty crop marketing agreements and orders by contacting Jay Guerber, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, P.O. Box 96456, room 2525–S, Washington, DC 20090–6456; telephone (202) 720–2491, Fax: (202) 720–5698, or E-mail: Jay__N__Guerber@usda.gov. You may view the marketing agreement and order small business compliance guide at the following web site:

http://www.ams.usda.gov/fv/moab.html.

SUPPLEMENTARY INFORMATION: This rule is issued under Marketing Agreement No. 121 and Order No. 915, both as amended (7 CFR part 915), regulating the handling of avocados grown in South Florida, hereinafter referred to as the ''order.'' The marketing agreement and order are effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the ''Act.''

The Department of Agriculture (Department) is issuing this rule in conformance with Executive Order 12866.

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. Under the marketing order now in effect, Florida avocado handlers are subject to assessments. Funds to administer the order are derived from such assessments. It is intended that the assessment rate as issued herein will be applicable to all assessable avocados beginning on April 1, 1999, and continue until amended, suspended, or terminated. This rule will not preempt any State or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rule.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file with the Secretary a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and request a modification of the order or to be exempted therefrom. Such handler is afforded the opportunity for a hearing on the petition. After the hearing the Secretary would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction to review the Secretary's ruling on the petition, provided an action is filed not later than 20 days after the date of the entry of the ruling.

This rule would increase the assessment rate established for the Committee for the 1999–2000 and subsequent fiscal years from $0.08 per 55-pound bushel container or equivalent to $0.16 per 55-pound bushel container or equivalent of South Florida avocados handled.

The Florida avocado marketing order provides authority for the Committee, with the approval of the Department, to formulate an annual budget of expenses and collect assessments from handlers to administer the program. The members of the Committee are producers and handlers of South Florida avocados. They are familiar with the Committee's needs and with the costs for goods and services in their local area and are thus in a position to formulate an appropriate budget and assessment rate. The assessment rate is formulated and discussed in a public meeting. Thus, all directly affected persons have an opportunity to participate and provide input.

For the 1998–99 and subsequent fiscal years, the Committee recommended, and the Department approved, an assessment rate that would continue in effect from fiscal year to fiscal year unless modified, suspended, or terminated by the Secretary upon recommendation and information submitted by the Committee or other information available to the Secretary.

The Committee met on January 13, 1999, and unanimously recommended 1999–2000 expenditures of $167,335 and an assessment rate of $0.16 per 55-pound bushel container or equivalent of avocados handled. In comparison, last year's budgeted expenditures were $174,344. The assessment rate of $0.16 is $0.08 higher than the rate currently in

effect. For the 1998–99 fiscal period, the Committee voted to lower its assessment rate from $0.16 to $0.08 to reduce the funds in its operating reserve. It wanted to bring its reserve closer to one year's operating expenses. With this accomplished, the Committee voted to return the assessment rate to the previous level of $0.16 to cover 1999–2000 expenses. As discussed later, the Committee expects to use interest income and reserve funds to cover its anticipated expenses during 1999–2000 because the $0.16 per 55-pound bushel container or equivalent assessment rate is expected to generate $144,000, which is $23,335 less than the Committee's budgeted expenses.

The major expenditures recommended by the Committee for the 1999–2000 year include $46,000 for salaries, $39,500 for production research, $27,000 for local and national enforcement, $10,040 for employee benefits, $8,955 for insurance and bonds, and $5,500 for travel. Budgeted expenses for these items in 1998–99 were $46,000, $41,500, $32,000, $9,778, $8,516, and $7,000, respectively.

The assessment rate recommended by the Committee was derived by dividing anticipated expenses by expected shipments of Florida avocados. Avocado shipments for the year are estimated at 900,000 55-pound bushel containers which should provide $144,000 in assessment income. Income derived from handler assessments, along with interest income and funds from the Committee's authorized reserve, would be adequate to cover budgeted expenses. Funds in the reserve (currently $187,615) would be kept within the maximum of 3 fiscal years' operational expenses permitted by the order (§§ 915.42 and 915.142).

The proposed assessment rate would continue in effect indefinitely unless modified, suspended, or terminated by the Secretary upon recommendation and information submitted by the Committee or other available information.

Although this assessment rate would be in effect for an indefinite period, the Committee would continue to meet prior to or during each fiscal period to recommend a budget of expenses and consider recommendations for modification of the assessment rate. The dates and times of Committee meetings are available from the Committee or the Department. Committee meetings are open to the public and interested persons may express their views at these meetings. The Department would evaluate Committee recommendations and other available information to determine whether modification of the assessment rate is needed. Further rulemaking would be undertaken as necessary. The Committee's 1999–2000 budget and those for subsequent fiscal years would be reviewed and, as appropriate, approved by the Department.

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA), the Agricultural Marketing Service (AMS) has considered the economic impact of this rule on small entities. Accordingly, AMS has prepared this initial regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory actions 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 Act, and the 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 149 producers of avocados in the production area and approximately 48 handlers subject to regulation under the marketing order. Small agricultural producers have been defined by the Small Business Administration (13 CFR 121.601) as those having annual receipts less than $500,000, and small agricultural service firms are defined as those whose annual receipts are less than $5,000,000.

The average price for fresh avocados during the 1996–97 season was $13.20 per 55-pound bushel box equivalent for all domestic shipments and the total shipments were 917,861 bushels. Approximately 10 percent of all handlers handled 90 percent of the South Florida avocado shipments during that season. Many handlers ship other tropical fruit and vegetable products which are not included in the Committee data but would contribute further to handler receipts. Using the average price per 55-pound container or equivalent, about 90 percent of the avocado handlers could be considered small businesses under SBA's definition and about 10 percent of the handlers could be considered large businesses. The majority of handlers and producers of Florida avocados may be classified as small entities.

This rule would increase the assessment rate established for the Committee and collected from handlers for the 1999–2000 and subsequent fiscal years from $0.08 per 55-pound bushel container or equivalent to $0.16 per 55-pound bushel container or equivalent of avocados. The Committee unanimously recommended 1999–2000 expenditures of $167,335 and an assessment rate of $0.16 per 55-pound bushel container or equivalent handled. The proposed assessment rate of $0.16 is $0.08 higher than the 1998–99 rate. The quantity of assessable avocados for the 1999–2000 season is estimated at 900,000 containers. Thus, the $0.16 rate should provide $144,000 in assessment income. Assessment income, along with interest income and funds from the Committee's authorized reserve, would be adequate to cover budgeted expenses.

The major expenditures recommended by the Committee for the 1999–2000 year include $46,000 for salaries, $39,500 for production research, $27,000 for local and national enforcement, $10,040 for employee benefits, $8,955 for insurance and bonds, and $5,500 for travel. Budgeted expenses for these items in 1998–99 were $46,000, $41,500, $32,000, $9,778, $8,516, and $7,000, respectively.

During the 1998–99 season, the Committee voted to decrease the assessment rate to bring its operating reserve closer to one year's operating expenses. For the 1999–2000 fiscal period, the Committee voted to return to the previous rate of $0.16 to cover authorized expenses. The Committee expects to use interest income and funds from its operating reserve to cover 1999–2000 expenses. This would be necessary because assessment income is expected to total $144,000, and the Committee's budget totals $167,335.

The Committee's 1999–2000 budgeted expenditures of $167,335 include increases in employee benefits and office equipment. Prior to arriving at this budget, the Committee considered information from various sources, such as the Committee's Budget Subcommittee. Alternative expenditure levels were discussed, based upon the relative value of various research projects to the South Florida avocado industry.

The assessment rate of $0.16 per 55-pound bushel container or equivalent of assessable avocados was then determined by dividing the total recommended budget by the quantity of assessable avocados, estimated at 900,000 55-pound bushel containers or equivalents for the 1999–2000 fiscal period. This rate is expected to provide $144,000 in assessment income, which is $23,335 below budgeted expenses. The Committee found this acceptable because interest income and funds from the Committee's operating reserve would be available to make up the deficit.

A review of historical information indicates that the grower price for the 1999–2000 season could range between

$13.20 and $14.90 per 55-pound bushel container or equivalent of avocados. Therefore, the estimated assessment revenue for the 1999–2000 fiscal year as a percentage of total grower revenue could range between 1 and 1.2 percent.

This action would increase the assessment obligation imposed on handlers. While assessments impose some additional costs on handlers, the costs are minimal and uniform on all handlers. Some of the additional costs may be passed on to producers. However, these costs would be offset by the benefits derived by the operation of the marketing order. In addition, the Committee's meeting was widely publicized throughout the Florida avocado industry and all interested persons were invited to attend the meeting and participate in Committee deliberations on all issues. Like all Committee meetings, the January 13, 1999, meeting was a public meeting and all entities, both large and small, were able to express views on this issue. Finally, interested persons are invited to submit information on the regulatory and informational impacts of this action on small businesses.

This proposed rule would impose no additional reporting or recordkeeping requirements on either small or large Florida avocado handlers. As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies.

The Department has not identified any relevant Federal rules that duplicate, overlap, or conflict with this rule.

A 30-day comment period is provided to allow interested persons to respond to this proposed rule. Thirty days is deemed appropriate because: (1) The 1999–2000 fiscal year begins on April 1, 1999, and the marketing order requires that the rate of assessment for each fiscal year apply to all assessable avocados handled during such fiscal year; (2) the Committee needs to have sufficient funds to pay its expenses which are incurred on a continuous basis; and (3) handlers are aware of this action which was unanimously recommended by the Committee at a public meeting and is similar to other assessment rate actions issued in past years.

List of Subjects in 7 CFR Part 915

Avocados, Marketing agreements, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 7 CFR part 915 is proposed to be amended as follows:

PART 915—AVOCADOS GROWN IN SOUTH FLORIDA

1. The authority citation for 7 CFR part 915 continues to read as follows:

Authority: 7 U.S.C. 601–674.

2. Section 915.233 is revised to read as follows:

§ 915.233 Assessment rate.

On and after April 1, 1999, an assessment rate of $0.16 per 55-pound bushel container or equivalent is established for avocados grown in South Florida.

Dated: March 11, 1999.

Robert C. Keeney,

Deputy Administrator, Fruit and Vegetable Programs.

[FR Doc. 99–6490 Filed 3–16–99; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 1065

[DA–99–01]

Milk in the Nebraska-Western Iowa Marketing Area; Proposed Suspension of Supply Plant Shipping Requirements

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed suspension of rule.

SUMMARY: This document invites written comments on a proposal to suspend portions of the supply plant shipping requirements for the Nebraska-Western Iowa order for the months of March through September 1999. This action was requested by North Central Associated Milk Producers, Inc. (AMPI), a cooperative association that supplies milk for the market's fluid needs. Suspension would enable AMPI producers historically associated with the order to share in the Nebraska-Western Iowa Federal order pool for March through August 1999.

DATES: Comments must be submitted on or before March 24, 1999.

ADDRESSES: Comments (two copies) should be filed with the USDA/AMS/Dairy Programs, Order Formulation Branch, Room 2971, South Building, P.O. Box 96456, Washington, DC 20090–6456. Advance, unofficial copies of such comments may be faxed to (202) 690–0552 or e-mailed to OFB__FMMO__Comments@usda.gov. Reference should be given to the title of action and docket number.

FOR FURTHER INFORMATION CONTACT: Constance M. Brenner, Marketing Specialist, USDA/AMS/Dairy Programs, Order Formulation Branch, Room 2971, South Building, P.O. Box 96456, Washington, DC 20090–6456, (202) 720–2357, e-mail address:

connie__m__brenner@usda.gov.

SUPPLEMENTARY INFORMATION: The Department is issuing this proposed rule in conformance with Executive Order 12866.

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule is not intended to have a retroactive effect. If adopted, this proposed rule will not preempt any state or local laws, regulations, or policies, unless they present an irreconcilable conflict with the rule.

The Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may request modification or exemption from such order by filing with the Secretary a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law. A handler is afforded the opportunity for a hearing on the petition. After a hearing, the Secretary would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has its principal place of business, has jurisdiction in equity to review the Secretary's ruling on the petition, provided a bill in equity is filed not later than 20 days after the date of the entry of the ruling.

Small Business Consideration

In accordance with the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), the Agricultural Marketing Service has considered the economic impact of this action on small entities and has certified that this proposed rule will not have a significant economic impact on a substantial number of small entities. For the purpose of the Regulatory Flexibility Act, a dairy farm is considered a ''small business'' if it has an annual gross revenue of less than $500,000, and a dairy products manufacturer is a ''small business'' if it has fewer than 500 employees. For the purpose of determining which dairy farms are ''small businesses,'' the $500,000 per year criterion was used to establish a production guideline of 326,000 pounds per month. Although this guideline does not factor in additional monies that may

be received by dairy producers, it should be an inclusive standard for most ''small'' dairy farmers. For purposes of determining a handler's size, if the plant is part of a larger company operating multiple plants that collectively exceed the 500-employee limit, the plant will be considered a large business even if the local plant has fewer than 500 employees.

For the month of January 1999, 1,248 dairy farmers were producers under Order 65. Of these producers, 1,176 producers (i.e., 94 percent) were considered small businesses having monthly milk production under 326,000 pounds. A further breakdown of the monthly milk production of the producers on the order during January 1999 is as follows: 753 produced less than 100,000 pounds of milk; 322 produced between 100,000 and 200,000; 101 produced between 200,000 and 326,000; and 72 produced over 326,000 pounds. During the same month, 5 handlers were pooled under the order. None are considered small businesses.

This rule would lessen the regulatory impact of the order on certain milk handlers and would tend to ensure that dairy farmers would continue to have their milk priced under the order and thereby receive the benefits that accrue from such pricing.

Interested parties are invited to submit comments on the probable regulatory and informational impact of this proposed rule on small entities. Also, parties may suggest modifications of this proposal for the purpose of tailoring their applicability to small businesses.

Preliminary Statement

Notice is hereby given that, pursuant to the provisions of the Agricultural Marketing Agreement Act, suspension for the months of March through September 1999 of the following language from the pool plant provisions of the order regulating the handling of milk in the Nebraska-Western Iowa marketing area is being considered:

In the first sentence of § 1065.7(b)(4), suspending the following language: ''each of the months of,'' ''through March,'' and ''for the following months of April.''

All persons who want to submit written data, views or arguments about the proposed suspension should send two copies of their views to the USDA/AMS/Dairy Programs, Order Formulation Branch, Room 2971, South Building, P.O. Box 96456, Washington, DC 20090–6456, by the 7th day after publication of this notice in the **Federal Register**. The period for filing comments is limited to 7 days because a longer period would not provide the time needed to complete the required procedures before the requested suspension is to be effective.

All written submissions made pursuant to this notice will be made available for public inspection in the Dairy Programs during regular business hours (7 CFR 1.27(b)).

Statement of Consideration

The proposed suspension was requested by AMPI, a cooperative association that supplies milk for the market's fluid needs. AMPI requests that language be suspended from the Nebraska-Western Iowa order's pool supply plant definition for the purpose of allowing producers who have historically supplied the fluid needs of Nebraska-Western Iowa distributing plants to maintain their pool status. AMPI contends that because a fluid milk plant operator reduced its purchase of fluid milk from AMPI by more than 50 percent, AMPI will not be able to pool milk historically associated with the Nebraska-Western Iowa order for March 1999, and thus will not qualify for the automatic qualification months of April through August.

AMPI maintains that through discussions with other handlers in the order, it is certain that no additional milk is needed at this time.

Accordingly, it may be appropriate to suspend the aforesaid regulatory language for the months of March through September 1999.

List of Subjects in 7 CFR Part 1065

Milk marketing orders.

The authority citation for 7 CFR Part 1065 continues to read as follows:

Authority: 7 U.S.C. 601–674.

Dated: March 11, 1999.

Richard M. McKee,

Deputy Administrator, Dairy Programs.

[FR Doc. 99–6488 Filed 3–16–99; 8:45 am]

BILLING CODE 3410–02–P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Parts 1615 and 1616

Standard for the Flammability of Children's Sleepwear: Sizes 0 Through 6X; Standard for the Flammability of Children's Sleepwear: Sizes 7 Through 14

AGENCY: Consumer Product Safety Commission.

ACTION: Proposed amendments.

SUMMARY: The Commission proposes to amend the flammability standards for children's sleepwear in sizes 0 through 6X and sizes 7 through 14 by revising the laundering procedure specified in those standards. These laundering procedures help assure that any chemical flame retardants are not removed or degraded with repeated washing and drying, thereby creating a flammability hazard. The Commission is proposing these amendments because the detergent specified by the existing laundering procedure is no longer available and the operating characteristics of the washing and drying machines required by that procedure are no longer representative of machines now used for home laundering.

DATES: Written comments concerning the proposed amendments must be received by the Office of the Secretary not later than June 1, 1999.

ADDRESSES: Written comments should be captioned ''Children's Sleepwear, Laundering Procedures'' and mailed to the Office of the Secretary, Consumer Product Safety Commission, Washington, D.C. 20207, or delivered to that office, room 502, 4330 East-West Highway, Bethesda, Maryland. Comments may also be filed by telefacsimile to (301) 504–0127 or by email to cpsc-os@cpsc.gov.

FOR FURTHER INFORMATION CONTACT: Margaret Neily, Project Manager, Directorate for Engineering Sciences, Consumer Product Safety Commission, Washington, D.C. 20207; telephone (301) 504–0508, extension 1293.

SUPPLEMENTARY INFORMATION:

A. Background

The Flammable Fabrics Act (''FFA'') (15 U.S.C. 1191 *et seq.*) authorizes issuance and amendment of flammability standards and regulations to protect the public from unreasonable risks of death, injury, and property damage from fire associated with products of wearing apparel made from fabric and related materials.

In 1971, the Secretary of Commerce issued a flammability standard for children's sleepwear in sizes 0 through 6X to protect young children from death and serious burn injuries which had been associated with ignition of sleepwear garments such as nightgowns and pajamas, by small open-flame sources. That standard became effective in 1972, and is codified at 16 CFR Part 1615.

In 1973, authority to issue flammability standards under the FFA was transferred from the Department of Commerce to the Consumer Product Safety Commission by section 30(b) of the Consumer Product Safety Act (15

U.S.C. 2079(b)). In 1974, the Commission issued a flammability standard for children's sleepwear in sizes 7 through 14. That standard became effective in 1975 and is codified at 16 CFR Part 1616.

Both standards prescribe a test which requires that specimens of fabrics, seams, and trim of children's sleepwear garments must self-extinguish after exposure to a small open flame. The standards do not require or prohibit the use of any particular type of fabric as long as the manufacturer successfully completes the prescribed prototype and production testing.

Each standard defines the term ''children's sleepwear'' to mean ''any product of wearing apparel'' in the sizes covered by the standard ''such as nightgowns, pajamas, or similar or related items, such as robes, intended to be worn primarily for sleeping or activities related to sleeping.'' The standard for sizes 0 through 6X excludes infant garments sized for children nine months of age or younger. Both standards exclude diapers, underwear, and certain tight-fitting garments. See 16 CFR 1615.1(a) and 1616.2(a), as amended September 9, 1996 (61 FR 47634).

B. Amending the Flammability Standards

As discussed below, laundering procedures are prescribed by the standards to help assure than any flame retardant treatment used in the production of children's sleepwear does not deteriorate over time and thereby create a flammability hazard. However, the current procedures are out of date in several respects, and the Commission is therefore proposing to change them.

1. Current Laundering Procedures

Each of the children's sleepwear standards describes the apparatus and procedure used to test items for compliance with the standard. See 16 CFR 1615.4 and 1616.5. The standards address the possibility that a flame-retardant treatment used in children's sleepwear might progressively deteriorate by washing or drying. Section 1615.4(g)(4) of the standard for sizes 0 through 6X and section 1616.5(c)(4) of the standard for sizes 7 through 14 require that testing shall be performed on finished items, as produced (or after one washing and drying in the case of garments labeled with instructions to wash before wearing) and after they have been washed and dried 50 times in accordance with a specified laundering procedure. That laundering procedure is AATCC Test Method 124–69, published by the American Association of Textile Chemists and Colorists (''AATCC''). (1) [1] Each standard incorporates specific aspects of that laundering procedure by reference.

The AATCC Test Method was developed in 1967 and revised in 1969. AATCC Test Method 124–69 specifies operating characteristics of the washing machine and dryer to be used, wash water and rinse water temperatures, exhaust temperature of the dryer, and a particular detergent, AATCC Standard Detergent 124. These specifications are representative of the equipment, wash, rinse, and drying temperatures, and detergent used for home laundering in the 1960s. For example, AATCC Standard Detergent 124 is a high-phosphate powder with optical brightener, similar to the phosphate-based detergents sold to consumers between 1950 and 1970. (3)

Since 1970, environmental concerns about water pollution have resulted in the elimination of phosphate-based detergents for home laundering. Today, all laundry detergents sold to consumers are nonphosphate-based. Additionally, energy-efficient washing machines and dryers currently sold for consumer use have operating characteristics and temperature settings which differ from those specified by AATCC Test Method 124–69. (3)

2. Revised Laundering Test Method

In 1996, AATCC revised AATCC Test Method 124, ''Appearance of Fabrics After Repeated Home Laundering.'' (2) The 1996 AATCC test method more closely resembles the equipment and practices currently used for household laundering of fabrics. The revised test method differs from AATCC Test Method 124–69 by specifying the use of a nonphosphate-based detergent. The 1996 test method also specifies use of a washing machine with different operating characteristics than those specified by AATCC Test Method 124–69, and rinse water temperatures which differ from those in the older test method. (3) Table 1, below, provides a summary comparison of the two test methods.

TABLE 1.—AATCC TEST METHOD 124

WASH/DRY CONDITIONS	VERSION 1969	VERSION 1996	
Washing Machine:			
Cycle	Normal	Normal/Cotton Sturdy.	
Wash Water Temp	60 ± 3°C	60 ± 3°C.	
Rinse Water Temp	41 ± 3°C	Less Than 29°C.	
Water Level	Full	18 ± 1 gal.	
Agitator Speed	70 ± 5 spm	179± 2 spm.	
Wash Time	12 minutes	12 minutes.	
Spin Speed	500–510 rpm	630–660 rpm.	
Final Spin Cycle	4 minutes	6 minutes.	
Dryer:			
Cycle	Normal	Cotton Sturdy	Durable Press.
Exhaust Temp	140–160°F	140–160°F	140–160°F.
Cool Down Cycle	5 minutes	5 minutes	10 minutes.

spm = strokes (or cycles) per minute.
rpm = revolutions per minute.

[1] Numbers in parentheses identify reference documents in the List of Relevant Documents at the end of this notice. Requests for inspection of any of these documents should be made at the Office of the Secretary, 4330 East-West Highway, room 502, or by calling that office at (301) 504–0800.

In 1996, AATCC also announced that when that organization's supply of Standard Detergent 124 is depleted, that detergent will no longer be available. AATCC is the only source for Standard Detergent 124. Additionally, washing machines now offered for sale do not have the settings and operating characteristics of the washing machine specified by AATCC Test Method 124–69. (3).

3. Review of Existing Standards

In addition to reviewing AATCC Test Method 124–1996, the Commission staff reviewed and analyzed twelve other international and technical association standards or test methods to determine if any were appropriate for consideration in this proceeding. Standards and test methods from AATCC, ASTM, the International Standards Organization, the United Kingdom, Australia, Canada, China and the Soap and Detergent Association were identified. All of these methods could be used for sleepwear fabrics and mattress pads.

All of the identified standards for fabric laundering have significant deficiencies. They are either based on earlier versions of AATCC Test Method 124 (with obsolete detergent and equipment), require equipment not available in the U.S., use only water in the laundering procedure, or specify significantly lower wash and rinse water temperatures than those still available for consumers.

4. Comparability of Test Results

In order to compare the results of laundering using AATCC Test Method 124–69 with those of the new AATCC Test Method 124–96 the Commission performed some tests of fabrics using each method. The staff conducted laundering comparisons using sleepwear made of cotton fabrics with the two known FR treatments being used to treat children's sleepwear at the time of the testing (organic phosphorous compound and antimony trioxide) and two untreated flame resistant polyester fabrics. All fabrics met the requirements of the children's flammability test in their original state (as marketed or after one laundering, as appropriate) and after 50 launderings with the old AATCC detergent and equipment specified in AATCC 124–69.

The laundering tests indicated that changes in washing machine and dryer operating conditions between the old and new versions of AATCC Test Method 124 did not make a difference in the flammability performance of the fabrics tested. However, the cotton sleepwear that was treated with the phosphorous-based Pyrovatex CP-new did not perform well in flammability testing after laundering with the new AATCC detergent. The Pyrovatex-treated sleepwear also did not perform well in flammability testing after laundering with common powder detergents. Liquid detergents did not seem to adversely affect flammability performance. Fabrics treated with the antimony-based FR showed some random failures that, according to laboratory chemical analyses, apparently were unrelated to the detergent and laundering conditions. The new AATCC detergent did not affect the flammability of the untreated polyester fabrics. However, one polyester fabric did show reduced flame resistance when a liquid fabric softener was used. Labels on both liquid and sheet fabric softener packages state that they should not be used on garments labeled as flame resistant.

After conducting these studies CPSC informed the manufacturer of Pyrovatex of the results. The manufacturer conducted additional studies to evaluate its product's performance on children's sleepwear as it is used and laundered by consumers. The manufacturer determined that such factors as the fabric, the application process, storage conditions, and consumer care practices can affect the flame resistance of the light weight fabrics used for children's sleepwear. Because the manufacturer has little control over these factors, the company decided, with one exception, to withdraw Pyrovatex from sale to the sleepwear industry.

With the withdrawal of Pyrovatex for treating children's sleepwear, the change in detergent and laundering equipment from AATCC 124–69 to AATCC 124–96 will not have any effect on the flammability performance of children's sleepwear on the market.

5. Proposed Amendment of Standards

The Commission proposes to revise the laundering procedures specified in the children's sleepwear standards at 16 CFR 1615.4(g)(4) and 1616.5(c)(4) to those of AATCC Test Method 124–1996.

The children's sleepwear standards were issued under section 4 of the FFA (15 U.S.C. 1193), which authorizes the issuance or amendment of flammability standards to protect the public against unreasonable risks of fire leading to death, personal injury, or significant property damage. As required by section 4(b) of the FFA, both standards are based on findings that they are needed to adequately protect the public against the unreasonable risk of the occurrence of fire leading to death, personal injury, or significant property damage. That section further requires findings that a flammability standard issued under the FFA is ''reasonable, technologically practicable, and appropriate.''

The proposed changes to the standards are needed to make the specified laundering procedures represent those currently used by consumers. The proposed amendments are also needed to assure that the standards will continue to be ''technologically practicable,'' for both the Commission's laboratory and those manufacturers of children's sleepwear required to use the laundering procedures and perform the testing required by the standards.

Section 4(g) of the FFA (15 U.S.C. 1193(g)) states that a proceeding ''for the promulgation of a regulation under this section'' shall be initiated by publication of an advance notice of proposed rulemaking (''ANPR''), and sets forth requirements for the contents of the ANPR. However, these proposed amendments are necessary because technical advances and the passage of time have rendered the existing test method obsolete. The amendments preserve the original intent and effect of the existing test method, modifying that method only as necessary to reflect the existence of modern equipment and detergent. Moreover, the existing regulations permit the Commission to employ a laundering test method different from AATCC Test Method 124 if it concludes that the test method is substantively as protective. Because the existing regulations allow the Commission to achieve without any amendment the substance of what it now proposes to achieve by amendment, and because the proposed amendments preserve the regulatory status quo, save for the reflection of modern equipment and detergent, the Commission has determined that it is not legally required to commence this proceeding with an ANPR, nor is it necessary for the Commission to make the findings that FFA sections 1193(g) and (h) would otherwise require.

The amendments proposed below would require specimens to be tested as produced (or after one washing and drying) and after washing and drying 50 times using the procedure specified in AATCC Test Method 124–1996. The proposed amendments would incorporate that test method into the sleepwear standard by reference.

The amendments proposed below also include minor changes to the enforcement regulations at 16 CFR 1615.32 and 1616.32 prescribing the procedure for seeking approval from the Commission for use of alternate

laundering procedures. The proposed amendments of those sections:

(i) update the laundering procedure prescribed by the sleepwear standards to AATCC Test Method 124–1996; and

(ii) substitute the words ''Assistant Executive Director for Compliance'' for ''Associate Executive Director for Compliance and Enforcement'' to reflect the current title for that position.

The proposed amendments of the enforcement rules implementing the standard for sizes 7 through 14 also include a revision of section 1616.32(g), Commission testing for compliance. The proposed amendment corrects an erroneous citation in the regulations to the laundering provisions of the standard. The correct citation in the proposed amendment is to section 1616.5(c)(4)(ii) of the standard rather than 1616.5(c)(4)(iii) in the existing text. No similar error exists in the enforcement rules implementing the standard for sizes 0 through 6X.

6. Effective Date

Section 4(b) of the FFA (15 U.S.C. 1193(b)) provides that an amendment of a flammability standard shall become effective one year from the date it is promulgated, unless the Commission finds for good cause that an earlier or later effective date is in the public interest, and publishes that finding. Section 4(b) also requires that an amendment of a flammability standard shall exempt products ''in inventory or with the trade'' on the date the amendment becomes effective, unless the Commission limits or withdraws that exemption because those products are so highly flammable that they are dangerous for use by consumers.

One reason for proposing these amendments of the children's sleepwear standards is that the standard detergent specified by the existing laundering method in the standards is no longer available. The Commission has reason to believe that an effective date 30 days after publication of final amendments will be in the public interest. The Commission does not propose to withdraw or limit the exemption for products in inventory or with the trade as provided by section 4(b) of the FFA.

The Commission believes that an effective date of thirty days would provide adequate notice to all interested persons of the change in laundering procedure, and at the same time would assure that the Commission will be able to test for compliance with the standards without interruption. Those manufacturers who perform premarket testing in accordance with the laundering procedures specified in the standards will also benefit from a relatively short effective date.

The Commission invites comments on the proposed effective date and factual information relating to that issue.

C. Other Issues

1. Impact on Small Businesses

In accordance with section 605(b) of the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Commission hereby certifies that the amendments to the children's sleepwear standards and enforcement rules proposed below will not have a significant economic impact on a substantial number of small entities, including small businesses, if issued on a final basis. As noted above, the requirements for washing and drying specimens 50 times before testing were included in the standards to assure that any flame retardant treatment used in children's sleepwear would not be removed by repeated laundering.

When the standards were issued in 1971 and 1974, some fabrics used in the production of children's sleepwear were treated with flame retardants. However, at this time, nearly all fabrics used for children's sleepwear are made without flame retardant treatments. The ability of these fabrics to pass the flammability tests in the standards is not affected by washing or drying. (3) Moreover, the proposed changes are intended to bring the standards promulgated in the 1970s into conformance with current practices. Independent testing laboratories report that they currently use the requirements of the revised test method (AATCC Test Method 124–96) that the Commission is proposing. Because the proposed amendment would codify existing industry testing practices (and reflect current consumer practices), the proposal is not expected to have an effect on small entities.

2. Environmental Considerations

The amendments proposed below fall within the categories of Commission actions described at 16 CFR 1021.5(c) that have little or no potential for affecting the human environment. The amendments are not expected to have a significant effect on production processes or on the types or amounts of materials used for construction or packaging of children's sleepwear. The amendments will not render existing inventories unsalable, or require destruction of existing goods. The Commission has no information indicating any special circumstances in which these amendments may affect the human environment. Accordingly, neither an environmental assessment nor an environmental impact statement is required.

3. Executive Orders

Executive Order 12988 (February 5, 1996), requires agencies to state in clear language the preemptive effect, if any, to be given to a new regulation. The amendments proposed below, if issued on a final basis, would modify two flammability standards issued under the FFA. With certain exceptions which are not applicable in this instance, no state or political subdivision of a state may enact or continue in effect ''a flammability standard or other regulation'' applicable to the same fabric or product covered by an FFA standard if the state or local flammability standard or other regulations is ''designed to protect against the same risk of the occurrence fire'' unless the state or local flammability standard or regulation ''is identical'' to the FFA standard. See section 16 of the FFA (15 U.S.C. 1203). Consequently, if issued on a final basis, the amendments proposed below will preempt nonidentical state or local flammability standards or regulations that are intended to address the unreasonable risk of fire associated with ignition of children's sleepwear in sizes 0 through 14.

In accordance with Executive Order 12612 (October 26, 1987), the Commission certifies that the proposed amendments do not have sufficient implications for federalism to warrant a Federalism Assessment.

List of Subjects in 16 CFR Parts 1615 and 1616

Clothing, Consumer protection, Flammable materials, Infants and children, Labeling, Records, Sleepwear, Textiles, Warranties

Conclusion

Therefore, pursuant to the authority of section 30(b) of the Consumer Product Safety Act (15 U.S.C. 2079(b)) and sections 4 and 5 of the Flammable Fabrics Act (15 U.S.C. 1193, 1194), the Commission hereby proposes to amend title 16 of the Code of Federal Regulations, Chapter II, Subchapter D, Parts 1615 and 1616 to read as follows:

PART 1615—STANDARD FOR THE FLAMMABILITY OF CHILDREN'S SLEEPWEAR: SIZES 0 THROUGH 6X

1. The authority for subpart A of part 1615 continues to read as follows:

Authority: Sec. 4, 67 Stat. 112, as amended, 81 Stat. 569–570; 15 U.S.C. 1193.

2. Section 1615.4 is amended by revising paragraph (g)(4)(i) and (ii) to read as follows:

§ 1615.4 Test procedure.

(g) Testing * * *

(4) Laundering. (i) The procedures described in paragraphs (b) through (g) of this section shall be carried out on finished items (as produced or after one washing and drying) and after they have been washed and dried 50 times in accordance with sections 8.2.2, 8.2.3, and 8.3.1(A) of AATCC Test Method 124–1996 ''Appearance of Fabrics After Repeated Home Laundering,'' Technical Manual of the American Association of Textile Chemists and Colorists, vol. 73, 1997, which is incorporated by reference. Copies of this document are available from the American Association of Textile Chemists and Colorists, P.O. Box 12215, Research Triangle Park, North Carolina 27709. This document is also available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., Suite 700, Washington, DC. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. These materials are incorporated as they exist in the edition which has been approved by the Director of the Federal Register and which has been filed with the Office of the Federal Register. Items which do not withstand 50 launderings shall be tested at the end of their useful service life.

(ii) Washing shall be performed in accordance with sections 8.2.2 and 8.2.3 of AATCC Test Method 124–1996, using wash temperature V (60°±3°C, 140°±5°F) specified in Table II of that method, and the water level, agitator speed, washing time, spin speed and final spin cycle specified for ''Normal/Cotton Sturdy'' in Table III. A maximum washer load shall be 3.64 Kg (8 pounds) and may consist of any combination of test samples and dummy pieces. Drying shall be performed in accordance with section 8.3.1(A) of that test method, Tumble Dry, using the exhaust temperature (66°±5°C, 150°±10°F) and cool down time of 10 minutes specified in the ''Durable Press'' conditions of Table IV.

* * * * * *

3. The authority for subpart B of part 1615 continues to read as follows:

Authority: Sec. 5, 67 Stat. 112–113, as amended, 81 Stat. 570; 15 U.S.C. 1194.

4. Section 1615.32 is amended by revising paragraphs (a)(1), (b)(1), introductory text and (b)(2), the first 3 sentences of (c)(1), (c)(2), the first sentence of (d)(3), the first sentence of (e)(1), the first sentence of (e)(2), and (f) to read as follows:

§ 1615.32 Method for establishment and use of alternate laundering procedures under section 4(g)(4)(ii) of the standard.

(a) Scope. (1) Section 1615.4(g)(4)(ii) of the Standard for the Flammability of Children's Sleepwear in sizes 0–6X (16 CFR 1615.4(g)(4)(ii)) requires that all fabrics and certain garments subject to the standard be tested for flammability as produced (or after one washing and drying) and after the items have been washed and dried 50 times in machines, using the procedure specified in AATCC Test Method 124–1996.[5] This section also provides that items may be laundered a different number of times under another washing and drying procedure if the Commission finds that such an alternate laundering procedure is equivalent to the procedure specified in the standard.

* * * * *

(b) Application procedure. (1) Applicants seeking approval for use of an alternate laundering procedure under section 1615.4(g)(4)(iii) of the standard must submit the following information to the Assistant Executive Director for Compliance, Consumer Product Safety Commission, Washington, DC 20207:

* * * * *

(2) Applications shall be certified by the chief executive officer of the applicant or the official to whom the duty to certify has been delegated in writing. The Commission's Assistant Executive Director for Compliance must be notified in writing of any such delegation.

(c) Use of alternate laundering procedure. (1) The applicant may begin to use the alternate laundering procedure 30 days after the application is received by the Assistant Executive Director for Compliance unless notified to the contrary. The Assistant Executive Director for Compliance will normally furnish an applicant with written notice of approval within 30 days. The applicant may be notified that a longer time is needed for evaluation of the application, and in the discretion of the Assistant Executive Director for Compliance, may be authorized to use the alternate laundering procedure pending the final decision. * * *

(2) As provided in detail in 1615.32(e), applicants must immediately discontinue use of an alternate procedure, and must immediately notify the Assistant Executive Director for Compliance if there are test failures during revalidation testing.

(d) Revalidation testing. * * *

(3) Records of revalidation testing need not be submitted to the Assistant Executive Director for Compliance.

* * *

(e) Revalidation testing failures. (1) If revalidation testing for any fabric or garment does not meet the criteria of paragraph (f) of this section, the applicant must immediately discontinue use of the alternate laundering procedure for the fabric or garment and must immediately notify the Assistant Executive Director for Compliance in writing of the failure to meet the criteria. * * *

(2) When use of an alternate laundering procedure for a particular fabric or garment has been discontinued because of a failure to meet the criteria of paragraph (f) of this section, the alternate laundering procedure shall not be used again unless a new application for approval is submitted to the Assistant Executive Director for Compliance and that officer approves the application in writing. * * *

(f) Commission criteria for evaluating applications. (1) The Assistant Executive Director for Compliance will approve the alternate laundering procedure as equivalent to the laundering procedure specified in section 1615.4(g)(4)(ii) of the standard if testing from 20 specimens laundered by the proposed alternate procedure yields as many or more char lengths in excess of five inches as does testing from the twenty specimens laundered by the 50-laundering cycle method prescribed in the standard.

(2) If the alternate laundering procedure yields fewer char lengths in excess of five inches than does the 50-wash and dry cycle, then the Assistant Executive Director for Compliance will not consider the alternate procedure to be equivalent with the following exception: If the number of five-inch chars from the alternate procedure is within one of the number of five-inch chars obtained from the 50-cycle procedure, the applicant may repeat the original test with new specimens and if the combined results of both tests show the count of chars exceeding five inches from the alternate is equal to, or greater than, the count from the 50-wash cycle procedure, the Assistant Executive Director for Compliance will approve the alternate laundering procedure.

* * * * *

PART 1616—STANDARD FOR THE FLAMMABILITY OF CHILDREN'S SLEEPWEAR: SIZES 7 THROUGH 14

1. The authority for subpart A of part 1616 continues to read as follows:

[5] American Association of Textile Chemists and Colorists, Technical Manual. Vol 73, 1997.

Authority: Sec. 4, 67 Stat. 112, as amended, 81 Stat. 569–570; 15 U.S.C. 1193.

2. Section 1616.5 is amended by revising paragraphs (c)(4)(i) and (ii) to read as follows:

§ 1616.5 Test procedure.

(c) Testing * * *

(4) Laundering. (i) The procedures described under § 1616.4 Sampling and acceptance procedures, paragraph (b) of this section, Mounting and conditioning of specimens, and paragraph (c) of this section *Testing* shall be carried out on finished items (as produced or after one washing and drying) and after they have been washed and dried 50 times in accordance with sections 8.2.2, 8.2.3, and 8.3.1(A) of AATCC Test Method 124–1996 ''Appearance of Fabrics After Repeated Home Laundering,'' Technical Manual of the American Association of Textile Chemists and Colorists, vol. 73, 1997, which is incorporated by reference. Copies of this document are available from the American Association of Textile Chemists and Colorists, P.O. Box 12215, Research Triangle Park, North Carolina 27709. This document is also available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., Suite 700, Washington, DC. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. These materials are incorporated as they exist in the edition which has been approved by the Director of the Federal Register and which has been filed with the Office of the Federal Register. Items which do not withstand 50 launderings shall be tested at the end of their useful service life with prior approval of the Consumer Product Safety Commission.

(ii) Washing shall be performed in accordance with sections 8.2.2 and 8.2.3 of AATCC Test Method 124–1996, using wash temperature V (60°±3–C, 140°±5–F) specified in Table II of that method, and the water level, agitator speed, washing time, spin speed and final spin cycle specified for ''Normal/Cotton Sturdy'' in Table III. A maximum washer load shall be 3.64 Kg (8 pounds) and may consist of any combination of test samples and dummy pieces. Drying shall be performed in accordance with section 8.3.1(A) of that test method, Tumble Dry, using the exhaust temperature (66°±5–C, 150°±10–F) and cool down time of 10 minutes specified in the ''Durable Press'' conditions of Table IV.

* * * * *

3. The authority for subpart B of part 1616 continues to read as follows:

Authority: Sec. 5, 67 Stat. 112–113, as amended, 81 Stat. 570; 15 U.S.C. 1194.

4. Section 1616.32 is amended by revising paragraphs (a)(1), (b)(1) introductory text and (b)(2), the first 3 sentences of (c)(1), (c)(2), the first sentence of (d)(3), the first sentence of (e)(1), the first sentence of (e)(2), (b) and (g)(1) to read as follows:

§ 1616.32 Method for establishment and use of alternate laundering procedures under section 5(c)(4)(ii) of the standard.

(a) Scope. (1) Section 1616.5(c)(4)(ii) of the Standard for the Flammability of Children's Sleepwear in sizes 7–14 (16 CFR 1616.5(c)(4)(ii)) requires that all fabrics and certain garments subject to the standard be tested for flammability as produced (or after one washing and drying) and after the items have been washed and dried 50 times in machines, using the procedure specified in AATCC Test Method 124–1996.[3] This section also provides that items may be laundered a different number of times under another washing and drying procedure if the Commission finds that such an alternate laundering procedure is equivalent to the procedure specified in the standard.

* * * * *

(b) Application procedure. (1) Applicants seeking approval for use of an alternate laundering procedure under section 1616.5(c)(4)(ii) of the standard must submit the following information to the Assistant Executive Director for Compliance, Consumer Product Safety Commission, Washington, DC 20207:

* * *

* * * * *

(2) Applications shall be certified by the chief executive officer of the applicant or the official to whom the duty to certify has been delegated in writing. The Commission's Assistant Executive Director for Compliance must be notified in writing of any such delegation.

(c) Use of alternate laundering procedure. (1) The applicant may begin to use the alternate laundering procedure 30 days after the application is received by the Assistant Executive Director for Compliance unless notified to the contrary. The Assistant Executive Director for Compliance will normally furnish an applicant with written notice of approval within 30 days. The applicant may be notified that a longer time is needed for evaluation of the application, and in the discretion of the Assistant Executive Director for Compliance, may be authorized to use the alternate laundering procedure pending the final decision. * * *

(2) As provided in detail in paragraph (e) of this section, applicants must immediately discontinue use of an alternate procedure, and must immediately notify the Assistant Executive Director for Compliance if there are test failures during revalidation testing.

(d) Revalidation testing. * * *

(3) Records of revalidation testing need not be submitted to the Assistant Executive Director for Compliance.

* * *

(e) Revalidation testing failures. (1) If revalidation testing for any fabric or garment does not meet the criteria of paragraph (f) of this section, the applicant must immediately discontinue use of the alternate laundering procedure for the fabric or garment and must immediately notify the Assistant Executive Director for Compliance in writing of the failure to meet the criteria. * * *

(2) When use of an alternate laundering procedure for a particular fabric or garment has been discontinued because of a failure to meet the criteria of paragraph (f) of this section, the alternate laundering procedure shall not be used again unless a new application for approval is submitted to the Assistant Executive Director for Compliance and that officer approves the application in writing. * * *

(f) Commission criteria for evaluating applications. (1) The Assistant Executive Director for Compliance will approve the alternate laundering procedure as equivalent to the laundering procedure specified in section 1616.5(c)(4)(ii) of the standard if testing from 20 specimens laundered by the proposed alternate procedure yields as many or more char lengths in excess of five inches as does testing from the twenty specimens laundered by the 50-laundering cycle method prescribed in the standard.

(2) If the alternate laundering procedure yields fewer char lengths in excess of five inches than does the 50-wash and dry cycle, then the Assistant Executive Director for Compliance will not consider the alternate procedure to be equivalent with the following exception: If the number of five-inch chars from the alternate procedure is within one of the number of five-inch chars obtained from the 50-cycle procedure, the applicant may repeat the original test with new specimens and if the combined results of both tests show the count of chars exceeding five inches from the alternate is equal to, or greater than, the count from the 50-wash cycle procedure, the Assistant Executive

[3] American Association of Textile Chemists and Colorists, Technical Manual. Vol 73, 1997.

Director for Compliance will approve the alternate laundering procedure.

(g) Commission testing for compliance. (1) For the purpose of determining compliance with the standard, the Commission will rely on testing employing the laundering procedure now prescribed by section 1616.5(c)(4)(ii) of the standard. (15 U.S.C. 1193, 1194; 15 U.S.C. 2079(b))

* * * * *

Dated: March 8, 1999.

Sadye E. Dunn,

Secretary, Consumer Product Safety Commission.

List of Relevant Documents

1. American Association of Textile Chemists and Colorists, ''Appearance of Durable Press Fabrics After Repeated Home Launderings,'' AATCC Test Method 124–1969. AATCC Technical Manual, Vol. 46, 1970.

2. American Association of Textile Chemists and Colorists, ''Appearance of Fabrics After Repeated Home Laundering,'' AATCC Test Method 124–1996. AATCC Technical Manual, Vol. 73, 1997.

3. Briefing memorandum from Margaret Neily, Project Manager, Directorate for Engineering Sciences, to the Commission, ''Proposed Amendments to Flammable Fabrics Act Standards to Replace Obsolete Standard Detergent and Update Laundering Procedures Required for Tests,'' __, 1998.

4. Memorandum from Gail Stafford, Directorate for Laboratory Sciences, to Margaret Neily, Project Manager, ''Amending the Laundering Provisions of the CPSC Flammability Regulations,'' August 18, 1998.

5. Memorandum from Gail Stafford, Directorate for Laboratory Sciences, to Margaret Neily, Project Manager, ''Textile Laundering Standards,'' August 18, 1998.

6. Memorandum from Gail Stafford and Shing-Bong Chen, Directorate for Laboratory Sciences, to Margaret Neily, Project Manager, ''Detergent Comparison Tests,'' August 19, 1998.

7. Log of Meeting on January 21, 1998 concerning Flammability Test of Pyrovatex-treated Flame Resistant Fabrics.

8. Memorandum from Terrance R. Karels, Directorate for Economic Analysis, to Margaret Neily, Project Manager, ''Amendments to FFA Standards,'' August 10, 1998.

9. Memorandum from Margaret Neily, Project Manager, Directorate for Engineering Sciences, to the Commission, ''Briefing Package Supplement: Laundering/Detergent Update for Flammable Fabrics Act Standards—The Soap and Detergent Association (SDA) Laundering Procedures,'' January 11, 1999.

10. Memorandum from Gail Stafford, Directorate for Laboratory Sciences, to Margaret Neily, Project Manager, ''Soap and Detergent Association Proposed Laundering Procedure,'' December 23, 1998.

11. Letter from Jenan Al-Atrash, Director, Human Health & Safety, The Soap and Detergent Association, to Margaret Neily, Technical Program Coordinator, Office of the Executive Director, including SDA Recommended Wash Conditions for CFR 1615.4, September 15, 1998.

12. Letter from Jenan Al-Atrash, Director, Human Health & Safety, The Soap and Detergent Association, to Margaret Neily, Technical Program Coordinator, Office of the Executive Director, follow-up comments to September 15, 1998, letter, November 12, 1998.

13. Memorandum from Margaret L. Neily, Project Manager, Directorate for Engineering Sciences, to the Commission, ''Laundering/Detergent Updates—FR notice supplements,'' February 19, 1999.

[FR Doc. 99–6075 Filed 3–16–99; 8:45 am]

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CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Parts 1630 and 1631

Standard for the Surface Flammability of Carpets and Rugs; Standard for the Surface Flammability of Small Carpets and Rugs

AGENCY: Consumer Product Safety Commission.

ACTION: Proposed amendments.

SUMMARY: The Commission proposes to amend the flammability standards for carpets and rugs and for small carpets and rugs by revising the laundering procedure specified in those standards. The laundering procedures help assure that any fire retardant treatment used on carpets or on fibers used in the manufacture of carpets will not be removed or degraded by cleaning, thereby creating a flammability hazard. The Commission is proposing these amendments because the detergent specified by the existing laundering procedure is no longer available and the operating characteristics of the washing and drying machines required by that procedure are no longer representative of machines now used for home laundering.

DATES: Written comments concerning the proposed amendments must be received by the Office of the Secretary not later than June 1, 1999.

ADDRESSES: Written comments should be captioned ''Carpet and Rug Standards, Laundering Procedures'' and mailed to the Office of the Secretary, Consumer Product Safety Commission, Washington, D.C. 20207, or delivered to that office, room 502, 4330 East-West Highway, Bethesda, Maryland. Comments may also be filed by telefacsimile to (301) 504–0127 or by email to cpsc-os@cpsc.gov.

FOR FURTHER INFORMATION CONTACT: Margaret Neily, Project Manager, Directorate for Engineering Sciences, Consumer Product Safety Commission, Washington, DC 20207; telephone (301) 504–0508, extension 1293.

SUPPLEMENTARY INFORMATION:

A. Background

The Flammable Fabrics Act (''FFA'') (15 U.S.C. 1191 *et seq.*) authorizes issuance and amendment of flammability standards and regulations to protect the public from unreasonable risks of death, injury, and property damage from fire associated with products of interior furnishing made from fabric and related materials.

In 1970, the Secretary of Commerce issued two flammability standards for carpets and rugs to protect the public from risks of deaths, injuries, and economic losses associated with ignition of carpets and rugs by small ignition sources. The Standard for the Surface Flammability of Carpets and Rugs, now codified at 16 CFR Part 1630, is applicable to carpets and rugs with a surface area greater than 24 square feet and one dimension longer than six feet. The Standard for the Surface Flammability of Small Carpets and Rugs, now codified at 16 CFR Part 1631, is applicable to carpets and rugs which have an area of 24 square feet or less, and no dimension longer than six feet.

Both standards prescribe a test which involves exposing specimens from a carpet or rug to a standard ignition source. Eight specimens, each measuring nine inches by nine inches, are taken from the product to be tested. A specimen passes the test in the standards if charring does not extend more than three inches in any direction from the ignition source. The flammability standard for large carpets and rugs requires that seven of the eight specimens taken from a carpet or rug must pass the test. See 16 CFR 1630.3.

The standard for small carpets and rugs requires that seven of eight specimens taken from a carpet or rug must pass the test, or that the product must be permanently labeled indicating that it fails the flammability standard. See 16 CFR 1631.3, 1631.5(a) and 1631.34.

In 1973, authority to issue and amend flammability standards under the FFA was transferred from the Department of Commerce to the Consumer Product Safety Commission by section 30(b) of the Consumer Product Safety Act (15 U.S.C. 2079(b)).

B. Amending the Flammability Standards

As discussed below, laundering procedures are required by the standards to help assure that any fire-

retardant chemicals used in the production of carpets or rugs will not be removed or degraded by repeated cleaning and create a flammability hazard. However, the current procedures are out of date in several respects, and the Commission therefore proposes to change them.

1. Current Procedures

The carpet flammability standards describe the apparatus and procedure to be used to test carpets and rugs for compliance with the standards. See 16 CFR 1630.4 and 1631.4.

At the time the carpet standards were issued, some carpets and rugs were treated with fire retardants or made from fibers that were treated with fire retardants. The standards address the possibility that any fire-retardant treatment used on carpets or rugs or on fibers used in the production of carpets or rugs might be progressively reduced by cleaning. Section 1630.4(b)(1)(ii) of the standard for large carpets and rugs and section 1631.4(b)(1)(ii) of the standard for small carpets and rugs require that specimens of a carpet or rug that has a fire-retardant treatment or that is made from fibers which have had a fire-retardant treatment shall be tested after they have been washed and dried 10 times in accordance with a specified laundering procedure, or ''such number of times under such other washing and drying procedures as shall have been found to be equivalent by the Consumer Product Safety Commission.''

The laundering procedure specified by the standards is AATCC Test Method 124–67, published by the American Association of Textile Chemists and Colorists (''AATCC''). (1)[1] This procedure involves washing and drying the specimens in a household washing machine and dryer. The AATCC test method is similar to the method that might be used by consumers to clean small carpets and rugs such as bath mats and small area rugs.

Although the AATCC laundering procedure does not resemble the method that consumers could be expected to use for cleaning wall-to-wall carpeting and large carpets or rugs, the Commission has not made a finding that any other washing and drying procedure is equivalent to AATCC Test Method 124–67.

AATCC Test Method 124–67 specifies operating characteristics of the washing machine and dryer to be used, wash water and rinse water temperatures, exhaust temperature of the dryer, and a particular detergent, AATCC Standard Detergent 124. AATCC Test Method 124–67 was developed in 1967. These specifications are representative of the equipment, wash, rinse, and drying temperatures, and detergent used for home laundering in the 1960s. For example, AATCC Standard Detergent 124 is a high-phosphate powder with optical brightener, similar to the phosphate-based detergents sold to consumers between 1950 and 1970. (3)

Since 1970, environmental concerns about water pollution have resulted in the elimination of phosphate-based detergents for home laundering. Today, all laundry detergents sold to consumers are nonphosphate-based. Additionally, energy-efficient washing machines and dryers currently sold for consumer use have operating characteristics and temperature settings which differ from those specified by AATCC Test Method 124–67. (3)

2. Revised Laundering Test Method

In 1996, AATCC revised AATCC Test Method 124, ''Appearance of Fabrics After Repeated Home Laundering.'' (2) The 1996 AATCC test method more closely resembles the equipment and practices used for household laundering of fabrics at this time. The revised test method differs from AATCC Test Method 124–67 by specifying the use of 1993 AATCC detergent, a nonphosphate-based detergent. The 1996 test method also specifies use of a washing machine with different operating characteristics than those specified by AATCC Test Method 124–67, and rinse water temperatures which differ from those in the older test method. (3) Table 1, below, provides a summary comparison of the two test methods.

TABLE 1.—AATCC TEST METHOD 124

Wash/dry conditions	Version 1967	Version 1996	
Washing Machine:			
Cycle	Normal	Normal/Cotton Sturdy.	
Wash Water Temp	60 ± 3°C	60 ± 3°C.	
Rinse Water Temp	41 ± 3°C	Less Than 29°C.	
Water Level	Full	18 ± 1 gal.	
Agitator Speed	70 ± 5 spm	179 ± 2 spm.	
Wash Time	12 minutes	12 minutes.	
Spin Speed	500–510 rpm	630–660 rpm.	
Final Spin Cycle	4 minutes	6 minutes.	
Dryer:			
Cycle	Normal	Cotton Sturdy	Durable Press.
Exhaust Temp	140–160°F	140–160°F	140–160°F.
Cool Down Cycle	5 minutes	5 minutes	10 minutes.

spm = strokes (or cycles) per minute.
rpm = revolutions per minute.

In 1996, AATCC also announced that when that organization's supply of Standard Detergent 124 is depleted, that detergent will no longer be available. AATCC is the only source for Standard Detergent 124. Additionally, washing machines offered for sale at this time do not have the settings and operating characteristics of the washing machine specified by AATCC Test Method 124–67. (3)

The laundering procedures specified in the carpet flammability standards must be followed by the Commission when testing carpets manufactured with a fire-retardant treatment to determine their compliance. Information available

[1] Numbers in parentheses identify reference documents in the List of Relevant Documents at the end of this notice. Requests for inspection of any of these documents should be made at the Office of the Secretary, 4330 East-West Highway, room 502, or by calling that office at (301) 504–0800.

to the Commission indicates that at this time, no carpets or rugs treated with a fire retardant or made from fibers which have been treated with a fire retardant are offered for sale. However, it is possible that carpets treated with fire retardants may be marketed in the future.

Section 8 of the FFA (15 U.S.C. 1197) provides that no person shall be subject to criminal prosecution under section 7 of the FFA (15 U.S.C. 1196) if that person holds in good faith a written guaranty to the effect that ''reasonable and representative tests conducted in accordance with the applicable standard'' show that a product subject to a flammability standard issued under the FFA complies with that standard. Enforcement regulations codified at 16 CFR 1630.31 and 1631.31 establish minimum requirements for reasonable and representative tests to support guaranties of compliance with the carpet flammability standards.

Although issuance of a guaranty is not mandatory, manufacturers who elect to issue guaranties must perform the testing required by the standard, including the laundering procedure specified by the standard for those carpets and rugs manufactured with a fire-retardant treatment unless exempted from the use of that procedure by other provisions of the standards.

3. Review of Other Existing Standards

In addition to reviewing AATCC Test Method 124–1996, the Commission staff reviewed and analyzed fourteen other international and technical association standards or test methods to determine if any were appropriate for consideration in this proceeding. Standards and test methods from AATCC, ASTM, the International Standards Organization, the United Kingdom, Australia, Canada, China and the Soap and Detergent Association were identified.

All of the standards designed for fabric laundering have significant deficiencies. They are either based on earlier versions of AATCC Test Method 124 (with obsolete detergent and equipment), require equipment not available in the U.S., use only water in the laundering procedure, or specify significantly lower wash and rinse water temperatures than those still available for consumers.

Two of these methods (AATCC 138 and a Canadian standard CAN/CGSB–4.2 No. 30.2–M90) were specifically developed for carpets. However, they use different liquid detergents, and neither of these methods approximates the typical home laundering used in the Flammability Standard for Carpets and Rugs. Further, the AATCC 138 was judged to be too harsh for the hand washable flokati rugs because of the brushing specified by the method.

4. Proposed Amendment

The carpet flammability standards were issued under section 4 of the FFA (15 U.S.C. 1193), which authorizes the issuance or amendment of flammability standards to protect the public against unreasonable risks of fire leading to death, personal injury, or significant property damage. As required by section 4(b) of the FFA, both standards are based on findings that they are needed to adequately protect the public against the unreasonable risk of the occurrence of fire leading to death, personal injury, or significant property damage. That section further requires findings that a flammability standard issued under the FFA is ''reasonable, technologically practicable, and appropriate.''

The proposed change to the standards is needed to make the specified laundering procedures represent those currently used by consumers. The proposed amendments are also needed to assure that the carpet flammability standards will continue to be ''technologically practicable'' for both the Commission's laboratory and those manufacturers of carpets and rugs required to use the laundering procedures when testing for guaranty purposes.

Section 4(g) of the FFA (15 U.S.C. 1193(g)) states that a proceeding ''for the promulgation of a regulation under this section'' shall be initiated by publication of an advance notice of proposed rulemaking (''ANPR''), and sets forth requirements for the contents of the ANPR. However, these proposed amendments are necessary because technical advances and the passage of time have rendered the existing test method obsolete. The amendments preserve the original intent and effect of the existing test method, modifying that method only as necessary to reflect the existence of modern equipment and detergent. Moreover, the existing regulations permit the Commission to employ a laundering test method different from AATCC Test Method 124 if it concludes that the test method is substantively as protective. Because the existing regulations allow the Commission to achieve without any amendment the substance of what it now proposes to achieve by amendment, and because the proposed amendments preserve the regulatory status quo, save for the reflection of modern equipment and detergent, the Commission has determined that it is not legally required to commence this proceeding with an ANPR, nor is it necessary for the Commission to make the findings that FFA sections 1193(g) and (h) would otherwise require.

The amendments proposed below would require specimens of carpet manufactured with a fire-retardant treatment to be tested after washing and drying 10 times using the procedure specified in AATCC Test Method 124–1996. The proposed amendments would incorporate that test method into the carpet flammability standards by reference.

Existing sections 1630.4(b)(1)(ii) and 1631.4(b)(1)(ii) contain the following language:

> *Alternatively,* the selected sample or oversized specimens thereof may be *washed, dry-cleaned, or shampooed* 10 times prior to cutting of test specimens, *in such manner* as the manufacturer or other interested party shall previously have established to the satisfaction of the Consumer Product Safety Commission is *normally used* for that type of carpet or rug in service. [Emphasis added.]

Alternative laundering procedures have been approved in accordance with provisions of sections 1630.4(b)(1)(ii) and 1631.4(b)(1)(ii) for hide carpets and rugs and wool flokati carpets and rugs. See 16 CFR 1630.61, 1630.62 and 1630.63; 16 CFR 1631.61 and 1631.62. The amendments proposed below would change the references in Subpart C of sections 1630 and 1631 to the revised AATCC Test Method 124–1996 so that they are consistent with the other proposed changes.

5. Effective Date

Section 4(b) of the FFA (15 U.S.C. 1193(b)) provides that an amendment of a flammability standard shall become effective one year from the date it is promulgated, unless the Commission finds for good cause that an earlier or later effective date is in the public interest, and publishes that finding. Section 4(b) also requires that an amendment of a flammability standard shall exempt products ''in inventory or with the trade'' on the date the amendment becomes effective, unless the Commission limits or withdraws that exemption because those products are so highly flammable that they are dangerous for use by consumers.

One reason for proposing these amendments of the carpet flammability standards is that the standard detergent specified by the existing laundering method in the standard is no longer available. The Commission has reason to believe that an effective date 30 days after publication of final amendments will be in the public interest. The Commission does not propose to withdraw or limit the exemption for

products in inventory or with the trade as provided by section 4(b) of the FFA.

The Commission believes that an effective date of thirty days would give adequate notice to all interested persons of the change in laundering procedure, and at the same time would assure that the Commission will be able to test for compliance with the standards without interruption. Those manufacturers who perform testing in accordance with the laundering procedure specified in the standard will also benefit from a relatively short effective date.

The Commission invites comments on the proposed effective date and factual information relating to that issue.

C. Other Issues

1. Impact on Small Businesses

In accordance with section 605(b) of the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Commission hereby certifies that the amendments to the carpet flammability standards proposed below will not have a significant economic impact on a substantial number of small entities, including small businesses, if issued on a final basis.

As noted above, the Commission has not been able to find any carpets or rugs currently offered for sale which have been treated with a fire-retardant treatment or made from fibers treated with a fire-retardant. In the event that some carpets treated with a fire-retardant or made from fibers treated with a fire-retardant treatment come onto the market in the future, manufacturers will be able to apply for approval of any alternate laundering procedure which is normally used for cleaning those products if the procedure specified by the amendments is not appropriate.

Consequently, the Commission estimates that the amendments proposed below will have no economic consequences to any manufacturers, large or small, of carpets and rugs.

2. Environmental Considerations

The amendments proposed below fall within the categories of Commission actions described at 16 CFR 1021.5(c) that have little or no potential for affecting the human environment. The amendments are not expected to have a significant effect on production processes or on the types or amounts of materials used for the manufacture of carpets and rugs. The amendments will not render existing inventories unsalable, or require destruction of existing goods. The Commission has no information indicating any special circumstances in which these amendments may affect the human environment. For that reason, neither an environmental assessment nor an environmental impact statement is required.

3. Executive Orders

Executive Order 12988 (February 5, 1996), requires agencies to state in clear language the preemptive effect, if any, to be given to any new regulation. The amendments proposed below, if issued on a final basis, would modify two flammability standards issued under the FFA. With certain exceptions which are not applicable here, no state or political subdivision of a state may enact or continue in effect ''a flammability standard or other regulation'' applicable to the same fabric or product as an FFA standard if the state or local flammability standard or regulation is ''designed to protect against the same risk of the occurrence of fire'' unless the state or local flammability standard or regulation ''is identical'' to the FFA standard. See section 16 of the FFA (15 U.S.C. 1203). Consequently, if issued on a final basis, the amendments proposed below will preempt nonidentical state or local flammability standards or regulations that are intended to address the unreasonable risk of the occurrence of fire associated with ignition of carpets and rugs.

In accordance with Executive Order 12612 (October 26, 1987), the Commission certifies that the proposed amendments do not have sufficient implications for federalism to warrant a Federalism Assessment.

List of Subjects in 16 CFR Parts 1630 and 1631

Carpets and rugs, Consumer protection, Flammable materials, Floor coverings, Labeling, Records, Rugs, Textiles, Warranties.

Conclusion

Therefore, pursuant to the authority of section 30(b) of the Consumer Product Safety Act (15 U.S.C. 2079(b)) and sections 4 and 5 of the Flammable Fabrics Act (15 U.S.C. 1193, 1194), the Commission hereby proposes to amend title 16 of the Code of Federal Regulations, Chapter II, Subchapter D, Parts 1630 and 1631 to read as follows:

PART 1630—STANDARD FOR THE SURFACE FLAMMABILITY OF CARPETS AND RUGS

1. The authority for subpart A of part 1630 continues to read as follows:

Authority: Sec. 4, 67 Stat. 112, as amended, 81 Stat. 569–570; 15 U.S.C. 1193.

2. Section 1630.4 is amended by revising paragraph (b)(1)(ii), removing footnote 3, redesignating footnotes 4 and 5 as footnotes 3 and 4 respectively, and adding new paragraph (b)(1)(iii) to read as follows:

§ 1630.4 Test procedure.

* * * * *

(b) *Sampling*—(1)(i) * * *

(ii) If the carpet or rug has had a fire-retardant treatment, or is made of fibers which have had a fire-retardant treatment, the selected sample or over-sized specimens thereof shall be washed, prior to cutting of test specimens after they have been washed and dried either 10 times in accordance with sections 8.2.2, 8.2.3, and 8.3.1(A) of AATCC Test Method 124–1996 ''Appearance of Fabrics After Repeated Home Laundering,'' using wash temperature V (60° ±3° C, 140° ±5° F) specified in Table II of that method, and the water level, agitator speed, washing time, spin speed and final spin cycle specified for ''Normal/Cotton Sturdy'' in Table III, and drying shall be performed in accordance with section 8.3.1(A) of that test method, Tumble Dry, maximum load 3.64 Kg (8 pounds), using the exhaust temperature (66° ±5° C,150° ±10° F) and cool down time of 10 minutes specified in the ''Durable Press'' conditions of Table IV; or such number of times by another washing and drying procedure which the Consumer Product Safety Commission has determined to be equivalent of AATCC Test Method 124–1996. Alternatively, the selected sample or oversized specimens thereof may be washed, drycleaned, or shampooed 10 times, prior to cutting of test specimens, in such manner as the manufacturer or other interested party shall previously have established to the satisfaction of the Consumer Product Safety Commission is normally used for that type of carpet or rug in service.

(iii) AATCC Test Method 124–1996 ''Appearance of Fabrics After Repeated Home Laundering,'' is found in Technical Manual of the American Association of Textile Chemists and Colorists, vol. 73, 1997, is incorporated by reference. Copies of this document are available from the American Association of Textile Chemists and Colorists, P.O. Box 12215, Research Triangle Park, North Carolina 27709. This document is also available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., Suite 700, Washington, DC. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. These materials are incorporated as they exist in the edition which has been approved

by the Director of the Federal Register and which has been filed with the Office of the Federal Register.

* * * * *

3. The authority for subpart C of part 1630 continues to read as follows:

Authority: Secs. 4, 5, 67 Stat. 112, as amended, 81 Stat. 569–570; 15 U.S.C. 1193, 1194.

4. Section 1630.61 is amended by revising the first sentence of paragraph (a) to read as follows:

§ 1630.61 Hide carpets and rugs—alternative washing procedure.

(a) The Standard for the Surface Flammability of Carpets and Rugs (FF 1–70) at § 1630.4(b)(1)(ii) provides that if a carpet or rug has had a fire-retardant treatment, or is made of fibers which have had a fire-retardant treatment, the sample or oversized specimens thereof selected for testing under the standard shall be washed prior to the cutting of test specimens either 10 times under the washing and drying procedure prescribed in Method 124–1996 of the American Association of Textile Chemists and Colorists or such number of times under such other washing and drying procedure as shall previously have been found to be equivalent by the Consumer Product Safety Commission. * * *

* * * * *

5. Section 1630.62 is amended by revising the first sentences in paragraphs (a) and (d)(3) as follows:

§ 1630.62 Wool flokati carpets and rugs—alternative washing procedure.

(a) The Standard for the Surface Flammability of Carpets and Rugs (FF 1–70) at § 1630.4(b)(1)(ii) provides that if a carpet or rug has had a fire-retardant treatment, or is made of fibers which have had a fire-retardant treatment, the sample or oversized specimens thereof selected for testing under the standard shall be washed prior to the cutting of test specimens either 10 times under the washing and drying procedure prescribed in Method 124–1996 of the American Association of Textile Chemists and Colorists or such number of times under such other washing and drying procedure as shall previously have been found to be equivalent by the Consumer Product Safety Commission. * * *

* * * * *

(d) * * *

(3) Place individual specimen face down in a shallow pan which has been filled to a depth of 2″ with a wash solution of 1.1 grams of AATCC (American Association of Textile Chemists and Colorists) Standard Detergent as specified in AATCC Method 124–1996 (or equivalent) per liter of water preheated to 105 °F. * * *

* * * * *

6. Section 1630.63 is amended by revising the first sentence in paragraph (a)(1) to read as follows:

§ 1630.63 Suspension of washing requirements for carpets and rugs with alumina trihydrate in the backing.

(a)(1) The Standard for the Surface Flammability of Carpets and Rugs (FF 1–70) at § 1630.4(b)(1)(ii) provides that if a carpet or rug has had a fire-retardant treatment, or is made of fibers which have had a fire-retardant treatment, the sample or oversized specimens thereof selected for testing under the standard shall be washed prior to the cutting of test specimens either 10 times under the washing and drying procedure prescribed in Method 124–1996 of the American Association of Textile Chemists and Colorists or such number of times under such other washing and drying procedure as shall previously have been found to be equivalent by the Consumer Product Safety Commission. * * *

* * * * *

PART 1631—STANDARD FOR THE SURFACE FLAMMABILITY OF SMALL CARPETS AND RUGS

1. The authority for subpart A of part 1631 continues to read as follows:

Authority: Sec. 4, 67 Stat. 112, as amended, 81 Stat. 569–570; 15 U.S.C. 1193.

2. Section 1631.4 is amended by revising paragraph (b)(1)(ii), removing footnote 3, redesignating footnotes 4 and 5 as footnotes 3 and 4 respectively, and adding new paragraph (b)(1)(iii) to read as follows:

1631.4 Test procedure.

* * * * *

(b) Sampling—(1) * * *

(ii) If the carpet or rug has had a fire-retardant treatment, or is made of fibers which have had a fire-retardant treatment, the selected sample or oversized specimens thereof shall be washed, prior to cutting of test specimens after they have been washed and dried either 10 times in accordance with sections 8.2.2, 8.2.3, and 8.3.1(A) of AATCC Test Method 124–1996 ''Appearance of Fabrics After Repeated Home Laundering,'' using wash temperature V (60° ±3 °C, 140° ±5 °F) specified in Table II of that method, and the water level, agitator speed, washing time, spin speed and final spin cycle specified for ''Normal/Cotton Sturdy'' in Table III, and drying shall be performed in accordance with section 8.3.1(A) of that test method, Tumble Dry, maximum load 3.64 Kg (8 pounds), using the exhaust temperature (66° ±5 °C, 150° ±10 °F) and cool down time of 10 minutes specified in the ''Durable Press'' conditions of Table IV; or such number of times by another washing and drying procedure which the Consumer Product Safety Commission has determined to be equivalent of AATCC Test Method 124–1996. Alternatively, the selected sample or oversized specimens thereof may be washed, drycleaned, or shampooed 10 times, prior to cutting of test specimens, in such manner as the manufacturer or other interested party shall previously have established to the satisfaction of the Consumer Product Safety Commission is normally used for that type of carpet or rug in service.

(iii) AATCC Test Method 124–1996 ''Appearance of Fabrics After Repeated Home Laundering,'' is found in Technical Manual of the American Association of Textile Chemists and Colorists, vol. 73, 1997, is incorporated by reference. Copies of this document are available from the American Association of Textile Chemists and Colorists, P.O. Box 12215, Research Triangle Park, North Carolina 27709. This document is also available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., Suite 700, Washington, DC. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. These materials are incorporated as they exist in the edition which has been approved by the Director of the Federal Register and which has been filed with the Office of the Federal Register.

* * * * *

3. The authority for subpart C of part 1631 continues to read as follows:

Authority: Secs. 4, 5, 67 Stat. 112, as amended, 81 Stat. 569–70; 15 U.S.C. 1193, 1194.

4. Section 1631.61 is amended by revising the first sentence of paragraph (a) as follows:

§ 1631.61 Hide carpets and rugs—alternative washing procedure.

(a) The Standard for the Surface Flammability of Carpets and Rugs (FF 1–70) at § 1630.4(b)(1)(ii) provides that if a carpet or rug has had a fire-retardant treatment, or is made of fibers which have had a fire-retardant treatment, the sample or oversized specimens thereof selected for testing under the standard shall be washed prior to the cutting of test specimens either 10 times under the washing and drying procedure

prescribed in Method 124–1996 of the American Association of Textile Chemists and Colorists or such number of times under such other washing and drying procedure as shall previously have been found to be equivalent by the Consumer Product Safety Commission.
* * *

* * * * *

5. Section 1631.62 is amended by revising the first sentences in paragraphs (a) and (d)(3) to read as follows:

§ 1631.62 Wool flokati carpets and rugs—alternative washing procedure.

(a) The Standard for the Surface Flammability of Carpets and Rugs (FF 1–70) at § 1630.4(b)(1)(ii) provides that if a carpet or rug has had a fire-retardant treatment, or is made of fibers which have had a fire-retardant treatment, the sample or oversized specimens thereof selected for testing under the standard shall be washed prior to the cutting of test specimens either 10 times under the washing and drying procedure prescribed in Method 124–1996 of the American Association of Textile Chemists and Colorists or such number of times under such other washing and drying procedure as shall previously have been found to be equivalent by the Consumer Product Safety Commission.
* * *

* * * * *

(d) * * *

(3) Place individual specimen face down in a shallow pan which has been filled to a depth of 2″ with a wash solution of 1.1 grams of AATCC (American Association of Textile Chemists and Colorists) Standard Detergent as specified in AATCC Method 124–1996 (or equivalent) per liter of water preheated to 105 °F. * * *
* * * * *

Dated: March 8, 1999.

Sadye E. Dunn,

Secretary, Consumer Product Safety Commission.

List of Relevant Documents

1. American Association of Textile Chemists and Colorists, ''Appearance of Durable Press Fabrics After Repeated Home Launderings,'' AATCC Test Method 124–1969. AATCC Technical Manual, Vol. 46, 1970.

2. American Association of Textile Chemists and Colorists, ''Appearance of Fabrics After Repeated Home Laundering,'' AATCC Test Method 124–1996. AATCC Technical Manual, Vol. 73, 1997.

3. Briefing memorandum from Margaret Neily, Project Manager, Directorate for Engineering Sciences, to the Commission, ''Proposed Amendments to Flammable Fabrics Act Standards to Replace Obsolete Standard Detergent and Update Laundering Procedures Required for Tests,'' _____, 1998.

4. Memorandum from Gail Stafford, Directorate for Laboratory Sciences, to Margaret Neily, Project Manager, ''Amending the Laundering Provisions of the CPSC Flammability Regulations,'' August 18, 1998.

5. Memorandum from Gail Stafford, Directorate for Laboratory Sciences, to Margaret Neily, Project Manager, ''Textile Laundering Standards,'' August 18, 1998.

6. Memorandum from Gail Stafford and Shing-Bong Chen, Directorate for Laboratory Sciences, to Margaret Neily, Project Manager, ''Detergent Comparison Tests,'' August 19, 1998.

7. Log of Meeting on January 21, 1998 concerning Flammability Test of Pyrovatex-treated Flame Resistant Fabrics.

8. Memorandum from Terrance R. Karels, Directorate for Economic Analysis, to Margaret Neily, Project Manager, ''Amendments to FFA Standards,'' August 10, 1998.

9. Memorandum from Margaret Neily, Project Manager, Directorate for Engineering Sciences, to the Commission, ''Briefing Package Supplement: Laundering/Detergent Update for Flammable Fabrics Act Standards—The Soap and Detergent Association (SDA) Laundering Procedures,'' January 11, 1999.

10. Memorandum from Gail Stafford, Directorate for Laboratory Sciences, to Margaret Neily, Project Manager, ''Soap and Detergent Association Proposed Laundering Procedure,'' December 23, 1998.

11. Letter from Jenan Al-Atrash, Director, Human Health & Safety, The Soap and Detergent Association, to Margaret Neily, Technical Program Coordinator, Office of the Executive Director, including SDA Recommended Wash Conditions for CFR 1615.4, September 15, 1998.

12. Letter from Jenan Al-Atrash, Director, Human Health & Safety, The Soap and Detergent Association, to Margaret Neily, Technical Program Coordinator, Office of the Executive Director, follow-up comments to September 15, 1998, letter, November 12, 1998.

13. Memorandum from Margaret L. Neily, Project Manager, Directorate for Engineering Sciences, to the Commission, ''Laundering/Detergent Updates—FR notice supplements,'' February 19, 1999.

[FR Doc. 99–6074 Filed 3–16–99; 8:45 am]

BILLING CODE 6355–01–P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1632

Standard for the Flammability of Mattresses and Mattress Pads

AGENCY: Consumer Product Safety Commission.

ACTION: Proposed amendments.

SUMMARY: The Commission proposes to amend the flammability standard for mattresses and mattress pads by revising the laundering procedure specified in that standard for mattress pads which contain a chemical fire retardant. These laundering procedures help assure that any chemical flame retardant is not removed or degraded by repeated washing and drying, thereby creating a flammability hazard. The Commission is proposing these amendments because the detergent specified by the existing laundering procedure is no longer available and the operating characteristics of the washing and drying machines required by that procedure are no longer representative of machines now used for home laundering.

DATES: Written comments concerning the proposed amendments must be received by the Office of the Secretary not later than June 1, 1999.

ADDRESSES: Written comments should be captioned ''Mattress Pads, Laundering Procedures'' and mailed to the Office of the Secretary, Consumer Product Safety Commission, Washington, D.C. 20207, or delivered to that office, room 502, 4330 East-West Highway, Bethesda, Maryland. Comments may also be filed by telefacsimile to (301) 504–0127 or by email to cpsc-os@cpsc.gov.

FOR FURTHER INFORMATION CONTACT: Margaret Neily, Project Manager, Directorate for Engineering Sciences, Consumer Product Safety Commission, Washington, D.C. 20207; telephone (301) 504–0508, extension 1293.

SUPPLEMENTARY INFORMATION:

A. Background

The Flammable Fabrics Act (''FFA'') (15 U.S.C. 1191 *et seq.*) authorizes issuance and amendment of flammability standards and regulations to protect the public from unreasonable risks of death, injury, and property damage from fire associated with products of interior furnishing made from fabric and related materials.

In 1972, the Secretary of Commerce issued a flammability standard for mattresses and mattress pads to protect the public from death and serious burn injuries associated with ignition of mattresses and mattress pads by smoldering cigarettes. That standard became effective in 1973, and is codified at 16 CFR Part 1632.

The standard prescribes a test for mattresses and mattress pads which requires placement of lighted cigarettes at specified locations on the surface of the mattress or mattress pad. An individual mattress or mattress pad prototype passes the test in the standard if no cigarette test location produces a

char length more than two inches in any direction.

In 1973, authority to issue flammability standards under the FFA was transferred from the Department of Commerce to the Consumer Product Safety Commission by section 30(b) of the Consumer Product Safety Act (15 U.S.C. 2079(b)).

On June 8, 1973, the Commission amended the standard by adding requirements for premarket testing of mattresses and mattress pads by manufacturers. As amended in 1973, the standard required manufacturers to perform prototype testing on each combination of materials and construction methods used in the production of mattresses or mattress pads. After successful completion of prototype testing, the standard required manufacturers to obtain samples at specified intervals during production and test those samples for compliance with the standard. See 38 FR 15095 (June 8, 1973).

In 1984, the Commission amended the standard to eliminate the requirements for production sampling and testing. The amended standard requires that manufacturers perform prototype testing with acceptable results before introducing products subject to the standard into commerce, but does not require manufacturers to perform production sampling and testing. See 49 FR 39780 (October 10, 1984).

B. Amending the Flammability Standard

As discussed below, laundering procedures are prescribed by the standard to help assure that any fire-retardant chemicals used in the production of mattress pads will not be removed or degraded by repeated washing and drying and create a flammability hazard. However, the current procedures are out of date in several respects and the Commission therefore proposes to change them.

1. Current Procedures

The mattress flammability standard describes the apparatus and procedure used to test mattress pads for compliance with the standard. See 16 CFR 1632.4 and 1632.5(a). The standard addresses the possibility that a fire-retardant chemical used in the production of mattress pads might be progressively reduced or degraded by washing and drying. Sections 1632.5(a) and (b) of the standard require that any mattress pad manufactured with a fire retardant chemical shall be tested in the condition in which it is intended to be sold, and after it has been washed and dried ten times in accordance with a specified laundering procedure. That laundering procedure is AATCC Test Method 124–82, published by the American Association of Textile Chemists and Colorists (''AATCC'').(1) [1] The mattress standard incorporates that laundering procedure by reference. See 16 CFR 1632.5(b)(2)(iv).

AATCC Test Method 124–82 specifies operating characteristics of the washing machine and dryer to be used, wash water and rinse water temperatures, exhaust temperature of the dryer, and a particular detergent, AATCC Standard Detergent 124. AATCC Test Method 124–82 was originally developed in 1967 and subsequently revised. These specifications are representative of the equipment, wash, rinse, and drying temperatures, and the detergent used for home laundering in the 1960s. For example, AATCC Standard Detergent 124 is a high-phosphate powder with optical brightener, similar to the phosphate-based detergents sold to consumers between 1950 and 1970.(3)

Since 1970, environmental concerns about water pollution have resulted in the elimination of phosphate-based detergents for home laundering. Today, all laundry detergents sold to consumers are nonphosphate-based. Additionally, energy-efficient washing machines and dryers currently sold for consumer use have operating characteristics and temperature settings which differ from those specified by AATCC Test Method 124–82.(3)

2. Revised Laundering Test Method

In 1996, AATCC revised AATCC Test Method 124, ''Appearance of Fabrics After Repeated Home Laundering''. (2) The 1996 AATCC test method more closely resembles the equipment and practices currently used for household laundering of fabrics. The revised test method differs from AATCC Test Method 124–82 by specifying the use of 1993 AATCC detergent, a nonphosphate-based detergent. The 1996 test method also specifies use of a washing machine with different operating characteristics than those specified by AATCC Test Method 124–82, and rinse water temperatures which differ from those in the older test method. (3) Table 1, below, provides a summary comparison of the two test methods.

In 1996, AATCC also announced that when that organization's supply of Standard Detergent 124 is depleted, that detergent will no longer be available. AATCC is the only source for Standard Detergent 124. Additionally, washing machines now offered for sale do not have the settings and operating characteristics of the washing machine specified by AATCC Test Method 124–82.(3)

TABLE 1.—AATCC TEST METHOD 124

Wash/Dry conditions	Version 1982	Version 1996	
Washing Machine:			
Cycle	Normal	Normal/Cotton Sturdy.	
Wash Water Temp	60 ± 3°C	60 ± 3°C.	
Rinse Water Temp	41 ± 3°C	Less Than 29°C.	
Water Level	Full	18 ± 1 gal.	
Agitator Speed	70 ± 5 spm	179 ± 2 spm.	
Wash Time	12 minutes	12 minutes.	
Spin Speed	500–510 rpm	630–660 rpm.	
Final Spin Cycle	4 minutes	6 minutes	
Dryer:			
Cycle	Normal	Cotton Sturdy	Durable Press.
Exhaust Temp	140–160°F	140–160°F	140–160°F.

[1] Numbers in parentheses identify reference documents in the List of Relevant Documents at the end of this notice. Requests for inspection of any of these documents should be made at the Office of the Secretary, 4330 East-West Highway, room 502, Bethesda, Md., or by calling that office at (301) 504–0800.

Cool Down Cycle	5 minutes	5 minutes	10 minutes.

spm = strokes (or cycles) per minute.
rpm = revolutions per minute.

3. Review of Other Existing Standards

In addition to reviewing AATCC Test Method 124–1996, the Commission staff reviewed and analyzed twelve other international and technical association standards or test methods to determine if any were appropriate for consideration in this proceeding. Standards and test methods from AATCC, ASTM, the International Standards Organization, the United Kingdom, Australia, Canada, China and the Soap and Detergent Association were identified. All of these methods could be used for sleepwear fabrics and mattress pads.

All of the identified standards for fabric laundering have significant deficiencies. They are either based on earlier versions of AATCC Test Method 124 (with obsolete detergent and equipment), require equipment not available in the U.S., use only water in the laundering procedure, or specify significantly lower wash and rinse water temperatures than those still available for consumers.

4. Comparability of Test Results

The Commission intended to perform some testing of mattress pads manufactured with chemical fire retardants after washing and drying 10 times in accordance with AATCC Test Method 124–82 and after washing and drying 10 times using AATCC Test Method 124–1996 to compare the two test methods. However, the staff has been unable to locate any flame retardant-treated mattress pads for this comparison. The mattress pads located by the staff are made of fabric and filling materials that do not need to be treated to pass the flammability test of the mattress standard. However, since there is a demand for natural fibers such as cotton (which may need to be FR treated to pass the flammability standard) in other products, the Commission believes it is appropriate to propose revising the laundering method so that it is consistent with actual consumer and industry laundering practices should cotton mattress pads return to the market in the future.

5. Proposed Amendment

The Commission proposes to revise the laundering procedures specified in 16 CFR 1632.5(b) to those of AATCC Test Method 124–1996.

The mattress flammability standard was issued and amended under section 4 of the FFA (15 U.S.C. 1193), which authorizes the issuance or amendment of flammability standards to protect the public against unreasonable risks of fire leading to death, personal injury, or significant property damage. As required by section 4(b) of the FFA, the standard is based on findings that it is needed to adequately protect the public against the unreasonable risk of the occurrence of fire leading to death, personal injury, or significant property damage. That section further requires findings that a flammability standard issued under the FFA is ''reasonable, technologically practicable, and appropriate.''

The proposed change to the standard is needed to make the specified laundering procedures represent those currently used by consumers. The proposed amendments are also needed to assure that the standard will continue to be ''technologically practicable'' for both the Commission's laboratory and those manufacturers of mattress pads required to use the laundering procedures before prototype testing.

Section 4(g) of the FFA (15 U.S.C. 1193(g)) states that a proceeding ''for the promulgation of a regulation under this section'' shall be initiated by publication of an advance notice of proposed rulemaking (''ANPR''), and sets forth requirements for the contents of the ANPR. However, these proposed amendments are necessary because technical advances and the passage of time have rendered the existing test method obsolete. The amendments preserve the original intent and effect of the existing test method, modifying that method only as necessary to reflect the existence of modern equipment and detergent. Moreover, the existing regulations permit the Commission to employ a laundering test method different from AATCC Test Method 124 if it concludes that the test method is substantively as protective. Because the existing regulations allow the Commission to achieve without any amendment the substance of what it now proposes to achieve by amendment, and because the proposed amendments preserve the regulatory status quo, save for the reflection of modern equipment and detergent, the Commission has determined that it is not legally required to commence this proceeding with an ANPR, nor is it necessary for the Commission to make the findings that FFA sections 1193(g) and (h) would otherwise require.

The amendments proposed below would require a mattress pad containing a fire retardant chemical to be tested in the condition in which it is intended to be sold and after washing and drying 10 times using the procedure specified in AATCC Test Method 124–1996. The proposed amendments would incorporate that test method into the mattress standard by reference.

The mattress flammability standard and enforcement rules exempt any ''one-of-a-kind'' mattress or mattress pad manufactured to a physician's written prescription from all requirements of the standard. See sections 1632.2(b)(4) and 1632.31(f). Those sections are not affected by the amendments proposed below.

Additionally, existing section 1632.5(b)(1)(i) exempts from the laundering requirements of the standard any mattress pad intended for ''one time use'' and any mattress pad which is not intended to be laundered. Existing section 1632.5(b)(1)(ii) states that mattress pads that cannot be laundered and are labeled ''dryclean only'' shall be drycleaned by a procedure which has been found to be acceptable by the Commission before testing. Existing section 1632.5(b)(2)(v) allows manufacturers of mattress pads manufactured with a chemical fire retardant to test specimens after laundering ''a different number of wash and dry cycles using another procedure . . . if that procedure has previously been found to be equivalent by the Consumer Product Safety Commission.'' These sections are not affected by the amendments proposed below.

6. Effective Date

Section 4(b) of the FFA (15 U.S.C. 1193(b)) provides that an amendment of a flammability standard shall become effective one year from the date it is promulgated, unless the Commission finds for good cause that an earlier or later effective date is in the public interest, and publishes that finding. Section 4(b) also requires that an amendment of a flammability standard shall exempt products ''in inventory or with the trade'' on the date the amendment becomes effective, unless the Commission limits or withdraws that exemption because those products are so highly flammable that they are dangerous for use by consumers.

One reason for proposing these amendments of the mattress flammability standard is that the

standard detergent specified by the existing laundering method in the standard is no longer available. The Commission has reason to believe that an effective date 30 days after publication of final amendments will be in the public interest. The Commission does not propose to withdraw or limit the exemption for products in inventory or with the trade as provided by section 4(b) of the FFA.

The Commission believes that an effective date of thirty days would give adequate notice to all interested persons of the change in laundering procedure, and at the same time would assure that the Commission will be able to test for compliance with the standards without interruption. Those manufacturers who perform prototype testing in accordance with the laundering procedure specified in the standard will also benefit from a relatively short effective date.

The Commission invites comments on the proposed effective date and factual information relating to that issue.

C. Other Issues

1. Impact on Small Businesses

In accordance with section 605(b) of the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Commission hereby certifies that the amendments to the mattress flammability standard proposed below will not have a significant economic impact on a substantial number of small entities, including small businesses, if issued on a final basis. The requirements for washing and drying mattress pads manufactured with a fire retardant chemical were included in the standards to assure that any flame retardant treatment used in mattress pads would not be removed or degraded by repeated laundering.

At this time, all mattress pads subject to the standard are made without flame retardant treatments. Accordingly, most manufacturers of mattress pads are not required to launder mattress pads before testing, and the Commission does not expect that the proposed amendments will have a significant effect on any businesses, large or small.

2. Environmental Considerations

The amendments proposed below fall within the categories of Commission actions described at 16 CFR 1021.5(c) that have little or no potential for affecting the human environment. The amendments are not expected to have a significant effect on production processes or on the types or amounts of materials used for construction or packaging of mattress pads. The amendments will not render existing inventories unsalable, or require destruction of existing goods. The Commission has no information indicating any special circumstances in which these amendments may affect the human environment. Accordingly, neither an environmental assessment nor an environmental impact statement is required.

3. Executive Orders

Executive Order 12988 (February 5, 1996), requires agencies to state in clear language the preemptive effect, if any, to be given to a new regulation. The amendments proposed below, if issued on a final basis, would modify a flammability standard issued under the FFA. With certain exceptions which are not applicable here, no state or political subdivision of a state may enact or continue in effect ''a flammability standard or other regulation'' applicable to the same fabric or product covered by an FFA standard if the state or local flammability standard or regulation is ''designed to protect against the same risk of the occurrence of fire'' unless the state or local standard or regulation is ''identical'' to the FFA standard. See section 16 of the FFA (15 U.S.C. 1203). Consequently, if issued on a final basis, the amendments proposed below will preempt nonidentical state or local flammability standards or regulations that are intended to address the unreasonable risk of fire from ignition of mattress pads.

In accordance with Executive Order 12612 (October 26, 1987), the Commission certifies that the proposed amendments do not have sufficient implications for federalism to warrant a Federalism Assessment.

List of Subjects in 16 CFR Part 1632

Consumer protection, Flammable materials, Labeling, Mattresses and mattress pads, Records, Textiles, Warranties.

Conclusion

Therefore, pursuant to the authority of section 30(b) of the Consumer Product Safety Act (15 U.S.C. 2079(b)) and sections 4 and 5 of the Flammable Fabrics Act (15 U.S.C. 1193, 1194), the Commission hereby proposes to amend title 16 of the Code of Federal Regulations, Chapter II, Subchapter D, Part 1632 to read as follows:

PART 1632—STANDARD FOR THE FLAMMABILITY OF MATTRESSES AND MATTRESS PADS

1. The authority for part 1632 continues to read as follows:

Authority: 15 U.S.C. 1193, 1194; 15 U.S.C. 2079(b).

2. Section 1632.5 is amended by revising paragraphs (b)(2)(i) through (iv) and by removing the undesignated paragraph following (b)(2)(iv) to read as follows:

§ 1615.5 Mattress pad test procedure.

* * * * *

(b) * * *

(2) *Laundering procedure.* (i) Washing shall be performed in accordance with sections 8.2.2 and 8.2.3 of AATCC Test Method 124–1996, using wash temperature V (60° ± 3°C, 140° ± 5°F) specified in Table II of that method, and the water level, agitator speed, washing time, spin speed and final spin cycle specified for ''Normal/Cotton Sturdy'' in Table III.

(ii) Drying shall be performed in accordance with section 8.3.1(A) of AATCC Test Method 124–1996 ''Appearance of Fabrics After Repeated Home Laundering,'' Tumble Dry, using the exhaust temperature (66° ± 5°C, 150° ± 10°F) and cool down time of 10 minutes specified in the ''Durable Press'' conditions of Table IV.

(iii) Maximum washer load shall be 3.64 Kg (8 pounds) and may consist of any combination of test samples and dummy pieces.

(iv) AATCC Test Method 124–1996 ''Appearance of Fabrics After Repeated Home Laundering,'' is found in Technical Manual of the American Association of Textile Chemists and Colorists, vol. 73, 1997, which is incorporated by reference. Copies of this document are available from the American Association of Textile Chemists and Colorists, P.O. Box 12215, Research Triangle Park, North Carolina 27709. This document is also available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., Suite 700, Washington, DC. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. These materials are incorporated as they exist in the edition which has been approved by the Director of the Federal Register and which has been filed with the Office of the Federal Register.

* * * * *

Dated: March 8, 1999.

Sadye E. Dunn,

Secretary, Consumer Product Safety Commission.

List of Relevant Documents

1. American Association of Textile Chemists and Colorists, ''Appearance of Durable Press Fabrics After Repeated Home Launderings,'' AATCC Test Method 124–1969. AATCC Technical Manual, Vol. 46, 1970.

2. American Association of Textile Chemists and Colorists, ''Appearance of Fabrics After Repeated Home Laundering,'' AATCC Test Method 124–1996. AATCC Technical Manual, Vol. 73, 1997.

3. Briefing memorandum from Margaret Neily, Project Manager, Directorate for Engineering Sciences, to the Commission, ''Proposed Amendments to Flammable Fabrics Act Standards to Replace Obsolete Standard Detergent and Update Laundering Procedures Required for Tests,'' ————, 1998.

4. Memorandum from Gail Stafford, Directorate for Laboratory Sciences, to Margaret Neily, Project Manager, ''Amending the Laundering Provisions of the CPSC Flammability Regulations,'' August 18, 1998.

5. Memorandum from Gail Stafford, Directorate for Laboratory Sciences, to Margaret Neily, Project Manager, ''Textile Laundering Standards,'' August 18, 1998.

6. Memorandum from Gail Stafford and Shing-Bong Chen, Directorate for Laboratory Sciences, to Margaret Neily, Project Manager, ''Detergent Comparison Tests,'' August 19, 1998.

7. Log of Meeting on January 21, 1998 concerning Flammability Test of Pyrovatex-treated Flame Resistant Fabrics.

8. Memorandum from Terrance R. Karels, Directorate for Economic Analysis, to Margaret Neily, Project Manager, ''Amendments to FFA Standards,'' August 10, 1998.

9. Memorandum from Margaret Neily, Project Manager, Directorate for Engineering Sciences, to the Commission, ''Briefing Package Supplement: Laundering/Detergent Update for Flammable Fabrics Act Standards—The Soap and Detergent Association (SDA) Laundering Procedures,'' January 11, 1999.

10. Memorandum from Gail Stafford, Directorate for Laboratory Sciences, to Margaret Neily, Project Manager, ''Soap and Detergent Association Proposed Laundering Procedure,'' December 23, 1998.

11. Letter from Jenan Al-Atrash, Director, Human Health & Safety, The Soap and Detergent Association, to Margaret Neily, Technical Program Coordinator, Office of the Executive Director, including SDA Recommended Wash Conditions for CFR 1615.4, September 15, 1998.

12. Letter from Jenan Al-Atrash, Director, Human Health & Safety, The Soap and Detergent Association, to Margaret Neily, Technical Program Coordinator, Office of the Executive Director, follow-up comments to September 15, 1998, letter, November 12, 1998.

13. Memorandum from Margaret L. Neily, Project Manager, Directorate for Engineering Sciences, to the Commission, ''Laundering/Detergent Updates—FR notice supplements,'' February 19, 1999.

[FR Doc. 99–6073 Filed 3–16–99; 8:45 am]

BILLING CODE 6355–01–P

DEPARTMENT OF THE TREASURY

19 CFR Part 24

RIN 1515–AC40

Expanded Methods of Payment of Duties, Taxes, Interest and Fees

AGENCY: Customs Service, Department of the Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document proposes to amend the Customs Regulations to expand the number of ways that Customs will accept payment of duties, taxes, fees, interest and other charges. Currently, the regulations allow payment by credit or charge cards that have been authorized by the Commissioner of Customs only at designated locations, and then only by non-commercial entities. In this document, Customs is proposing to allow payment by any electronic technology or charge cards (debit cards or credit cards) that are authorized by the Commissioner of Customs and to remove the limitation that these methods of payment may only be used by non-commercial entities. These changes, if adopted, will assist Customs in improving customer service and financial management.

DATE: Comments must be received on or before May 17, 1999.

ADDRESS: Written comments may be submitted to and comments submitted may be inspected at the Regulations Branch, Office of Regulations and Rulings, U.S. Customs Service, 1300 Pennsylvania Avenue NW., Third Floor, Washington, DC 20229.

FOR FURTHER INFORMATION CONTACT: Elizabeth Dichysyn, Accounting Services Division, U.S. Customs Service, 317–298–1200, extension 1339.

SUPPLEMENTARY INFORMATION:

Background

Section 24.1(a)(7) of the current Customs Regulations (19 CFR 24.1(a)(7)) provides for the use of credit or charge cards that have been authorized by the Commissioner of Customs for the payment of duties, taxes and/or other charges at Customs service locations for non-commercial entries, subject to ultimate collection from the credit card company. Payment by this manner is currently limited to non-commercial entries. Persons paying by charge or credit card remain liable for all such charges until paid.

This proposed regulation would extend this privilege to commercial entries and allow payment through the use of electronic technology or by the use of credit cards (either debit cards or credit cards) authorized by the Commissioner of Customs. These changes will assist Customs in improving customer service and financial management. The proposal affords Customs customers the broadest range of payment options.

Also, Customs proposes to revise the heading and text of both introductory paragraph (a) and paragraph (a)(1) to include the terms ''fees'' and ''interest'' to reflect that the proposed payment methods may be used to pay fees assessed pursuant to 19 U.S.C. 58a through 58c and to pay fees and interest pursuant to 19 U.S.C. 1505, as amended by section 642 of the North American Free Trade Agreement Implementation Act.

Comments

Before adopting this proposal, consideration will be given to any written comments timely submitted to Customs. Comments submitted will be available for public inspection in accordance with the Freedom of Information Act (5 U.S.C. 552), § 1.4, Treasury Department Regulations (31 CFR 1.4), and § 103.11(b), Customs Regulations (19 CFR 103.11(b)), on regular business days between the hours of 9:00 a.m. and 4:30 p.m. at the Regulations Branch, Office of Regulations and Rulings, U.S. Customs Service, 1300 Pennsylvania Avenue NW., Third Floor, Washington, DC 20229.

Regulatory Flexibility Act

Because this proposal expands the options available for payments due to Customs and facilitates the public payment process, it is certified that the amendment will not have a significant economic impact on a substantial number of small entities. Accordingly, the proposed amendment is not subject to the regulatory analysis or other requirements of 5 U.S.C. 603 or 604.

Executive Order 12866

This document does not meet the criteria for a significant regulatory action under Executive Order (E.O.) 12866.

Drafting Information

The principal author of this document was Janet L. Johnson, Regulations Branch. However, personnel from other offices participated in its development.

List of Subjects in 19 CFR Part 24

Accounting, Claims, Fees, Financial and accounting procedures, Imports, Taxes.

Proposed Amendments to the Regulations

It is proposed to amend part 24, Customs Regulations (19 CFR part 24), as set forth below.

PART 24—CUSTOMS FINANCIAL AND ACCOUNTING PROCEDURE

1. The general authority citation for part 24 and the relevant specific authority for § 24.1 would continue to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 58a–58c, 66, 1202 (General Note 20, Harmonized Tariff Schedule of the United States), 1450, 1624; 31 U.S.C. 9701. § 24.1 also issued under 19 U.S.C. 197, 198, 1648;

* * * * *

2. It is proposed to amend § 24.1 by revising the heading, paragraph (a), introductory text, and paragraph (a)(7) to read as follows:

§ 24.1 Collection of Customs duties, taxes, fees, interest and other charges.

(a) Except as provided in paragraph (b) of this section, the following procedure applies to the collection of Customs duties, taxes, fees, interest and other charges (see §§ 111.29(b) and 141.1(b) of this chapter):

* * * * *

(7) Wherever authorized by the Commissioner of Customs, transfer of funds through electronic technology or use of charge cards (either debit cards or credit cards) authorized by the Commissioner of Customs may be used for payment of duties, taxes, fees, interest and/or other charges to Customs. Persons using these methods to make payment to Customs remain liable for the amounts transferred or charged until Customs receives payment. Payment by these methods is subject to ultimate collection from the financial institution or charge card company. Information about authorized methods of payment at specific Customs locations may be obtained from Customs officers.

* * * * *

Raymond W. Kelly,

Commissioner of Customs.

Approved: February 16, 1999.

Dennis M. O'Connell,

Acting Deputy Assistant Secretary of the Treasury.

[FR Doc. 99–6468 Filed 3–16–99; 8:45 am]

BILLING CODE 4820–02–P

DEPARTMENT OF THE TREASURY

Customs Service

19 CFR Part 146

RIN 1515–AC05

Weekly Entry Procedure for Foreign Trade Zones

AGENCY: Customs Service, Department of the Treasury.

ACTION: Proposed rule; withdrawal.

SUMMARY: This document withdraws the proposed amendments to the Customs Regulations that would have expanded the weekly entry procedure for foreign trade zones to include merchandise involved in activities other than exclusively assembly-line type production operations. Customs has determined that the proposed expanded weekly entry procedure would significantly reduce the collection of the merchandise processing fee (MPF) that Customs needs to offset its administrative costs incurred in processing imported merchandise that is formally entered or released.

DATE: The withdrawal is effective on March 17, 1999.

FOR FURTHER INFORMATION CONTACT: Linda Walfish, Office of Field Operations, (202–927–0042).

SUPPLEMENTARY INFORMATION:

Background

The Foreign Trade Zones Act of 1934, as amended (19 U.S.C. 81a–u) (the ''FTZA'') provides for the establishment and regulation of foreign trade zones. Foreign trade zones are secured areas to which foreign and domestic merchandise, except that prohibited by law, may be exempted from the Customs laws of the United States for the purposes enumerated in the FTZA. Foreign trade zones, by virtue of their potential to allow exemption from the Customs laws, are intended to attract and promote legitimate international trade and commerce.

Part 146, Customs Regulations (19 CFR part 146), sets forth the documentation and recordkeeping requirements governing, among other things, the admission of merchandise into a zone, its manipulation, manufacture, storage, destruction or exhibition while in the zone, and its entry and removal from the zone.

To this latter end, Customs has in place a weekly entry procedure for foreign trade zones, as prescribed in § 146.63(c)(1), Customs Regulations (19 CFR 146.63(c)(1)). Under the procedure, instead of requiring a separate entry for each removal of merchandise from a zone, as would otherwise be the case, Customs accepts one entry from a zone user covering all its anticipated removals fro an entire weekly period. The use of this procedure, however, has been limited exclusively to merchandise that is manufactured or changed into its final form just shortly (within 24 hours) before physical transfer from the zone.

The weekly entry procedure is believed to be especially necessary for assembly-line type manufacturing operations because, in these circumstances, there would otherwise be little time for examination of the merchandise and furnishing of entry documentation after the merchandise was in its final form but before its physical removal from the zone. Thus, under the weekly entry process, the assembly-line operation would not have to be delayed pending acceptance of an entry and Customs examination of the merchandise.

On March 14, 1997, Customs published in the **Federal Register** (62 FR 12129) a notice of proposed rulemaking that would have expanded the use of weekly entry by adding a weekly entry procedure to cover merchandise involved in activities other than manufacturing operations. It was expected that the expanded weekly entry procedure would be available to zones (including subzones) having large quantities of different types of merchandise.

The principal purpose of the proposed expanded weekly entry procedure, which would have required electronic entry filing, was to reduce the number of paper entries from zones and further facilitate the processing of zone entries, with resulting reductions in paperwork and associated industry costs.

In order to test the expanded weekly entry procedure, a pilot program had been authorized in September 1994 for a selected number of zones/subzones.

Effect on Merchandise Processing Fee

Based upon further evaluation of the pilot program, and comments made by zone operators and others on the proposed rule, it is clear that the expanded procedure would significantly impact Customs collection of the merchandise processing fee (MPF). This poses a serious funding concern for the Government.

Under 19 U.S.C. 58c(a)(9)(A) and (B)(i), the MPF is the fee that Customs assesses on importers in order to offset its administrative costs (salaries and expenses) incurred in connection with the processing of imported merchandise that is formally entered or released. The fees collected are deposited in the

general fund of the Treasury in a separate account known as the ''Customs User Fee Account'' (19 U.S.C. 58c(f)).

Specifically, except as otherwise provided, merchandise that is formally entered is subject to an ad valorem MPF of .21 percent (19 CFR 24.23(b)(1)(i)(A)); however, on any one such entry of merchandise, the fee may not exceed $485, subject to certain provisions not here relevant (19 CFR 24.23(b)(1)(i)(B)).

As a result, in those cases where a company must now make a separate entry for each of its removals of merchandise from a zone, and its total payment of the MPF for all entries so made during a week greatly exceeds $485, the company would be able to lower this payment substantially if it could instead make one entry covering all its removals from the zone for the week, with the MPF thereby capped at $485.

Clearly, Customs collection of the MPF would be significantly reduced under an expanded weekly entry program. Indeed, some parties expressing interest in the proposed rule even asserted that they would apply for foreign trade zone status just to gain the benefit of the reduced MPF through the use of a weekly entry.

Moreover, other industries, such as bonded warehouse associations, stated that similar entry procedures should as well be available to them, which also raised a fairness concern.

Withdrawal of Proposal

In view of the foregoing, and following further consideration of the matter, Customs has determined to withdraw the notice of proposed rulemaking that was published in the **Federal Register** (62 FR 12129) on March 14, 1997. Customs, however, will continue to cooperate with the trade in seeking mutually satisfactory ways in which to further facilitate entry processing or imported merchandise, so as to reduce associated paperwork and costs to industry, while at the same time reasonably preserving the integrity of the MPF which is necessary to offset merchandise processing costs incurred by the Government in this regard.

Raymond W. Kelly,

Commissioner of Customs.

Approved: February 9, 1999.

John P. Simpson,

Deputy Assistant Secretary of the Treasury.

[FR Doc. 99–6467 Filed 3–16–99; 8:45 am]

BILLING CODE 4820–02–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[CA 211–0140; FRL–6310–2]

Approval and Promulgation of Implementation Plans; California State Implementation Plan Revision, Bay Area Air Quality Management District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing a limited approval and limited disapproval of a revision to the California State Implementation Plan (SIP) which concerns the control of volatile organic compound (VOC) emissions from adhesive and sealant products.

The intended effect of proposing a limited approval and limited disapproval of this rule is to regulate emissions of VOCs in accordance with the requirements of the Clean Air Act, as amended in 1990 (CAA or the Act). EPA's final action on this proposed rule will incorporate this rule into the federally approved SIP. EPA has evaluated the rule and is proposing a simultaneous limited approval and limited disapproval under provisions of the CAA regarding EPA action on SIP submittals and general rulemaking authority because this revision, while strengthening the SIP, does not fully meet the CAA provisions regarding plan submissions and requirements for nonattainment areas.

DATES: Comments must be received on or before April 16, 1999.

ADDRESSES: Comments may be mailed to: Andrew Steckel, Rulemaking Office [AIR–4], Air Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105–3901.

Copies of the rule and EPA's evaluation report of the rule are available for public inspection at EPA's Region IX office during normal business hours. Copies of the submitted rule are also available for inspection at the following locations:

Bay Area Air Quality Management District, 939 Ellis Street, San Francisco, CA 94109.

California Air Resources Board, Stationary Source Division, Rule Evaluation Section, 2020 ''L'' Street, Sacramento, CA 95812.

FOR FURTHER INFORMATION CONTACT: Yvonne Fong, Rulemaking Office, [AIR–4], Air Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105–3901, Telephone: (415) 744–1199.

SUPPLEMENTARY INFORMATION:

I. Applicability

The rule being proposed for approval into the California SIP is Bay Area Air Quality Management District, BAAQMD, Rule 8–51, Adhesive and Sealant Products. This rule was submitted by the California Air Resources Board to EPA on June 23, 1998.

II. Background

On March 3, 1978, EPA promulgated a list of ozone nonattainment areas under the provisions of the 1977 Clean Air Act (1977 CAA or pre-amended Act), that included the San Francisco Bay Area. 43 FR 8964. The San Francisco Bay Area did not attain the ozone standard by the approved attainment date. On May 26, 1988, EPA notified the Governor of California, pursuant to section 110(a)(2)(H) of the pre-amended Act, that the Bay Area Air Quality Management District's portion of the SIP was inadequate to attain and maintain the ozone standard and requested that deficiencies in the existing SIP be corrected (EPA's SIP-Call). On November 15, 1990, amendments to the 1977 CAA were enacted. Pub. L. 101–549, 104 Stat. 2399, codified at 42 U.S.C. 7401–7671q. In amended section 182(a)(2)(A) of the CAA, Congress statutorily adopted the requirement that nonattainment areas fix their deficient reasonably available control technology (RACT) rules for ozone and established a deadline of May 15, 1991 for states to submit corrections of those deficiencies.

Section 182(a)(2)(A) applies to areas designated as nonattainment prior to enactment of the amendments and classified as marginal or above as of the date of enactment. It requires such areas to adopt and correct RACT rules pursuant to pre-amended section 172(b) as interpreted in pre-amendment guidance.[1] EPA's SIP-Call used that guidance to indicate the necessary corrections for specific nonattainment areas. The San Francisco Bay Area is designated as nonattainment without

[1] Among other things, the pre-amendment guidance consists of those portions of the proposed Post-1987 ozone and carbon monoxide policy that concern RACT, 52 FR 45044 (November 24, 1987) and the document ''Issues Relating to VOC Regulation Cutpoints, Deficiencies, and Deviations, Clarification to Appendix D of November 24, 1987 **Federal Register** Notice'' (Blue Book) (notice of availability was published in the **Federal Register** on May 25, 1988).

further classification;[2] therefore, this area is subject to the RACT fix-up requirement and the May 15, 1991 deadline.

The State of California submitted many revised RACT rules for incorporation into its SIP on June 23, 1998, including the rule being acted on in this document. This document addresses EPA's proposed action for BAAQMD Rule 8–51, Adhesives and Sealant Products. The BAAQMD adopted this rule on January 7, 1998. This submitted rule was found to be complete on August 25, 1998, pursuant to EPA's completeness criteria that are set forth in 40 CFR Part 51, Appendix V;[3] and is being proposed for limited approval and limited disapproval.

BAAQMD Rule 8–51 limits the volatile organic compound (VOC) emissions resulting from the application of adhesive and sealant products. VOCs contribute to the production of ground level ozone and smog. Rule 8–51 is a new rule which has been adopted to meet the EPA's SIP-Call and the section 182(a)(2)(A) CAA requirement. The following is EPA's evaluation and proposed action for BAAQMD Rule 8–51.

III. EPA Evaluation and Proposed Action

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

In addition, this rule was evaluated against the SIP enforceability guidelines found in the EPA Region IX—California Air Resources Board document entitled ''Guidance Document for Correcting VOC Rule Deficiencies'' (April, 1991) and against other EPA policies. In general, these guidance documents have been set forth to ensure that VOC rules are fully enforceable and strengthen or maintain the SIP.

There is currently no version of BAAQMD Rule 8–51, Adhesive and Sealant Products in the SIP. The submitted rule includes provisions which:

- Specify VOC content limits for adhesives, aerosol adhesives, and sealants (Sections 301, 302, 303, and 304);
- Allow sources to comply using emission control systems with an overall abatement efficiency of at least 85 percent (Section 305);
- Prohibit the specification and sale of any adhesives, aerosol adhesives, or sealants that would result in a violation of the provisions of Rule 8–51 (Section 306 and 307);
- Require any person using organic solvents for surface preparation and clean-up to use closed containers and to minimize evaporation of organic compounds to the atmosphere (Section 320);
- Require facilities within the District that use more than 20 gallons of adhesive and/or sealant products per year to keep monthly records (Section 501);
- Mandate that persons using an emission control system keep daily records of key system operating parameters and amounts of adhesive or sealant product used (Section 502); and
- Provide test methods for determining the amount of VOC in adhesives and sealants, aerosol adhesives, and low solids adhesives, sealant products and primers and for determining control and collection efficiency (Sections 601 and 602).

Although these provisions will strengthen the SIP, this rule also contains deficiencies which are required to be corrected pursuant to the section 182(a)(2)(A) requirement of Part D of the CAA. Rule 8–51 contains the following deficiencies:

- The rule does not require users of adhesive and sealant products to record their daily use of non-compliant coatings;
- The rule allows for director's discretion in the approval of alternate recordkeeping plans; and
- The rule contains a number of deviations from RACT level controls which have not been substantiated by an adequate 5% equivalency demonstration based on source specific data.

A detailed discussion of rule deficiencies can be found in the Technical Support Document for Rule 8–51 (February 1999), which is available from the U.S. EPA, Region IX office. Because of these deficiencies, the rule is not approvable pursuant to section 182(a)(2)(A) of the CAA because it is not consistent with the interpretation of section 172 of the 1977 CAA as found in the Blue Book and may lead to rule enforceability problems.

Because of the above deficiencies, EPA cannot grant full approval of this rule under section 110(k)(3) and Part D. Also, because the submitted rule is not composed of separable parts which meet all the applicable requirements of the CAA, EPA cannot grant partial approval of the rule under section 110(k)(3). However, EPA may grant a limited approval of the submitted rule under section 110(k)(3) in light of EPA's authority pursuant to section 301(a) to adopt regulations necessary to further air quality by strengthening the SIP. The approval is limited because EPA's action also contains a simultaneous limited disapproval. In order to strengthen the SIP, EPA is proposing a limited approval of BAAQMD's submitted Rule 8–51 under sections 110(k)(3) and 301(a) of the CAA.

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

[2] The San Francisco Bay Area, originally designated as an ozone nonattainment area on March 3, 1978, retained its designation and was classified by operation of law pursuant to sections 107(d) and 181(a) upon the date of enactment of the CAA. See 56 FR 56694 (November 6, 1991). On May 22, 1995 EPA approved BAAQMD's request for redesignation and the San Francisco Bay Area was reclassified as an attainment area. See 60 FR 27028. Based on a number of violations of the National Ambient Air Quality Standards, EPA redesignated the San Francisco Bay Area back to nonattainment for ozone on July 10, 1998 without assigning it a specific classification of marginal, moderate, serious, severe, or extreme. See 63 FR 37258.

[3] EPA adopted completeness criteria on February 16, 1990 (55 FR 5830) and, pursuant to section 110(k)(1)(A) of the CAA, revised the criteria on August 26, 1991 (56 FR 42216).

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

IV. Administrative Requirements

A. Executive Order 12866

The Office of Management and Budget (OMB) has exempted this regulatory action from Executive Order (E.O.) 12866, Regulatory Planning and Review.

B. Executive Order 12875

Under E.O. 12875, Enhancing the Intergovernmental Partnership, EPA may not issue a regulation that is not required by statute and that creates a mandate upon a state, local, or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments, or EPA consults with those governments. If EPA complies by consulting, E.O. 12875 requires EPA to provide to the OMB a description of the extent of EPA's prior consultation with representatives of affected state, local, and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, E.O. 12875 requires EPA to develop an effective process permitting elected officials and other representatives of state, local, and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

Today's rule does not create a mandate on state, local or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of E.O. 12875 do not apply to this rule.

C. Executive Order 13045

Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997), applies to any rule that: (1) is determined to be ''economically significant'' as defined under E.O. 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

This rule is not subject to E.O. 13045 because it does not involve decisions intended to mitigate environmental health or safety risks.

D. Executive Order 13084

Under E.O. 13084, Consultation and Coordination with Indian Tribal Governments, EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments, or EPA consults with those governments. If EPA complies by consulting, E.O. 13084 requires EPA to provide to the OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, E.O. 13084 requires EPA to develop an effective process permitting elected and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. Accordingly, the requirements of section 3(b) of E.O. 13084 do not apply to this rule.

E. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and small governmental jurisdictions. This final rule will not have a significant impact on a substantial number of small entities because SIP approvals under section 110 and subchapter I, Part D of the Clean Air Act do not create any new requirements but simply approve requirements that the State is already imposing. Therefore, because the Federal SIP approval does not create any new requirements, I certify that this action will not have a significant economic impact on a substantial number of small entities. Moreover, due to the nature of the Federal-State relationship under the Clean Air Act, preparation of a flexibility analysis would constitute Federal inquiry into the economic reasonableness of state action. The Clean Air Act forbids EPA to base its actions concerning SIPs on such grounds. *Union Electric Co.*, v. *U.S. EPA*, 427 U.S. 246, 255–66 (1976); 42 U.S.C. 7410(a)(2).

F. Unfunded Mandates

Under Section 202 of the Unfunded Mandates Reform Act of 1995 (''Unfunded Mandates Act''), signed into law on March 22, 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a Federal mandate that may result in estimated annual costs to State, local, or tribal governments in the aggregate; or to the private sector, of $100 million or more. Under Section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule.

EPA has determined that the approval action promulgated does not include a Federal mandate that may result in estimated annual costs of $100 million or more to either State, local, or tribal governments in the aggregate, or to the private sector. This Federal action approves pre-existing requirements under State or local law, and imposes no new requirements. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, result from this action.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Hydrocarbons, Incorporation by reference, Intergovernmental relations, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: March 4, 1999.

Laura Yoshii,

Deputy Regional Administrator, Region IX.

[FR Doc. 99–6506 Filed 3–16–99; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 52 and 81

[OH 121–1b; FRL–6239–4]

Approval and Promulgation of Implementations; Ohio Designation of Areas for Air Quality Planning Purposes; Ohio

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is approving the SIP revision request submitted by the State of Ohio on August 20, 1998, which replaces the federally promulgated limits by state promulgated limits for the relevant portion of Lake County. The revision affects rule OAC 3745–18–49(G) (containing emission limits applicable to the First Energy, EastLake plant) and rule OAC 3745–18–49 (H) (containing the emission limitations applicable to the Ohio Rubber Company plant in Lake County). In addition, EPA also approves the sulfur dioxide (SO_2) maintenance plan for Lake and Jefferson Counties. This plan ensures that the reductions in minor source emissions, in combination with the limits on major source emissions, will provide for continued attainment in Lake and Jefferson Counties. Finally, USEPA is approving two redesignation requests from the State of Ohio. This action, which was requested on October 26, 1995, and also on August 20, 1998, redesignates Lake and Jefferson Counties to attainment of National Ambient Air Quality Standard (NAAQS) for SO_2.

In the final rules section of this **Federal Register**, the EPA is approving the State's request as a direct final rule without prior proposal because EPA views this action as noncontroversial and anticipates no adverse comments. A detailed rationale for approving the State's request is set forth in the direct final rule. The direct final rule will become effective without further notice unless EPA receives relevant adverse written comment. Should EPA receive such comment, it will publish a timely withdrawal informing the public that the direct final rule will not take effect and such public comment received will be addressed in a subsequent final rule based on the proposed rule. If no adverse written comments are received, the direct final rule will take effect on the date stated in that document, and no further action will be taken. USEPA does not plan to institute a second comment period on this action. Any parties interested in commenting on this action should do so at this time.

DATES: Written comments must be received on or before April 16, 1999.

ADDRESSES: Written comments may be mailed to J. Elmer Bortzer, Chief, Regulation Development Section, Air Programs Branch (AR–18J), Region 5 at the address listed below.

Copies of the materials submitted by the Ohio Environmental Protection Agency may be examined during normal business hours at the following location: Regulation Development Section, Air Programs Branch (AR–18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois, 60604.

FOR FURTHER INFORMATION CONTACT: Phuong Nguyen at (312) 886–6701.

SUPPLEMENTARY INFORMATION: For additional information see the direct final rule published in the rules section of this **Federal Register**.

Dated: February 26, 1999.

Jo Lynn Traub,

Acting Regional Administrator, Region 5.

[FR Doc. 99–6257 Filed 3–16–99; 8:45 am]

BILLING CODE 6560–50–P

Notices

Federal Register

Vol. 64, No. 51

Wednesday, March 17, 1999

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 Marketing Service

[Docket No. FV99–981–2 NC]

Notice of Request for Extension and Revision of a Currently Approved Information Collection

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), this notice announces the Agricultural Marketing Service's (AMS) intention to request an extension for and revision to a currently approved information collection for Almonds Grown in California, Marketing Order 981.

DATES: Comments on this notice must be received by May 17, 1999.

FOR FURTHER INFORMATION CONTACT: Contact Tershirra T. Yeager, Program Assistant, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, room 2525-S., P.O. Box 96456, Washington, DC 20090–6456; Tel: (202) 720–2491, Fax: (202) 720–5698, or E-mail: moabdocket__clerk@usda.gov.

SUPPLEMENTARY INFORMATION:

Title: Almonds Grown in California, Marketing Order 981.

OMB Number: 0581–0071.

Expiration Date of Approval: August 31, 1999.

Type of Request: Extension and revision of a currently approved information collection.

Abstract: Marketing order programs provide an opportunity for producers of fresh fruits, vegetables and specialty crops, in a specified production area, to work together to solve marketing problems that cannot be solved individually. Order regulations help ensure adequate supplies of high quality product and adequate returns to producers. Under the Agricultural Marketing Agreement Act of 1937 (AMAA), as amended (7 U.S.C. 601–674), marketing order programs are established if favored in referendum among producers. The handling of the commodity is regulated. The Secretary of Agriculture is authorized to oversee the order's operations and issue regulations recommended by a committee of representatives from each commodity industry. The Almond Board of California (Board) is responsible for locally administering the program.

The information collection requirements in this request are essential to carry out the intent of the AMAA, to provide the respondents the type of service they request, and to administer the California almond marketing order program, which has been operating since 1950.

The California almond marketing order authorizes the issuance of quality and volume control regulations, as well as inspection requirements. Regulatory provisions apply to almonds shipped within and outside of the production area, except those specifically exempt. The order also has authority for production and marketing research and development projects, including paid advertising. Handlers who advertise may receive credit for their advertising expenses according to specific guidelines.

The order, and rules and regulations issued thereunder, require handlers and growers to submit certain information. Much of this information is compiled by the Board in aggregate and provided to the industry to assist in marketing decisions.

The Board has developed forms as a means for persons to file required information with the Board relating to almond supplies, shipments, dispositions, and other information needed to effectively carry out the purpose of the AMAA and order. As shipments of California almonds are normally year-round, these forms are utilized accordingly. A USDA form is used to allow growers to vote on amendments or continuance of the marketing order. In addition, almond growers and handlers who are nominated by their peers to serve as representatives on the Board must file nomination forms with the Secretary.

The information collected is used only by authorized representatives of the USDA, including AMS, Fruit and Vegetable Programs' regional and headquarter's staff, and authorized employees of the Board. Authorized Board employees and the industry are the primary users of the information and AMS is the secondary user.

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 0.40 hours per response.

Respondents: California almond growers, handlers and accepted users of inedible almonds.

Estimated Number of Respondents: 7,658.

Estimated Number of Responses per Respondent: .86.

Estimated Total Annual Burden on Respondents: 2,638 hours.

Comments are invited on: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments should reference OMB No. 0581–0071 and the California Almond Marketing Order No. 981, and be mailed to Docket Clerk, Fruit and Vegetable Programs, AMS, USDA, P.O. Box 96456, Room 2525-S, Washington, DC, 20090–6456; Fax: (202) 720-5698; or E-mail: moabdocket__clerk@usda.gov. All comments received will be available for public inspection during regular business hours at the same address.

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Dated: March 11, 1999.

Robert C. Keeney,

Deputy Administrator, Fruit and Vegetable Programs.

[FR Doc. 99–6489 Filed 3–16–99; 8:45 am]

BILLING CODE 3410–22–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–201–802]

Gray Portland Cement and Clinker From Mexico; Final Results of Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of final results of antidumping duty administrative review.

SUMMARY: On September 10, 1998, the Department of Commerce published the preliminary results of its administrative review of the antidumping duty order on gray portland cement and clinker from Mexico. The review covers one manufacturer/exporter, CEMEX, S.A. de C.V. (CEMEX), and an affiliated party, Cementos de Chihuahua, S.A. de C.V. (CDC), and the period August 1, 1996, through July 31, 1997. We gave interested parties an opportunity to comment on the preliminary results. Based on our analysis of the comments received, we have made changes, including corrections of certain inadvertent programming and clerical errors, in the margin calculation. These corrections and adjustments to margin calculation program are described in the sections entitled ''6. Difference-in-Merchandise Information'' and ''18. Ministerial Errors,'' of the Issues Appendix. The final weighted-average dumping margin for CEMEX and CDC is 49.58 percent *ad valorem*.

EFFECTIVE DATE: March 17, 1999.

FOR FURTHER INFORMATION CONTACT: Diane Krawczun, Anne Copper, or George Callen; Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC. 20230; telephone (202) 482–0198, (202) 482–0090, and (202) 482–0180, respectively.

SUPPLEMENTARY INFORMATION:

Applicable Statute and Regulations

Unless otherwise indicated, all citations to the statute are references to the provisions effective January 1, 1995, the effective date of the amendments made to the Tariff Act of 1930 (the Act) by the Uruguay Round Agreements Act (URAA). In addition, unless otherwise indicated, all citations to the Department of Commerce's (the Department's) regulations are to the regulations at 19 CFR part 351 (1998).

Background

On September 10, 1998, the Department published in the **Federal Register** the preliminary results of its administrative review of the antidumping duty order on gray portland cement and clinker from Mexico. *Preliminary Results of Antidumping Duty Administrative Review: Gray Portland Cement and Clinker From Mexico*, 63 FR 48471 (1998) (preliminary results). The Southern Tier Cement Committee (the petitioner) submitted its case brief on October 13, 1998; CEMEX and CDC submitted case briefs on October 30, 1998. CDC re-submitted its case brief on December 2, 1998. The petitioner, CEMEX, and CDC submitted their rebuttal briefs on November 3, 1998. The Department held a public hearing on November 20, 1998. All issues raised in the case and rebuttal briefs by parties to this administrative review are addressed in the ''Issues Appendix,'' which is appended to this notice of final results. The Department has now completed this review in accordance with section 751(a) of the Act.

Scope of the Review

The products covered by this review include gray portland cement and clinker. Gray portland cement is a hydraulic cement and the primary component of concrete. Clinker, an intermediate material product produced when manufacturing cement, has no use other than being ground into finished cement. Gray portland cement is currently classifiable under the Harmonized Tariff Schedule (HTS) item number 2523.29 and cement clinker is currently classifiable under HTS item number 2523.10. Gray portland cement has also been entered under HTS item number 2523.90 as ''other hydraulic cements.'' The HTS subheadings are provided for convenience and customs purposes only. The Department's written description remains dispositive as to the scope of the product coverage.

Verification

Pursuant to section 782(i) of the Act, we verified information provided by CEMEX using standard verification procedures, including on-site inspection of the manufacturer's facilities and the examination of relevant sales and financial records, and selection of original documentation containing relevant information. Our verification results are outlined in public versions of the verification reports, dated August 21, 1998, and located in the public file in Room B–099 of the Department's main building.

Final Results of Review

We determine that the following weighted-average margin exists for the period August 1, 1996, through July 31, 1997:

Company	Margin
CEMEX/CDC	49.58%

The Department shall determine, and the Customs Service shall assess, antidumping duties on all appropriate entries. The Department shall issue appraisement instructions directly to the Customs Service. For assessment purposes, we have calculated an importer-specific duty assessment rate for the merchandise based on the ratio of the total amount of antidumping duties calculated for the examined sales to the total entered value of sales examined.

Furthermore, the following deposit requirements shall be effective upon publication of this notice of final results of review for all shipments of gray portland cement and clinker from Mexico, entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided for by section 751(a)(1) of the Act: (1) The cash deposit rate for CEMEX/CDC will be 49.58 percent; (2) for previously investigated or reviewed companies not listed above, the cash deposit rate will continue to be the company-specific rate published for the most recent period; (3) if the exporter is not a firm covered in this or any previous reviews or the original less-than-fair-value (LTFV) investigation, but the manufacturer is, the cash deposit rate will be the rate established for the most recent period for the manufacturer of the merchandise; and (4) if neither the exporter nor the manufacturer is a firm covered in this review, the cash deposit rate will continue to be 61.85 percent, which was the ''all others'' rate in the LTFV investigation. *See Final Determination of Sales at Less Than Fair Value: Gray Portland Cement and Clinker from Mexico*, 55 FR 29244 (1990).

The deposit requirements shall remain in effect until publication of the final results of the next administrative review.

This notice serves as a final reminder to importers of their responsibility

under 19 CFR 351.402(f) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

This notice also serves as a reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305. Timely notification of return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

We are issuing and publishing this determination in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: March 9, 1999.

Robert S. LaRussa,

Assistant Secretary for Import Administration.

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1. Revocation of the Underlying Order

CEMEX and CDC argue that the Department must terminate this review and revoke the underlying antidumping duty order. CEMEX contends that at the time of the initiation of the original LTFV investigation (October 16, 1989), the Department assumed that the petition was filed ''on behalf of'' a regional industry without measuring whether a majority of the industry actually supported the request. The Department should have done so, CEMEX argues, because a July 1992 General Agreement on Tariffs and Trade (GATT) panel decided that the 1979 antidumping code required that an antidumping petition filed ''on behalf of'' an industry must be supported by an appropriate majority of the industry and that such support must be ascertained prior to initiating an investigation. According to CEMEX, the panel's decision applies to the instant administrative review for two reasons:

(1) The Antidumping Agreement resulting from the Uruguay Round negotiations adopted the requirement of industry support articulated by the GATT panel. CEMEX asserts U.S. law incorporated the new standing requirements contained in the Antidumping Agreement, citing section 732(c)(4)(C) of the Act.

(2) Even if the pre-URAA antidumping law applies, the antidumping statute that was in effect in 1989 did not define the term ''on behalf of.'' CEMEX argues that the Department is compelled by the decision in *Murray* v. *Schooner Charming Betsy,* 6 U.S. 64, 2 Cranch 64 (1804), to reinterpret U.S. law in accordance with the international obligations of the United States.

Based on the above, CEMEX asserts that the Department is therefore required in this review to revisit the issue of initiation in the original LTFV investigation.

According to CDC, the plain language of section 771(4)(C) of the Act requires petitions in regional-industry cases to be filed on behalf of the producers which account for ''all, or almost all, of the production in the region.'' Since the antidumping order covering cement from Mexico was based on a petition that was unsupported by producers accounting for all or almost all of the region's production, CDC asserts, the Department issued the order in violation of U.S. law.

CDC argues that lack of standing to file an antidumping duty petition is a ''jurisdictional'' defect which parties may raise at any time. Citing *Zenith Electronics Corp.* v. *United States,* 872 F. Supp. 992 (CIT 1994) (*Zenith Electronics*), *Gilmore Steel Corp.* v. *United States,* 585 F. Supp. 670 (CIT 1984) (*Gilmore Steel*), and *Oregon Steel Mills, Inc.* v. *United States,* 862 F.2d 1541 (Fed. Cir. 1988) (*Oregon Steel Mills*), CDC contends that the Department has the authority to revoke an order that never had the requisite level of industry support.

The petitioner argues that the Department initiated the original antidumping investigation properly. The petitioner notes that CEMEX and CDC raised the issue of whether the Department initiated the investigation improperly in the third, fourth, fifth, and sixth reviews and were unsuccessful without exception. The petitioner also notes that both parties challenged the initiation of the LTFV investigation before a North American Free Trade Agreement (NAFTA) panel to review the final results of the third administrative review. In a unanimous opinion issued on September 13, 1996, according to the petitioner, the panel rejected the claims that CEMEX and CDC advance here.

The petitioner also contends that respondents' claim is barred by the statute of limitations, requiring that appeals to the decision to initiate an investigation be filed within 30 days of the publication of the antidumping order. The petitioner also contends that respondents did not raise the issue in the now-concluded U.S. Court of International Trade (CIT) appeal from the Department's final determination in the original investigation. Furthermore, the petitioner cites the Department's sixth review final results (*Gray Portland Cement and Clinker From Mexico,* 63 FR 12764 (March 16, 1998) (*Sixth Review Final Results*)), in which the Department noted that panel reports under the 1947 GATT were not self-executing and had no legal effect under U.S. law and that neither the 1947 GATT nor the 1979 GATT Antidumping Code obligated the United States to establish industry support in regional-industry cases.

The petitioner contends that the Department lacks authority under the statute to rescind its decision to initiate or to re-examine the issue of industry support in a review. Finally, citing *Suramerica de Aleaciones Laminada, C.A.* v. *United States,* 966 F. 2d 660 (Fed. Cir. 1992) (*Suramerica*), and the *Sixth Review Final Results,* the petitioner asserts that courts have affirmed the Department's presumption of industry support.

Department's Position: We agree with the petitioner that, as we stated in our *Sixth Review Final Results,* the Department has no obligation to determine whether a majority of the industry or the region supported the petition.

Neither the 1947 GATT nor the 1979 GATT Antidumping Code obligated the United States to establish affirmatively prior to the initiation of a regional-industry case that all or almost all of the producers in the region supported the petition. Neither instrument suggested that the standing requirements in regional-industry cases were any more rigorous than the standing requirements in national-industry cases.

Furthermore, GATT panel reports, such as the report issued in 1992, had no legal effect or formal status unless and until they were adopted by the

GATT Council or, in the case of antidumping measures, the GATT Antidumping Code Committee. This followed from the fact that the 1947 GATT operated, throughout its history, on the basis of consensus for purposes of decision-making in general and the resolution of disputes in particular. It is undisputed in the present case that the Antidumping Code Committee never adopted the GATT panel report. Thus, the recommendations contained in the report were never binding, did not impose any international obligations upon the United States, and did not trigger the rule of statutory construction set forth in *Murray* v. *Schooner Charming Betsy*.

The object of respondents' comments is not the preliminary results of this review. Rather, respondents challenge the initiation of the original LTFV investigation—an event which occurred almost ten years ago and over five years before the effective date of the URAA. The time to voice such objections before the Department was during the investigation. Instead, CEMEX and CDC, as well as the other Mexican cement producer that participated in the original investigation (Apasco, S.A. de C.V.), did not raise this argument before the Department. *See Final Determination of Sales at Less Than Fair Value; Gray Portland Cement and Clinker From Mexico,* 55 FR 29244 (1990) (*Original LTFV Investigation*). Moreover, neither CEMEX nor any other party appealed the agency's final affirmative LTFV determination (including the decision to initiate) to the appropriate court, and the deadline for doing so has long expired. *See* section 516A of the Act. Therefore, even if the Department, of its own volition, were to reinterpret U.S. law in light of the 1992 GATT panel report, it lacks the legal authority in this review to revoke the order or otherwise rescind the initiation of the underlying investigation. *See also Gray Portland Cement and Clinker from Mexico; Final Results of Antidumping Duty Administrative Review,* 62 FR 17581 (1997) (Fourth Review Final Results); *Gray Portland Cement and Clinker from Mexico; Final Results of Antidumping Duty Administrative Review,* 62 FR 17148 (1997) (*Fifth Review Final Results*); *Sixth Review Final Results.*

The cases cited by CEMEX and CDC are inapposite. None of them supports the argument that the Department has the authority, in an administrative review under section 751(a) of the Act, to reach back almost ten years and reexamine the issue of industry support for the original petition. In *Gilmore Steel,* the plaintiff contended that the Department lacked the authority to rescind the investigation based upon insufficient industry support for the petition after the 20-day period established in section 732(c) of the Act had elapsed. 585 F. Supp. at 673. In *Zenith Electronics,* the plaintiff alleged that the petitioner was no longer a domestic ''interested party'' with standing to request an administrative review. 872 F. Supp. at 994. Nothing in *Zenith Electronics* or *Gilmore Steel* supports CDC's argument that a party may challenge industry support for a petition almost ten years after the fact in the context of an administrative review under section 751(a) of the Act.

Oregon Steel Mills involved a challenge to the Department's authority to revoke an antidumping duty order based upon new facts, *i.e.,* the industry's affirmative expression of no further support for the antidumping order, not upon a reexamination of the facts as they existed during the original LTFV investigation. The Federal Circuit held that it was lawful for the Department, in the context of a ''changed circumstances'' review pursuant to section 751(b) of the Act, to revoke an order over the objection of one member of the industry. 862 F.2d at 1544–46. The court did not state that industry support for an order must be affirmatively established throughout the life of an order. Indeed, the court went to lengths to explain that it was not ruling on the claim that ''loss of industry support for an existing order creates a 'jurisdictional defect.'" *Id.* at 1545 n. 4. As courts explained subsequently, the holding in *Oregon Steel Mills* is limited to the proposition that the Department may, but need not, revoke an order when presented with record evidence which demonstrates a lack of industry support for the continuation of the order. *See, e.g., Suramerica* at 666 and *Citrosuco Paulista, S.A.* v. *United States,* 704 F. Supp. 1075, 1085 (CIT 1988) (*Citrosuco*).

Finally, we note, as we did in the final results of the third, fourth, fifth, and sixth administrative reviews, that numerous courts upheld our practice under the pre-URAA statute of assuming, in the absence of evidence to the contrary, that a petition filed on behalf of a regional or national industry is supported by that industry. *See, e.g., NTN Bearing Corp.* v. *United States,* 757 F. Supp. 1425, 1427–30 (CIT 1991), *Citrosuco* at 1085, and *Comeau Seafoods* v. *United States,* 724 F. Supp. 1407, 1410–12 (CIT 1989). Indeed, this issue raised by CEMEX and CDC was before the Federal Circuit in the *Suramerica* case (966 F.2d at 665, 667). In *Suramerica* the plaintiffs challenged the Department's interpretation of the phrase ''on behalf of'' which applied to both national- and regional-industry cases. In affirming the Department's practice, the court observed that the phrase ''on behalf of'' was not defined in the statute. *Id.* at 666–67. The statute was, in fact, open ''to several possible interpretations.'' In the opinion of the court, the Department's practice with regard to standing and industry support for a petition reflected a reasonable ''middle position.'' 966 F.2d at 667. While there was a gap in the statute, the court stated, ''Congress did make (one thing) clear—Commerce has broad discretion in deciding when to pursue an investigation, and when to terminate one.'' *Id.* Therefore, we reject respondents' arguments that we lack the authority to assess antidumping duties pursuant to these final results of review and that we must revoke the underlying duty order.

2. Collapsing

CDC argues that the Department's decision to collapse CDC and CEMEX is contrary to law and the Department's established practice, and it is unsupported by the record of this review. CDC cites *Antifriction Bearings (Other Than Tapered Rolling Bearings) and Parts Thereof From the Federal Republic of Germany, Final Determination of Sales at Less Than Fair Value,* 54 FR 18992, 19089 (1989), in which the Department stated that ''it is the Department's general practice not to collapse related parties except in relatively unusual situations, where the type and degree of relationship is so significant that we find that there is strong possibility of price manipulation.''

CDC asserts that the preamble to the Department's 1997 regulations supports this policy by rejecting a recommendation that the Department collapse upon finding ''any potential for price manipulation.'' CDC notes further that, in *Nihon Cement Co.* v. *United States,* 17 CIT 400 (1993), the court criticized the Department for failing to discuss key collapsing criteria, adding that the Department had to consider all the criteria, although each of them need not be met.

CDC contends that the Department based its decision to collapse on an inadequate analysis of the collapsing factors (*i.e.,* affiliation, similar production facilities and the potential for price manipulation) and a lack of record evidence. CDC asserts that, although it is affiliated with CEMEX, affiliation alone is insufficient for

collapsing producers, according to the Department's policy.

CDC contends that the Department's conclusion regarding whether CEMEX and CDC have similar production facilities is without basis. CDC claims that the cement CEMEX and CDC export to the United States are not the same type product and that CDC would have to take on substantial retooling at its plant in order to produce the cement type that CEMEX exports to the United States.

CDC also contends that the Department erroneously determined that there was a significant potential for price manipulation. According to CDC, the Department relied on evidence of the level of common ownership and overlapping boards of directors, but not on intertwined business operations. Regarding common ownership, CDC notes that CEMEX is only a minority shareholder in CAMSA (CDC's parent company) and the majority of shares are still retained by CDC. CDC asserts that its sale of stock to CEMEX was purely a business decision and CEMEX's share does not constitute a controlling interest under Mexican law.

Regarding overlapping boards of directors, CDC acknowledges that members of CEMEX's management sit on the boards of directors of CDC and its affiliated companies. However, CDC asserts, (1) CEMEX's representatives are in the minority on all of these boards; (2) CDC's pricing and production are not discussed at the board meetings of CDC or any of the group's companies; (3) the Terrazas/Marquez families are in the majority on all boards; and (4) CEMEX's interest in CDC is only that of a passive investor.

As mentioned above, CDC argues that the Department did not address the criteria of intertwined business operations. CDC asserts that the factual basis upon which the Department relied in finding that this criterion was satisfied in prior reviews does not exist in this review. CDC claims that: (1) The companies do not share information on possible sales opportunities in Mexico or the United States and there is no coordination of sales, pricing or marketing policies; (2) CEMEX has no involvement in CDC's pricing, sales and production decisions; (3) CDC states that CDC and CEMEX do not share facilities or employees and that each company has its own facilities, employees, and accounting records; and (4) there were no commercial transactions between the parties during the POR.

CDC states that, in past cases, the Department has relied on other factors in determining whether to collapse affiliated companies and that all these factors support not collapsing. CDC claims that suppliers do not bill CDC and CEMEX jointly, each company has its own distinct sales and distribution process and U.S. importer, and the companies do not supply any material inputs to each other.

CDC distinguishes the facts in this case from those in *Queen's Flowers de Colombia* v. *United States,* 981 F. Supp 617 (CIT 1997) (*Queen's Flowers*). CDC asserts that, unlike the *Queen's Flowers* decision, collapsing is not needed to prevent circumvention of the antidumping law by means of significant manipulation of pricing or production. CDC asserts that in the cement industry high inland freight costs limit CDC's natural market; therefore, regardless of the antidumping margin, CDC cannot increase its market beyond these geographic constraints. Finally, CDC argues that CEMEX, as an indirect minority shareholder, cannot authorize CDC to change its pricing and production policies.

The petitioner argues that the Department should collapse CDC and CEMEX as it has in previous reviews and in the LTFV investigation. The petitioner asserts that CDC has provided no new evidence which would reverse the Department's position.

The petitioner states that CDC concedes that the first prong of the collapsing test (*i.e.,* affiliation) is met. Regarding similar production facilities, the petitioner asserts that the Department found that substantial retooling of CEMEX or CDC's facilities would not be necessary to produce cement Types II and V. The petitioner argues that CDC's claim that CDC and CEMEX do not produce the same product for export to the United States was rejected by the Department as untimely. However, even if the Department considers CDC's assertions, the petitioner argues, there is no evidence to support CDC's claims.

The petitioner agrees with the Department's determination that there is a potential for price manipulation. The petitioner asserts that the level of common ownership between CEMEX and CDC and other relationships demonstrates that CEMEX has effective control of CDC. The petitioner argues that the Department has collapsed in numerous cases where there is less than a majority interest in another party, focusing on joint manipulation of prices or production, not control.

Next, the petitioner claims that the level of shared board members indicates a significant potential for the sharing of information about pricing and production. Despite CDC's argument that pricing and production issues are not discussed at board meetings, the petitioner notes that nothing in Mexican law or company policy prohibits these issues from being discussed, including a scheme to manipulate production or price.

Furthermore, the petitioner asserts that the following facts demonstrate that CEMEX and CDC have intertwined business operations: (1) CEMEX and CDC formerly shipped to the United States through the same distribution channel; (2) CEMEX provides CDC with consulting services and assistance in marketing and exports; and (3) a 1996 financial report stated that CDC's affiliation with CEMEX positively influenced CDC's stock.

Finally, the petitioner claims that the Department has expressly rejected the argument that it may only collapse affiliated producers in ''exceptional'' circumstances. The petitioner cites the Department's determination in *Stainless Steel Wire Rod from Sweden,* 63 FR 40449, 40453 (1998). The petitioner disagrees with CDC's assertion that circumvention as described by the Department in *Fresh Cut Flowers from Columbia* is not practicable because of the special characteristics of the cement industry and ''the unique geographical features of CDC's market.'' According to the petitioner, the record evidence demonstrates that there is a natural overlap in the U.S. market for imports from CDC and CEMEX. The petitioner states that the two producers can reallocate their geographic shares of the Mexican market in a manner that manipulates the dumping margin and circumvents the order.

Department's Position: We agree with CDC that we must consider all relevant factors when collapsing two affiliated parties. Section 351.401(f) of the Department's regulations describes when the Department will treat two or more affiliated producers as a single entity (*i.e.,* ''collapse'') for purposes of calculating a dumping margin: (1) The producers must be affiliated, (2) the producers must have production facilities that are sufficiently similar so that a shift in production would not require substantial retooling, and (3) there must be a significant potential for the manipulation of price or production.

First, it is uncontested that CEMEX and CDC are affiliated within the meaning of section 771(33)(E) of the Act.

Second, a shifting of production between CEMEX and CDC would not require substantial retooling given the descriptions of respondents' production facilities and the fact that respondents produce a fungible product, gray

portland cement. (*See* CEMEX's December 8, 1997, submission and CDC's November 10, 1997, submission.) Furthermore, we have not considered CDC's argument regarding the shifting of production since we rejected the information as untimely. (*See* Memorandum to File Removing Untimely Information Submitted by CDC, dated November 30, 1998.) Thus, based on the evidence on the record we have concluded that a shift in production would not require substantial retooling.

Third, the Department may consider, *inter alia*, the following factors in identifying the potential for manipulation of price or production: (1) Level of common ownership; (2) whether managerial employees or board members of one of the affiliated producers sit on the board of directors of the other affiliated person; and (3) whether operations are intertwined, such as through the sharing of sales information, involvement in production and pricing decisions, the sharing of facilities or employees, or significant transactions between the affiliated producer. The level of common ownership and cross-board members, provides a mechanism for the two parties to share pertinent pricing and production information, as well as intertwined business operations, given that CEMEX owns indirectly a large percentage of CDC and that CEMEX's managers and directors sit on the board of directors of CDC and its affiliated companies. The Department finds that, if CDC and CEMEX are not collapsed, there is a significant potential for price manipulation which could undermine the effectiveness of the order. The decision to collapse is based upon the facts established on the record for this period of review. These facts are similar to the facts established on the record of the fifth and sixth reviews. A complete analysis surrounding the Department's decision to collapse CDC and CEMEX, requiring reference to proprietary information, is contained in the Department's memorandum from Roland L. MacDonald to Joseph A. Spetrini, dated August 31, 1998, located in the official file of this case.

3. Facts Available/CEMEX's Hidalgo Sales

Comment 1: The petitioner argues that the Department should base CEMEX's dumping margin on total adverse facts available, *i.e.*, the 109.43 percent calculated on judicial remand in the second review, for this review completely. The petitioner contends that CEMEX's reporting of incorrect information regarding its Hidalgo sales, its cancellation of verification, its provision of inadequate and delayed explanations to the Department with respect to the cancellation, and its failure to provide requested difference-in-merchandise (DIFMER) information warrant the application of total adverse facts available in this review. The petitioner also argues that the Department should describe more fully, for the final results of this review, the circumstances surrounding the use of adverse facts available with regard to CEMEX's Hidalgo sales in the preliminary results of this review.

The petitioner asserts that, prior to May 15, 1998, CEMEX had represented to the Department that its Hidalgo plant produced only Type I cement and not Type V cement. The petitioner argues that CEMEX, on May 15, 1998, canceled verification unilaterally, which was scheduled to begin on May 18, 1998, because it became obvious that the Department would discover at verification that CEMEX's Hidalgo plant produced and sold cement meeting Type V specifications. The petitioner argues that CEMEX, a highly experienced respondent, could have discovered the Hidalgo sales information readily prior to verification, should have provided the Department with corrected sales information prior to May 15, 1998, and should have proceeded with the verification on the scheduled date. The petitioner maintains that CEMEX provided inadequate and untimely explanations for its cancellation of verification that could only be seen as an effort to engage in damage control, which illustrates CEMEX's failure to provide full and accurate information. The petitioner contends that CEMEX's delay tainted the integrity of the Department's verification conducted July 20 through 31, 1998.

The petitioner asserts that the Department has used adverse facts available or best information available consistently in cases where a respondent refused to allow the Department to conduct verification, as in *Tapered Roller Bearings And Parts Thereof, Finished And Unfinished, From The People's Republic of China*, 62 FR 36,764 (1997), *Silicon Metal From Argentina*, 60 FR 35551 (1995), and *Sweaters Wholly Or In Chief Weight of Man-Made Fiber From Taiwan*, 58 FR 63913 (1993). The petitioner also contends that the Department erred in using partial adverse facts available as it was not sufficiently adverse to CEMEX, given CEMEX's failure to cooperate with the Department.

CEMEX responds that the Department's use of CEMEX's verified sales information as the basis of its dumping margin, rather than total facts available, is proper and that the petitioner's allegation is incorrect in law and fact. CEMEX contends that, after the Department conducted U.S. sales verifications but before the home market (HM) verifications were to begin, CEMEX discovered a discrepancy in its database regarding its Hidalgo sales which amounted to less than one percent of CEMEX's total HM sales. CEMEX argues that, to correct its submissions and reschedule verification, it requested an extension of time in accordance with the Department's statutory scheme. CEMEX notes that the Department verified CEMEX's U.S. and HM database and issued the preliminary results within its statutory deadlines. CEMEX concludes that the Department's decision was in accordance with the statutory requirement that determinations be based upon record information as verified by the Department set forth in section 782(i)(3) of the Act.

CDC asserts that the petitioner's argument that the Department should apply total facts available to CEMEX reinforces CDC's argument that it should not be collapsed with CEMEX. Rather, according to CDC, it should receive a separate rate as discussed in Issue 2, ''Collapsing,'' above. CDC maintains that a decision by the Department to rely on facts available, to any extent, for CDC's indirect minority shareholder punishes CDC unfairly.

Department's Position: Section 776(a) of the Act requires the Department to use facts otherwise available when necessary information is not on the record or an interested party withholds requested information, fails to provide such information in a timely manner, significantly impedes a proceeding, or provides information that cannot be verified. Section 776(b) of the Act authorizes the Department to use an adverse inference in determining the facts otherwise available whenever an interested party has not cooperated with the Department by not acting to the best of its ability to comply with requests for information.

First, with respect to its Hidalgo sales, CEMEX provided inaccurate information and sought to submit corrected information after the deadline for the submission of factual information had passed. Because CEMEX provided information regarding its Hidalgo sales in an untimely manner, we were unable to verify this information. Therefore, pursuant to section 776(d) of the Act, we have used facts available to establish the normal value (NV) of CEMEX's Hidalgo sales in

the home market. In addition, we note that the nature and timing of CEMEX's cancellation of the home-market verification the last business day before it was scheduled to begin was unprecedented. Given CEMEX's actions, we determine that CEMEX did not act to the best of its ability to provide accurate and timely information for use in our review and therefore our use of an adverse inference is appropriate under section 776(b) of the Act. Therefore, as facts available, we substituted the highest calculated NV in this review for all HM sales of cement produced at Hidalgo.

We disagree with the petitioner that we should have used total adverse facts available in determining a margin. In determining whether the use of total adverse facts available was appropriate, we considered several factors. We considered the degree of overall cooperation we received from CEMEX at the time of our initially planned verification and the small proportion of HM sales affected by CEMEX's error. We determined that, despite the delay caused by CEMEX's cancellation, we were able to verify, with the exception of CEMEX's Hidalgo sales data, CEMEX's timely reported data and complete the administrative review within the timelines prescribed by the statute and our regulations. Accordingly, by using the highest calculated NV in this review for all sales of cement produced by Hidalgo as adverse facts available, we have applied facts available in a manner that is significantly adverse to CEMEX's interests. (*See* our response to Comment 2, below.) We consider this decision to be consistent with the Statement of Administrative Action, Agreement on Implementation of Article VI of the GATT (SAA) (at 870), and section 776 of the Act.

Comment 2: CEMEX contends that the Department should use its corrected sales database for the Hidalgo plant to calculate NV. The Department, CEMEX claims, has the authority under § 351.301(c)(2) of the regulations to accept and use this information which the Department rejected as untimely filed. CEMEX also contends that the Department's two-week verification confirms the overall integrity of CEMEX's response, including data not verified.

The petitioner responds that the Department relied correctly upon adverse facts available for CEMEX's Hidalgo sales and that CEMEX provided no reason why the Department erred in using adverse facts available for its Hidalgo sales. The petitioner notes that the Department's regulations require the rejection of Hidalgo sales information as untimely filed and that for the Department to accept CEMEX's Hidalgo sales information would deprive the petitioner of the chance to comment. The petitioner rejects CEMEX's argument that the Department verified the overall integrity of CEMEX's home-market data, noting that the Department rejected and returned CEMEX's revised Hidalgo sales data.

Department's Position: As noted in the preliminary results, although all data from the Hidalgo plant was reported as relating to sales or production of only Type I cement, prior to the commencement of verification, CEMEX notified the Department that the merchandise produced at its Hidalgo plant was either Type V or Type I. *See* CEMEX's June 3, 1998, submission explaining the discovery of misreported sales at Hidalgo. CEMEX filed a submission on June 16, 1998, revising the home-market sales database for sales of Type V cement from Hidalgo. As this submission constituted unsolicited factual information received after the deadline for submitting factual information under § 351.302(d)(1)–(2) of our regulations, we rejected the submission on June 25, 1998. (*See* Department's Letter to CEMEX Rejecting Revised Database as Untimely Filed Information, dated June 25, 1998.)

While we recognize that § 351.301(c)(2) of our regulations authorizes us to request factual information at any time during the proceeding, allowing a party to re-submit information already rejected as untimely would contravene the purpose of the established deadline for the submission of factual information. As a result, we did not request this information pursuant to § 351.301(c)(2) of our regulations. In addition, we reject CEMEX's assertion that we should accept its untimely filed Hidalgo information because we verified the overall integrity of its HM database. We did not verify the accuracy of the Hidalgo information that CEMEX submitted improperly; rather we rejected it as described above. Accordingly, CEMEX's revised, rejected HM database cannot be considered part of the information we verified.

4. As Invoiced vs. As Produced

The petitioner contends that the Department erred by matching merchandise in this review on the basis of the ASTM cement type ''as produced'' rather than matching, as it had done in the original investigation and in the first five administrative reviews, on an ''as invoiced'' basis. The petitioner notes that the Department departed from its consistent ''as invoiced'' matching methodology at CEMEX's request after the Department discovered in the sixth review that all cement produced in the Hermosillo plants, though sold as Types I, II, and V, was physically Type V. The petitioner asserts that CEMEX altered its production and shipping arrangements for Type II cement to lower the dumping margin artificially.

The petitioner contends that matching identical products by ASTM type ''as invoiced'' reflects commercial reality and allows for a fair comparison as required by the statute. The petitioner asserts that the Department has noted that courts have recognized the Department's ''broad discretion 'to choose the manner in which ''such or similar' merchandise shall be selected,'' '' citing *Certain Cold-Rolled Carbon Steel Flat Products From Germany*, 60 FR 65264, 65271 (1995) (*Cold-Rolled From Germany*). The petitioner states further that cement customers are only concerned that the cement they purchase meets the ASTM type they have specified and are indifferent to whether the type they purchase may satisfy the specifications of another cement type. Thus, the petitioner maintains, prices of cement vary according to the invoiced type and not the actual physical specifications. In addition, the petitioner argues, no cement meeting the same ASTM specifications is identical and cement can possess a broad range of characteristics. The petitioner contends that to base matching criteria on physical characteristics, as CEMEX propounds, results in a commercially meaningless and an ''apples-to-oranges'' comparison. Indeed, the petitioner asserts, CEMEX's arguments in prior segments of this proceeding establish that the differences in specifications of cement CEMEX sells are commercially significant.

The petitioner asserts that the Department should remain consistent with its longstanding approach of matching identical merchandise based on whether the products meet the same commercially significant characteristics, citing, *e.g., Certain Cut-To-Length Carbon Steel From Finland,* 62 FR 18468, 18470 (1997) (*Cut-To-Length From Finland*). The petitioner argues that neither new facts nor legal justification exist for departing from the Department's longstanding methodology of matching cement ''as invoiced'' in the final results of this review. Citing *Cut-To-Length From Finland*, the petitioner notes the Department's finding that it would be inconsistent with its matching criteria to consider products sold to

different specifications as identical. *Id.* at 18470.

CEMEX responds that the Department matched identical merchandise properly on the basis of the ASTM specification to which the cement was produced. CEMEX argues that matching merchandise according to how it was sold does not meet the statutory requirement of section 771(16) of the Act, which requires ''foreign like product'' to include only merchandise sold in the home market that is physically identical with the merchandise produced for sale to the United States. CEMEX argues that, as the Department recognized in the *Sixth Review Final Results*, the statute compels the Department to base NV on its sales of cement that meet the customers' specifications physically. CEMEX notes that the petitioner raises the same arguments and cites to the same cases already rejected by the Department in the sixth review and in the preliminary results of this review. CEMEX contends that the prior determinations which the petitioner cites do not support its argument because they involved the identification and order of matching characteristics, which are not at issue here. CEMEX notes that, in this case, no party disputes that product characteristics of cement are determined on the highest ASTM specifications that it meets. Therefore, CEMEX concludes, the Department's identification of HM cement sales pursuant to the highest ASTM specifications to which the cement is produced continues to be in accordance with law.

CDC, like CEMEX, argues that the Department's decision to match sales on cement type ''as produced'' is justified on the record of this review and that this methodology should be applied consistently to CDC's margin calculations.

Department's Position: We agree, in part, with CEMEX. Section 771(16)(A) of the Act expresses a clear preference for matching sales in the United States with sales in the home market of merchandise that is ''identical in physical characteristics.'' *See CEMEX, S.A.* v. *United States*, 133 F.3d 897 (Fed. Cir. 1988) (*CEMEX* v. *U.S.*). When circumstances require the Department to compare non-identical merchandise, the statute, at section 773(a)(6)(C)(ii) of the Act, provides for a ''difference-in-merchandise'' adjustment (DIFMER) which is normally equal to the difference in cost of production attributable to differences in physical characteristics. *See also* 19 CFR 351.411.

Since the inception of this proceeding, we have seen that all cement conforms generally to the standards established by the ASTM. These standards tend to classify cement according to all significant physical characteristics, dimensional characteristics and/or performance properties. Also from the outset, interested parties and the Department have used ASTM standards to identify merchandise subject to this antidumping order and to establish how, and on what basis, the Department should match sales of identical or similar merchandise. Specifically, the Department has sought, wherever possible, to match sales of ASTM standard Type II to Type II, ASTM standard Type V to Type V, and so forth.

During the period covered by the original investigation, the Department discovered one or more instances where Mexican producers sold cement meeting one ASTM standard on the basis of cement meeting a lower (included) ASTM standard. However, in the final determination, the Department described these sales as a mistake and not ''the ordinary practice in the industry.'' Original LTFV Investigation, 55 FR at 29248. Therefore, based on the fact that it was the normal industry practice to produce and sell on the same basis, the Department accepted that ''matching by ASTM standard was the most reasonable basis for making equitable identical merchandise comparisons.'' *Id.* at 29248.

Devising a methodology for matching sales is often a difficult task and the courts have recognized that the Department has broad discretion ''to choose the manner in which * * * merchandise shall be selected.'' *Koyo Seiko Co.* v. *United States*, 66 F.3d 1204, 1209 (Fed. Cir. 1995). We have sought, throughout the past reviews, and in the present one, to (i) match based on physical characteristics, (ii) rely on ASTM standards to distinguish one type of cement from another, and (iii) rely on sales documentation as a convenient surrogate for more direct evidence (*e.g.*, mill test certificates) of cement type.

In the instant review, the Department requested CEMEX to report HM and U.S. sales data on both an ''as produced'' basis (*i.e.*, reporting the physical properties of each product sold) and on an ''as sold'' basis. CEMEX reported that it produced cement meeting the physical characteristics of Type V cement and sold this cement in the home market as Types I, II, and V cement. CEMEX produced Type V cement at its Yaqui and Campana plants located in the Hermosillo region of Mexico. CEMEX noted, and the record reflects, that Yaqui and Campana are the only two CEMEX plants which, on a consistent basis, produce cement meeting the physical requirements of one type of cement and sell that cement as another type of cement.

As we stated in our preliminary results, under these circumstances, we believe it would be unreasonable to match merchandise on a ''sold as'' basis. The appropriate product to which U.S. sales should be matched is the HM product that is physically identical to the merchandise produced for U.S.-market sales. Therefore, we appropriately calculated NV based on respondents' sales of cement as produced. Further, such an approach would not address any sales that were merely ''gray portland cement'' or ''cement.'' Finally, a ''sold as'' approach would lend itself to the type of product manipulation about which the petitioner has so often expressed concern. Therefore, for purposes of the final results of this review, the Department has continued to apply the matching methodology applied in the sixth administrative review and the preliminary results of this review.

The petitioner has expressed concern that matching using physical characteristics will enable CEMEX to manipulate HM sales to conform to certain specifications, thereby limiting the Department's ability to review sales of merchandise in the comparison markets properly. In order to address these concerns, the Department will continue to review and monitor closely sales of both identical and similar merchandise in the home market to ensure that, in subsequent reviews, an accurate and reliable database of HM and U.S. sales are reported. For example, we will continue to request that CEMEX report its HM sales on both an ''as sold'' and ''as produced'' basis. This requirement will limit the possibility for manipulation and ensures additional scrutiny of CEMEX's production processes.

Finally, we agree with CDC that we should apply our matching methodology consistently to its margin calculations and have adjusted our analysis accordingly.

5. Ordinary Course of Trade

CEMEX argues that HM sales of cement produced at Hermosillo were in the ordinary course of trade and should be used in the calculation of NV. CEMEX maintains that the Department did not take into account all legally relevant factors, that sales invoiced as Type II and Type V were made pursuant to a *bona fide* home-market demand for

those types of cement, that the merchandise sold was not obsolete or of second quality, that it was sold for its intended purposes, and that there were no special sales arrangements for these sales as a category. CEMEX also argues that the Department applied selected factors in performing its ordinary-course-of-trade analysis and that the Department's analysis was not supported by substantial evidence. CEMEX contends that the Department's analysis relies incorrectly on the volume of the sales at issue relative to sales of Type I cement and that the volume of the sales at issue was significant in absolute terms and pursuant to a *bona fide* demand. CEMEX also argues that judicial precedent and prior administrative practice establish that relatively low sales volume signifies sales outside the ordinary course of trade only when coupled with an absence of *bona fide* HM demand, which does exist in this case.

CEMEX also contends that the Department should focus on the actual terms of delivery for the sales at issue, identical to those of Type I customers, rather than the geographic distance, and that the distance to the customers is a geographic fact rather than a condition or practice of sale. CEMEX argues that the Department has not relied on shipping distances in determining whether sales were outside of ordinary course of trade in prior cases. Furthermore, CEMEX argues, if the Department continues to consider shipping distance in its analysis, it should do so on an individual-sale basis. CEMEX also contends that the Department's reliance on the low profitability of the sales at issue ignores the fact that the profit levels on these sales, though not as high as sales invoiced as Type I, are substantial and significant in absolute terms. Moreover, CEMEX notes that the profit differential is not the result of price disparities but rather higher freight costs. CEMEX contends further that the Department's reliance on the small number and type of customers for these sales is improper because such evidence generally reflects sales outside the ordinary course of trade in cases of sales of export overrun and off-specification sales, rather than when sales are made to a *bona fide* home market, which exists in this case. Moreover, CEMEX argues that the twelve years of domestic sales of these products, before and after the imposition of the order, constitutes a ''reasonable period of time'' regardless of the fact that such domestic sales did not begin until after CEMEX began production for export.

With regard to Type V cement, CEMEX also argues that the Department's preliminary results are factually incorrect because those results failed to appreciate the prior history of this case. Specifically, CEMEX states that, although the Department incorporated portions of the second review analysis memorandum into this administrative review, the Department did not acknowledge that during the second administrative review the Department verified that Tolteca, a CEMEX subsidiary whose production is subject to this review, has made continuous HM sales of Type V cement since 1964. Thus, CEMEX contends that its sales of Types II and V in the home market meet the statutory definition of ordinary course of trade in section 771(15) of the Act. CEMEX maintains that, although the Department relied on facts available to infer that the sales at issue had a ''promotional quality'', there is evidence on the record showing that the sales were no more promotional than Type I sales. CEMEX challenges the overall relevance of ''promotional quality'' as a factor in an ordinary-course-of-trade inquiry and argues that there is no judicial or Departmental precedent which has referred to this factor in any other ordinary-course-of-trade analysis.

Finally, CEMEX argues that Hermosillo-produced cement sold as Type I is within the ordinary course of trade because four out of six factors (shipping distance, profit, promotional nature, and historical pattern of sales) upon which the Department relied for its analysis of Type II and Type V sales were not present and that the Department's two other factors (number and type of customers and freight costs) are not supported by substantial evidence. Specifically, CEMEX notes that the volume of its Hermosillo Type I sales exceeded five percent of its U.S. sales and, thus, constituted a viable basis to calculate NV under section 351.404(b)(2) of the Department's regulations. In addition, CEMEX contends that the freight cost differences upon which the Department relied were insignificant. CEMEX also assserts that the number and type of customers buying Type I from the Hermosillo plants were consistent with the number and type of customers buying from other plants. Last, CEMEX claims that the Department inaccurately relied upon differences in handling charges between Hermosillo and non-Hermosillo sales of Type I cement.

The petitioner maintains that CEMEX's HM sales of cement produced as Type V are outside the ordinary course of trade. First, the petitioner asserts that the Department must evaluate not just one factor taken in isolation but rather all the circumstances particular to the sales in question to determine whether the sales reflect the conditions and practices which, for a reasonable time prior to the exportation of the subject merchandise, have been normal. The petitioner notes that the Department relied upon five key factors in determining that Types II and V sales were outside the ordinary course of trade in the second review and that the CIT and Federal Circuit affirmed reliance on these five factors. The petitioner argues that the Department considered these same factors in the fifth and sixth administrative reviews when it found Types II and V to be outside the ordinary course of trade. The petitioner argues that there has been no material change in the evidence relating to these five factors which would justify a different decision.

In addition to discussing the record evidence regarding the above-described factors, the petitioner argues that there are additional factors (*e.g.*, changes in its shipping and production arrangements for cement Types II and V, absorption of freight costs on sales of cement Types II and V) supporting the Department's past determinations in this matter. The petitioner also states that CEMEX's HM sales produced as Type V but sold as Type I are outside the ordinary course of trade. Among a number of arguments to support this contention, the petitioner notes that the subject HM sales meet physical specifications for Type V and that the customers do not need these traits, suggesting production overruns as one possible explanation. Also, the petitioner notes, sales of this merchandise as Type I cement represent a small percentage of HM sales of Type I cement as well as a small percentage of CEMEX's production of Type V. The petitioner also notes that CEMEX's freight costs for these sales were significantly different from the freight costs for other sales of Type I, that the number and type of customers for these sales are unusual, and that CEMEX's profits on sales of physically Type V cement sold as Type I are unusual.

The petitioner contends that CEMEX's HM sales of all cement produced as Type V, regardless of how they were invoiced and sold, are outside of the ordinary course of trade when considered in the aggregate. In support, the petitioner discusses volume sold, freight cost differences, type of customers, and profit differences. The petitioner asserts that CEMEX's proposed ordinary-course-of-trade analysis is erroneous, that the

Department expressly considered the totality of the circumstances, and that the existence of a limited demand for sales of Type II and Type V does not establish that they are within the ordinary course of trade. Also, the petitioner maintains, only those factors relevant to HM sales of cement are probative with respect to whether CEMEX's sales are outside the ordinary course of trade and that the Department did not consider one factor in isolation. Further, the petitioner contends, the Department's analysis focuses on whether the sales are normal relative to sales of other products of the same class or kind or the respondent's usual practice with respect to the merchandise at issue.

Finally, the petitioner asserts that CEMEX's argument that its sales of Type II and V cement represent sound business judgment is irrelevant. The petitioner maintains that CEMEX has waived its claim that consolidation of production at Hermosillo was a legitimate business decision because it did not mention this argument in its case brief. Also, the petitioner contends, whether CEMEX's decisions regarding production and distribution arrangements were based on sound business judgment is not a factor in determining if those sales were outside the ordinary course of trade.

Department's Position: Consistent with our preliminary results, we have determined that CEMEX's HM sales of Type II and Type V cement produced at the Hermosillo plants were outside the ordinary course of trade during the POR. Section 773(a)(1)(B) of the Act states, in part, that NV is ''the price at which the foreign like product is first sold (or, in absence of a sale, offered for sale) for consumption in the exporting country, in the usual commercial quantities and in the ordinary course of trade.'' The term ''ordinary course of trade'' is defined as ''the conditions and practices which, for a reasonable time prior to the exportation of the subject merchandise, have been normal in the trade under consideration with respect to merchandise of the same class or kind.'' The SAA which accompanied the passage of the URAA clarifies this portion of the statute further when it states: ''Commerce may consider other types of sales or transactions to be outside the ordinary course of trade when such sales or transactions have characteristics that are not ordinary as compared to sales or transactions generally made in the same market.'' SAA, at 164. Thus, the statute and the SAA are clear that a determination of whether sales (other than those specifically addressed in section 771(15) of the Act) are in the ordinary course of trade must be based on an analysis comparing the sales in question with sales of merchandise of the same class or kind generally made in the home market (*i.e.*, the Department must consider whether certain HM sales of cement are ordinary in comparison with other HM sales of cement).

The purpose of the ordinary-course-of-trade provision ''is to prevent dumping margins from being based on sales which are not representative'' of the home market. *Thai Pineapple Public Co.* v. *United States,* 946 F. Supp. 11, 15 (CIT 1996) *(quoting Laclede Steel Co.* v. *United States,* Slip Op. 95–144 at 6 (CIT Aug. 11, 1995)). Congress has not specified any criteria that the agency should use in determining the appropriate ''conditions and practices.'' Thus, the Department, ''in its discretion, chooses how best to analyze the many factors involved in a determination of whether sales are made within the ordinary course of trade.'' *Id.* at 14–17.

In the instant review, the Department's decision to exclude sales of Type II and Type V cement from the calculation of NV centered around the unusual nature and characteristics of these sales compared to the vast bulk of CEMEX's other HM sales. The Department's ordinary-course-of-trade inquiry is far-reaching. The agency must evaluate not just ''one factor taken in isolation but rather all the circumstances particular to the sales in question.'' *Murata Mfg. Co.* v. *United States,* 820 F. Supp. 603, 607 (CIT 1993) *(quoting Certain Welded Carbon Steel Standard Pipes and Tubes from India, Final Results of Antidumping Duty Administrative Review,* 56 FR 64753, 64755 (1991)). This broad approach recognizes that each company has its own conditions and practices particular to its trade. In short, the Department examines the totality of the facts in each case to determine if sales are being made for ''unusual reasons'' or under ''unusual circumstances.'' *Electrolytic Manganese Dioxide from Japan; Final Results of Antidumping Duty Administrative Review,* 58 FR 28551, 28552 (1993).

We disagree with CEMEX that our analysis used selective factors and was not supported by substantial evidence. Pursuant to section 773(a)(1)(B) of the Act, the Department has examined the totality of the circumstances surrounding CEMEX's sales of cement in Mexico that are produced as Type V cement and marketed as Types I, II, and V (which are identical in physical characteristics to the cement that CEMEX sells in the United States).

In analyzing the ordinary-course-of-trade issue in arriving at its preliminary results in this administrative review, the Department considered the circumstances surrounding CEMEX's HM sales of Types I, II, and V cement from the Hermosillo plants, Yaqui and Campana. An expanded discussion of the most recent analysis can be found in a memorandum dated August 31, 1998 (Memorandum from Roland L. MacDonald to Joseph A. Spetrini, Seventh Antidumping Administrative Review on Gray Portland Cement and Clinker from Mexico—Ordinary Course of Trade). A public version of this memorandum is on file in room B–009 of the Department's main building. As part of that analysis, the Department considered certain data from the second, fifth, and sixth reviews which were placed on the record of the instant review. CEMEX provided no facts in this review that would alter the analysis. We find that the information on the record continues to support the decision that all three types of cement produced at the Hermosillo plants in the home market are sold outside the ordinary course of trade.

First, we found that during the POR, as in previous reviews, CEMEX sold very small amounts of Type II and Type V in the home market compared to sales of cement produced as Type I. We found that freight costs for Type II and Type V cement were higher than freight costs for Type I sales, with CEMEX absorbing some of these costs. While it is true, as CEMEX has pointed out, that shipping terms for Type II and Type V cement are in some respects similar to Type I, for the years preceding the antidumping order it was CEMEX's *normal* business practice to pass along the cost of pre-sale freight to purchasers of its Type II cement. Thus, we find it an ''unusual circumstance'' for CEMEX to absorb freight costs after the issuance of the order, particularly given the higher freight costs for Type II and Type V cement than for Type I cement. Third, we found that the normal practice for CEMEX is to ship cement, a heavy material, over relatively short distances. Over 95 percent of CEMEX's sales of cement in Mexico were shipped less than 150 miles and, during the POR, shipments of cement produced as Type I conformed to this pattern. Shipments of Type II and Type V, however, occurred over vastly greater distances. Fourth, we found that CEMEX's profits on Type II and Type V cement sales during the POR are small compared to those earned on sales of Type I cement. Fifth, we found that the number and type of customers that purchase Type II

and Type V cement from CEMEX is substantially different from those who purchase other cement types.

The Department disagrees with CEMEX's contention that (i) low sales volume is only relevant to the ordinary-course-of-trade issue if there is no *bona fide* HM demand, and (ii) the presence of HM demand is indicative of sales within the ordinary course of trade. First, the Department verified in the second review that there was a small, but apparently legitimate, HM demand for Type II and Type V cements. However, that finding did not lead to a determination that the subject sales were made within the ordinary course of trade. As we note above, the CAFC in *CEMEX* v. *U.S.* affirmed the Department's determination that CEMEX's HM sales of Types II and V were outside the ordinary course of trade. Second, the Department has often found sales to be outside the ordinary course of trade where volume was considered with other, non-demand-related, factors. For example, in *Final Determination of Sales at Less Than Fair Value; Sulfur Dyes Including Sulfur Vat Dyes From the United Kingdom*, 58 FR 3253, 3256 (1993), the Department concluded that sales were outside the ordinary course of trade based upon abnormally high volume, low price, and the existence of a ''special agreement'' to promote the product at issue. In *Tapered Roller Bearings and Parts Thereof, Finished and Unfinished, From Japan*, 52 FR 30700, 30704 (1987), the Department determined that sales were outside the ordinary course of trade because the sales in question were of small volume and high prices, most of the sales were canceled prior to invoice, and there were no comparable sales in the United States. We have also excluded transactions from the calculation of NV based upon sales made to employees and negligible volume. *See, e.g., New Minivans from Japan*, 57 FR 43, 46 (1992). In short, the Department's consistent and longstanding practice has been to consider sales volume along with numerous other factors, depending upon the specific product involved.

We also disagree with CEMEX's claim that, instead of considering shipping distances and freight costs, we should focus on shipping terms and practices. In fact, in analyzing this issue, the Department has examined both shipping distances and shipping terms and practices. With respect to shipping distances, we found that the normal practice in Mexico is to ship cement over relatively short distances. As we noted earlier, over 95 percent of all cement shipments in Mexico cover distances of less than 150 miles. While CEMEX's HM shipments of Type I cement conformed to this norm, its shipments of Type II and Type V occurred over substantially greater distances. CEMEX claims that the ''differences in shipping distances is simply a geographic fact'' and the result of a ''legitimate business decision'' and that the Department has not relied on shipping distances in determining whether sales were outside of ordinary course of trade in prior cases. These claims are inapposite. We are not questioning the reasoning behind but the effect of the decision to ship long distances. As we noted in earlier reviews, a company may have sound business reasons for changing its methods of operation but, if sales resulting from this new business practice are not normal for the company (for a reasonable time prior to exportation), then they cannot be said to be within that company's ordinary course of trade. The CIT and CAFC affirmed this analysis in its examination of the second administrative review. *CEMEX* v. *U.S.*

With respect to shipping terms, while it is true, as CEMEX points out, that shipping terms (*e.g.*, CIF or FOB plant) for Type II and Type V are in some respects similar to Type I, we believe this contention proceeds from an incorrect premise. In an ordinary-course-of-trade inquiry, the pertinent issue is whether the conditions and practices are ''normal'' for the company in question. For the years preceding the antidumping order, it was CEMEX's normal business practice to pass along the cost of pre-sale freight to purchasers of its Type II and Type V cement. For CEMEX to absorb freight costs after the issuance of the order is an ''unusual circumstance,'' particularly given the high freight costs for Type II and Type V cement. Thus, with respect to both shipping distances and terms we find sales of Type II and Type V to be outside the ordinary course of trade.

CEMEX argues that, in the preliminary results, the Department did not acknowledge a legitimate HM demand for the cement from those plants invoiced as Type II and Type V. However, the Department did consider this information in preparing the preliminary results. As CEMEX itself states in its case brief, the Department acknowledged that a legitimate HM demand existed for Type II and Type V in the second review. The Department acknowledged this in the *Sixth Review Final Results* and continues to recognize that a legitimate HM demand exists for Type II and Type V. But a range of other factors, such as the size of the home market for Type II and Type V cement and other characteristics noted above, were also considered, and we find, based on those factors, that this demand does not compel us to consider sales of Type II and Type V within CEMEX's ordinary course of trade.

Among the selected factors for which CEMEX argues the Department misapplied the record evidence were historical sales trends and ''promotional quality'' of the products. We disagree. On September 25, 1997, the Department issued a questionnaire requesting CEMEX to support its position that HM sales of Type V cement were in the ordinary course of trade by addressing, among other things,''historical sales trends'' and various non-profit motives for making these sales. CEMEX's response (copies of its submission from the fifth and sixth administrative reviews) did not address these two items. Thus, the Department found in the preliminary results that the facts regarding these items have not changed since the second review, that CEMEX did not sell Type II and Type V cement until it began production for export in the mid-eighties, despite the fact that a small domestic demand for such existed prior to that time, and that sales of Type II and Type V cement continue to exhibit a promotional quality that is not evidenced in CEMEX's ordinary sales of cement (for details on the conclusions reached in the second review, *see* memorandum from Holly A. Kuga to Joseph A. Spetrini, dated August 31, 1993).

For the reasons stated above, the Department has determined that CEMEX's HM sales of Type V cement during the review period were outside the ordinary course of trade. We note that the facts established in the record of this review are very similar to the facts which led us to determine in the second, fifth, and sixth reviews that HM sales of Type V cement were outside the ordinary course of trade. The decision in the second review, as noted above, was affirmed by the CIT and CAFC. In conclusion, the decision to exclude sales of Type V cement from the calculation of NV centers around the unusual nature and characteristics of these sales compared to the vast majority of CEMEX's other HM sales. Based upon these differences, the Department has determined that they are not representative of CEMEX's HM sales and, therefore, these sales were not within CEMEX's ordinary course of trade.

With respect to cement from the Hermosillo plants meeting Type V specifications but sold in the HM as Type I, as noted in the memorandum

referred to above (August 31, 1998 Memorandum from Roland L. MacDonald to Joseph A. Spetrini with subject: Seventh Antidumping Administrative Review on Gray Portland Cement and Clinker from Mexico—Ordinary Course of Trade), the record evidence indicates that only at the Hermosillo plants did CEMEX produce consistently a cement meeting one ASTM standard and sell that cement as a different ASTM type. That factor, and others discussed in that memorandum, distinguishes sales of Type I cement produced at Hermosillo from CEMEX's sales of Type I cement produced as Type I from other production facilities.

6. Difference-in-Merchandise Information

Comment 1: CEMEX argues that the Department should revise its treatment of difference-in-merchandise (DIFMER) information for the following reasons. First, CEMEX maintains that the issue of a DIFMER adjustment is moot because CEMEX's HM sales of Type V cement were made in the ordinary course of trade thus requiring no DIFMER adjustment. Second, CEMEX claims that it neither requested a DIFMER adjustment nor withdrew such a request and the Department described the record evidence incorrectly in the preliminary notice. CEMEX claims that its views on various options for a DIFMER adjustment have been consistent. Third, CEMEX contends that cost differences between Types I and V cement are the result of plant efficiencies. CEMEX maintains that the production process for all types of cement is identical. According to CEMEX, cost differences among cement types are solely a function of the extraction costs of clay and limestone, the two raw materials which compose cement. CEMEX argues that the cost of these materials depends upon the condition of the quarry and the distance between the plant and the quarry. Thus, CEMEX maintains, the cost differences among the cement types are not due to physical differences in the merchandise; rather they are a function of the quarry itself. In the alternative, CEMEX argues that the Department should either use CDC's DIFMER adjustment since the Department collapsed CDC and CEMEX or calculate a DIFMER using market values, as authorized by the Department's regulations and in the Department's decision in *Polyvinyl Alcohol From Taiwan*, 63 FR 32810 (June 16, 1998).

The petitioner responds that the Department based CEMEX's DIFMER adjustment on adverse facts available correctly. The petitioner maintains first that the DIFMER issue is not moot because the Department found correctly that all of CEMEX's sales of cement produced as Type V were outside the ordinary course of trade. The petitioner responds next that the inaccuracies contained in the Department's DIFMER discussion in the preliminary results are irrelevant to the Department's conclusion that CEMEX did not provide the requested DIFMER information. Moreover, the petitioner argues, CEMEX's description of the record is inaccurate. The petitioner asserts that CEMEX did not respond to the Department's requests for DIFMER information and that, by its provision of variable cost of manufacturing (VCOM) data and suggestions for DIFMER calculation, it led the Department to believe that it was requesting a DIFMER adjustment. After suggesting previously that a DIFMER adjustment should be made, the petitioner contends that CEMEX requested a DIFMER adjustment expressly in its April 27, 1998, submission to the Department, where it supplied VCOM data for Types V LA and Type I cement. According to the petitioner, CEMEX led the Department to believe that it was claiming a favorable DIFMER adjustment and then, in effect, withdrew its request on May 8, 1998. Third, the petitioner claims that the record evidence demonstrates affirmatively that physical differences between Types I and V cement contribute to different production costs, *e.g.*, Types V and I differ in the amount of an allowable raw material, tricalcium aluminate, and differing production processes are also required. Fourth, the petitioner argues that the Department should not apply CDC's DIFMER adjustment to CEMEX because to do so would reward CEMEX improperly for its lack of cooperation. The petitioner concludes that the Department should not base CEMEX's DIFMER adjustment on market values because CEMEX has not provided any information on which the Department could calculate such an adjustment. Moreover, the petitioner notes, the Department bases a DIFMER adjustment on differences in market value rarely and disfavors basing adjustments on market value rather than actual costs.

Department's Position: We agree with the petitioner that section 773(a)(6)(C)(ii) of the Act directs the Department to make an adjustment to NV to account for differences in the physical characteristics of merchandise where similar products are compared. Section 351.411(b) of our regulations directs us to consider differences in variable costs associated with the physical differences in the merchandise. Where appropriate, we may also consider differences in the market value. We determine that the record evidence demonstrates the existence of differences in the physical characteristics of cement Types I and V, and, therefore, a DIFMER adjustment is appropriate here.

Contrary to CEMEX's assertions, the data and product information on the record reflect the existence of differences in the physical characteristics of cement Types I and V. These physical differences were originally made apparent in CEMEX's reported variable manufacturing costs of producing Type I cement and Type V cement in the home market. In addition, the statements CEMEX made in its April 20, 1998, and May 8, 1998, submissions indicating that no DIFMER adjustment was necessary is contrary to the facts on the record of this and prior reviews (currently on the record of the instant review), wherein CEMEX has demonstrated that there are differences in the physical characteristics of Types I and V cement which contribute to a difference in their production costs.

Next, we note that CEMEX did not provide information regarding process or production differences that are attributable to the differences in physical characteristics of cement Types I and V from which we could calculate a DIFMER adjustment. While we acknowledge that our DIFMER discussion in the preliminary results of review contained some sequential inaccuracies, none of these minor errors affect our conclusion that CEMEX provided conflicting and incomplete DIFMER information. We first requested CEMEX to provide DIFMER information in our original questionnaire on October 3, 1997. CEMEX's response on December 8, 1997, provided no information regarding process or production differences that are attributable to the differences in physical characteristics of Types I and V. CEMEX again did not provide information with which we could make a DIFMER adjustment in its section D response filed on March 3, 1998. On March 31, 1998, we requested parties to submit information to assist in our determination of the appropriate DIFMER calculation. On April 17, 1998, we made a second request for DIFMER information. In response to our March 31 and April 17 requests, on April 20, 1998, CEMEX stated its belief that no DIFMER adjustment was necessary in this review but offered suggestions for the calculation of its DIFMER adjustment based upon hypothetical

data. However, CEMEX again did not demonstrate the existence of variable cost differences between Types I and V resulting from physical differences in the products. In a submission filed April 27, 1998, CEMEX suggested that the Department base the DIFMER adjustment on CEMEX's reported difference in variable costs for the production of Types I and V although CEMEX had not provided the requisite VCOM data. Finally, on May 8, 1998, CEMEX claimed in its second supplemental response that no variable cost differences existed between Types I and V. Thus the record of this review demonstrates that CEMEX did not comply with the Department's requests for data demonstrating the cost differences between cement Types I and V resulting from their physical differences and offered conflicting information several times.

Because record evidence indicates the existence of physical differences between cement Types I and V and because CEMEX did not submit viable bases for a DIFMER adjustment, we have calculated a DIFMER adjustment based upon facts otherwise available. Moreover, because CEMEX failed repeatedly to provide requested information, we conclude that CEMEX did not act to the best of its ability. Thus, in accordance with section 776(b) of the Act, we have used an adverse inference in applying facts available. Therefore, as facts available, and in order to minimize the effect of varying plant efficiencies, the Department has compared CEMEX's VCOM to produce cement at the Hermosillo plants (sold as Types I, II, and V but physically Type V) with the lowest variable costs reported by a CEMEX Type I facility. However, we have found that, in our preliminary results, we calculated DIFMER using the VCOM from CEMEX's second-most efficient plant rather than CEMEX's most efficient plant. We have based this determination on findings at the cost verification and Exhibit C–8 of the cost verification report. *See* Cost Verification Report, dated August 21, 1998. Therefore, we have adjusted the DIFMER calculation using the VCOM of CEMEX's most efficient Type I facility in accordance with the methodology we used in the sixth review. This recalculation results in an upward adjustment to NV in accordance with section 776(a) of the Act.

CEMEX's remaining arguments supporting the use of a different facts available are without merit. First, as we have concluded that CEMEX's HM sales of Type V cement are outside the ordinary course of trade (*see 5. Ordinary Course of Trade*, above), the DIFMER issue remains active. In addition, using CDC's DIFMER adjustment for CEMEX is contrary to our directive under section 776(b) of the Act to apply adverse facts available where an interested party has failed to cooperate by not acting to the best of its ability to comply with a request for information. We conclude that using CDC's DIFMER, as suggested by CEMEX, would reward CEMEX improperly for its failure to provide the information we requested. Further, we reject CEMEX's proposal that we base our DIFMER adjustment on differences in market value rather than actual costs. CEMEX provided no information upon which we could calculate such an adjustment and, although we retain the discretion to calculate DIFMER based upon market values, we do so rarely. *See* Preamble to the Department's Regulations, 62 FR at 27370.

Comment 2: The petitioner contends that the Department's selection of facts available for DIFMER was not sufficiently adverse. It concedes that CEMEX provided variable cost data for Types I and V but, despite the Department's requests, did not provide information on process/production differences attributable to physical differences. The petitioner argues that, instead, CEMEX offered a suggested DIFMER calculation based upon hypothetical data. The petitioner also notes that CEMEX stated later that there were no variable cost differences between Types I and V but that Type V is in fact more expensive to produce (physically) than Type I. The petitioner claims that CEMEX has also refused repeatedly to provide DIFMER information in the second, fifth, and sixth reviews. According to the petitioner, the Department should apply total facts available based on CEMEX's refusal to provide DIFMER or, at the very least, should use a 20-percent upward DIFMER adjustment to NV as facts available, consistent with the final remand results of the second review.

CEMEX argues that if the Department bases CEMEX's DIFMER on facts available a 20-percent DIFMER adjustment is unreasonable as the Department is authorized to rely on information placed on the record. CEMEX contends that its information was timely, verified, and reliable. According to CEMEX, a 20-percent DIFMER adjustment as applied for the second review is unreasonable because each review is a distinct proceeding and the facts differ. CEMEX argues that, in the second review, the Department had only weighted-average VCOM data for Types I and II and did not have plant-specific, cement type-specific VCOM data, as the Department has here.

Department's Position: We do not agree that a more adverse rate should be used. For the reasons stated in response to comment 1, above, our DIFMER calculation is consistent with prior practice and based upon review- and plant-specific reported data which we verified. We consider our choice of facts available to be sufficiently adverse in order to provide an incentive to respondents to provide complete and accurate responses to our requests for information.

7. Level-of-Trade Determination for CEP Sales

The petitioner argues that the Department's methodology for determining the level of trade (LOT) for CEP sales based on the level of the constructed export price (CEP) from the exporter to the related affiliated importer (after deductions required by section 772(d) of the Act) is contrary to the Act and inconsistent with the methodology the Department used to determine LOT for export price (EP) and NV sales. In *Borden, Inc.* v. *United States*, 4 F.Supp.2d 1221 (CIT 1998), the petitioner notes that the CIT found this methodology to be contrary to the requirements of the plain language of the statute.

The petitioner notes that, for EP and NV, the Department bases LOT on the unadjusted starting price in the relevant market. The petitioner asserts that, in order to make an ''apples-to-apples'' LOT comparison, the statute requires the Department to analyze the LOT for both HM and CEP sales equivalently, based on the selling functions performed with respect to the sales to the first unaffiliated customer in both markets. The petitioner concludes that the Department's practice results in an unfair, skewed comparison between an adjusted CEP and an unadjusted NV.

CEMEX and CDC respond that the Department interpreted section 772(d) of the Act properly and based the CEP LOT appropriately on the U.S. price after adjustments. CEMEX and CDC argue that the petitioner's sole reliance upon the CIT decision in *Borden* is misplaced because, as the Department stated in prior determinations, the decision is not final and the Department is appealing the decision. Respondents also assert that the Department's interpretation of the statute is supported in the SAA and the Department's regulations as well as by Department practice. In light of this interpretation of the statute, argues CDC, any comparison of selling functions for the purpose of determining CDC's eligibility for a CEP

offset must focus on CDC's activities in selling to the two markets, not on the activities of its U.S. affiliate. In addition, CDC argues that the Department applied the proper statutory interpretation in the sixth review.

Department's Position: As we stated in prior determinations, our practice of basing our LOT analysis on the CEP, rather than at the starting price of CEP, is in full compliance with the statute and the regulations. *See Professional Electric Cutting Tools from Japan*, 63 FR 54441, 54444 (1998). In addition, we have stated that the CIT's decision in *Borden* is not binding as we are appealing this decision while we continue to apply our current methodology. *See Porcelain-on-Steel Cookware from Mexico*, 63 FR at 38378. Accordingly, consistent with section 351.412 of our regulations, we have continued to base our LOT analysis on the CEP reflecting the sale from exporter to importer for these final results of review.

8. CEP Offset Justification

Comment 1: The petitioner argues that the Department determined erroneously that CEMEX's and CDC's HM sales were at a different LOT than their sales to the United States and, on that basis, granted CEMEX and CDC an inappropriate CEP offset adjustment to NV. According to the petitioner, the Department found no differences in LOT in the fifth review and the facts in this review are virtually identical to the facts in that review. Also, the petitioner claims that the Department's methodology for analyzing the LOT and CEP offset issues has not changed since the fifth review and, therefore, no basis exists for a different result with respect to the LOT and CEP offset issues in this review.

The petitioner argues that, in the preliminary results of this review, the Department found that CEMEX and CDC perform more selling functions for sales to end-users and ready-mixers in the home market than for sales to affiliated importers in the United States. The petitioner argues that, with regard to CEMEX and CDC, the record either contradicts or does not support the Department's finding that their HM and adjusted CEP sales were at different levels of trade. The petitioner argues that the Department must find more than different levels of selling activities to determine that a respondent's HM and U.S.-affiliate sales are at different levels. Also, the petitioner asserts that HM selling functions must be provided to at least the majority of customers, citing *Notice of Final Determination of Sales at Less Than Fair Value: Certain Pasta From Italy*, 61 FR 30326, 30338 (1996), and that minor or relatively insignificant selling functions cannot provide the basis for a determination that there are different LOTs and that a CEP offset adjustment is warranted. With regard to both CEMEX and CDC, the petitioner argues that the record does not support the Department's finding that their HM sales were at a more advanced stage of distribution than their CEP sales.

With regard to CEMEX, the petitioner argues that no basis exists for the Department's conclusion that CEMEX's sales to its affiliated U.S. distributor, Sunbelt Cement, were at a different place in the distribution chain than CEMEX's HM sales. To the contrary, the petitioner adds, the record evidence reflects that CEMEX's selling activities with respect to its Sunbelt Cement sales were virtually identical to its selling activities with respect to its HM sales.

The petitioner also contends that the Department's LOT memorandum for the preliminary results contains several inaccuracies. First, the petitioner maintains, for all but one expense, advertising, the activities listed in the Department's chart of expenses relating to CEMEX's indirect selling expenses do not correspond to CEMEX's itemized indirect selling expenses as CEMEX reported in its response. The petitioner next argues the Department relied incorrectly upon five selling functions in its determination that CEMEX's HM sales were at a more advanced LOT than its U.S. sales: strategic and economic planning, market research, personnel training/personnel exchange, procurement and sourcing services and after-sales servicing/warranty service. The petitioner argues that the record demonstrates that the Department found erroneously that CEMEX performs these functions only in the home market. The petitioner also asserts that what the Department describes separately as ''strategic and economic planning'' and ''market research'' are the same activity and should be merged for LOT-analysis purposes. The petitioner maintains further that CEMEX performed sales forecasting in neither the U.S. nor the home market. The petitioner also argues that CEMEX provided insufficient and inconsistent information regarding the after-sale services it provides and failed to establish that the selling functions were applied consistently ''to at least the vast majority of customers and sales in each level of trade,'' citing *Certain Pasta From Italy*. Finally, the petitioner argues that selling functions such as market research, advertising, and technical advice are insignificant in a mature market such as gray portland cement.

CEMEX asserts that, based on the law and verified information on the record, the Department's preliminary results properly included a CEP offset. First, CEMEX concurs with the Department's determination that the sales to CEMEX's unaffiliated U.S. distributor, Sunbelt Cement, were at a less-advanced LOT than the LOT of HM sales. CEMEX notes that the CEP adjustments made under section 772(d) of the Act remove all the marketing and distribution activities of Sunbelt Cement, thereby altering the LOT of the starting price to a less-remote link in the chain of distribution. CEMEX contends that the appropriate comparison is based on the selling functions performed by CEMEX with respect to its sales in Mexico and its sales to the United States.

CEMEX argues that the Department determined appropriately that CEMEX performed significantly different selling functions for CEP and HM sales and that the HM level was more advanced. CEMEX rejects the petitioner's implication that, because the Department reached a different determination in the fifth review, the sixth review results must be wrong. CEMEX also rejects the petitioner's hypothesis that, because the U.S. market is important to CEMEX's business, CEMEX's centralized strategic planning in Mexico must support exports to the United States. CEMEX states that activities with respect to procuring/sourcing materials and other assets for U.S. operations are performed by CEMEX's U.S. affiliate. Finally, CEMEX disagrees with the petitioner's argument that market research, advertising, after-sales service, and technical advice are all insignificant in selling cement. CEMEX notes that the list of selling activities that it included in its responses are representative of the activities that the Department has included in LOT questionnaires issued to companies in other cases.

Department's Position: In accordance with section 773(a)(1)(B) of the Act, to the extent practicable, we determine NV based on sales in the comparison market at the same LOT as the EP or CEP. The NV LOT is that of the starting-price sales in the comparison market or, when NV is based on constructed value (CV), that of sales from which we derive selling, general and administrative (SG&A) expenses and profit. For EP, the U.S. LOT is also the level of the starting-price sale, which is usually from exporter to importer. For CEP, it is the level of the constructed sales from the exporter to the importer.

To determine whether NV sales are at a different LOT than EP or CEP, we examine stages in the marketing process

and selling functions along the chain of distribution between the producer and the unaffiliated customer. If the comparison-market sales are at a different LOT, and the difference affects price comparability, as manifested in a pattern of consistent price differences between the sales on which NV is based and comparison-market sales at the LOT of the export transaction, we make a LOT adjustment under section 773(a)(7)(A) of the Act. Finally, for CEP sales, if the NV level is more remote from the factory than the CEP level and based on the available information, we are unable to determine the amount of a LOT adjustment, we adjust NV under section 773(a)(7)(B) of the Act (the CEP offset provision). *See Notice of Final Determination of Sales at Less Than Fair Value: Certain Cut-to-Length Carbon Steel Plate from South Africa,* 62 FR 61971 (November 19, 1997).

Based upon our analysis of the record, we determine, as in the preliminary results of review, that CEMEX's HM sales occurred at a different and more advanced stage of distribution than CEMEX's sales to its U.S. affiliate. While we note that the LOT memorandum outlining our analysis contains some minor errors, none of these inaccuracies alters our conclusion that CEMEX performs more selling functions at a more advanced stage of distribution in the home market than its CEP sales in the United States. The record reflects that CEMEX performed eleven selling functions in the home market: (1) Strategic and economic planning; (2) market research; (3) advertising; (4) technical advice; (5) personnel training/personnel exchange; (6) inventory maintenance; (7) procurement and sourcing services; (8) freight and delivery arrangements; (9) packaging; (10) credit; and (11) after-sales services/warranties. We note that our LOT memorandum relied incorrectly upon a function not performed by CEMEX, sales forecasting, and therefore we have excluded this function from our analysis.

Table 6 of our LOT memorandum regarding advertising for CEMEX's CEP sales is in error because the record reflects that CEMEX does not perform advertising functions for its sales to Sunbelt Cement. However, the record demonstrates that CEMEX performs strategic planning, market research, advertising, procurement and sourcing services, personnel training/personnel exchange, packaging, credit and after sales service/warranty service for its sales in the home market but not for its CEP sales to the U.S. affiliate after deducting the expenses pursuant to section 772(d) of the Act. Thus, contrary to the petitioner's assertions, we find adequate basis on the record to conclude that CEMEX performs eight of its eleven selling functions with respect to only its HM sales and not with respect to its CEP sales.

In addition, CEMEX performs a higher degree of inventory maintenance for its HM sales than for its CEP sales. Contrary to the petitioner's assertion, differences in the level of intensity with which a respondent performs a selling function is relevant to our analysis. *See Professional Electric Cutting Tools From Japan; Preliminary Results of Antidumping Duty Review,* 63 FR 30706, 30708 (1998).

Thus, as the record demonstrates, CEMEX performs the majority of its selling functions with respect to its HM sales and not with respect to its CEP sales. In addition, CEMEX performs no services for its CEP sales that it does not perform for its HM sales. Accordingly, we determine that CEMEX's HM sales occur at a different and more advanced stage of distribution than its CEP sales. We also determine that the data provided do not permit us to calculate a LOT adjustment; thus in accordance with section 773(a)(7)(B) of the Act, a CEP offset is appropriate for these final results.

Moreover, we disagree with the petitioner's remaining arguments. The petitioner challenges the Department's decision to grant a CEP offset to CEMEX by asserting that CEMEX's itemized list of indirect selling expenses and its selling functions do not correspond. However, the list to which the petitioner refers (Exhibit B–14 of CEMEX's December 8, 1997, Section B response) itemizes the names of CEMEX's accounts for its indirect selling expenses in the home market and does not provide the services performed as a result of those expenditures. Because the list of accounts upon which the petitioner relies is not an itemization of CEMEX's selling functions but rather lists the accounts to which CEMEX's selling functions are recorded, we would, therefore, not expect CEMEX's indirect selling expenses list and selling-functions chart to correspond. The petitioner also argues that ''strategic and economic planning'' and ''market research'' should be merged for LOT-analysis purposes. We disagree with the petitioner. The record characterizes strategic planning as relating to long-range production activity while market research relates to locating markets and gauging their activity, and these distinctions are commonly recognized and understood. Regardless, assuming *arguendo* that we should merge the two functions, our conclusion that CEMEX's HM sales were at a different and more advanced LOT would remain unchanged since the record demonstrates that CEMEX performed both selling functions for the home market but neither for its U.S. sales

Comment 2: The petitioner argues that the Department found erroneously that CDC's U.S. and HM sales were at different levels of distribution. Furthermore, according to the petitioner, the Department erred in finding that CDC's HM sales were at a more advanced stage of distribution because CDC performed fewer and different selling functions for CEP sales than for its HM sales. The petitioner argues that CDC did not describe in sufficient detail its selling functions, including ''market research,'' ''technical advice,'' ''customer approval,'' ''solicitation of orders/customer visits,'' ''sales promotion discount programs,'' and ''computer/legal/accounting/business system development,'' so that the Department could determine whether they involved distinct selling functions. Moreover, the petitioner contends, CDC's reported selling functions were not provided to at least a vast majority of customers and sales in the home market. Therefore, the petitioner concludes, CDC's claimed selling functions do not provide the basis for a determination that CDC's HM and U.S. sales were at different levels of trade. The petitioner also notes that the Department reported erroneously in its LOT memorandum that it confirmed CDC's selling functions performed in the home market during verification when, in fact, the Department did not verify CDC's response in this review.

CDC argues that the Department granted CDC a CEP offset properly. CDC argues that the record demonstrates that its HM sales were made at a more advanced LOT than its U.S. sales, thus satisfying the Department's standard for a CEP offset.

Department's Position: We disagree with the petitioner that CDC's U.S. and HM sales were at the same levels of distribution. Based upon our analysis of the record, we determine that CDC's HM sales occur at a different and more advanced stage of distribution than CDC's sales to its U.S. affiliate. The record reflects, and our LOT memorandum shows, that CDC performs ten selling functions in the home market: (1) Inventory maintenance; (2) market research; (3) technical advice; (4) advertising; (5) freight and delivery arrangement; (6) customer approval; (7) solicitation of orders/customer visits; (8) sales promotion/discount programs; (9) packing; and (10) computer/legal/accounting/business system

development. The record demonstrates that, with the exception of inventory maintenance and freight and delivery arrangements, CDC performs its selling functions for its sales in the home market but not for its CEP sales to the U.S. affiliate after deducting the expenses pursuant to section 772(d) of the Act. The record also demonstrates in sufficient detail for the Department to determine that the selling functions that CDC provides for its HM sales are greater in number and intensity than those selling functions that it provides for its CEP sales. Accordingly, we determine that CDC's HM sales occur at a different and more advanced stage of distribution than its CEP sales and that a CEP offset is appropriate for these final results. We also determine that the data does not provide an appropriate basis for a LOT adjustment; thus in accordance with section 773(a)(7)(B) of the Act, a CEP offset is appropriate for the final results. We note that although our LOT memorandum refers erroneously to a verification at CDC this error does not alter our conclusion for these final results.

9. CEP Calculation

Comment 1: The petitioner disagrees with the Department's decision not to deduct indirect selling expenses incurred in the home market on sales to its affiliate in the United States in calculating CEP. The petitioner believes that this decision, although consistent with the Department's current practice and regulations as well as the final results of the fifth and sixth reviews, is contrary to the Act, the URAA, the SAA and judicial precedent. The petitioner argues that the indirect selling expenses, inventory carrying costs and general advertising expenses CEMEX and CDC incurred in the home market with respect to U.S. sales to its affiliate all constitute selling expenses deductible under section 772(d)(1)(D) of the Act.

The petitioner challenges the Department's limitation of deductible indirect selling expenses incurred in the home market for its CEP calculation as artificial and unsupported by the statute and by legislative history. First, the petitioner argues that the Department has discretion over which expenses can be deducted from CEP and should deduct all indirect expenses associated with U.S. sales from CEP. Second, the petitioner argues that the Department's use of the term ''U.S. expenses'' is limited incorrectly to expenses incurred in connection with a sale in the United States and that it should be expanded to include expenses incurred in relation to sales by the affiliated importer to U.S. customers. Third, the petitioner disagrees with the Department's narrow interpretation of the language in section 772(d) referring to expenses ''associated with economic activities occurring in the United States'' to be defined as only those expenses related to sales by the affiliated importer to unaffiliated purchasers. The petitioner contends that the language is interpreted more properly to include all expenses related to U.S. sales. Fourth, the petitioner cites the final results of the fifth review to demonstrate that the Department acted inconsistently with section 772(d) by limiting the deduction of ''any'' expenses incurred in selling subject merchandise in the United States. Fifth, because the Department granted a CEP offset, the petitioner maintains that CEP and NV do not represent an ''apples-to-apples'' comparison. Sixth, the petitioner claims that the Department misinterprets Article 2.4 of the Antidumping Agreement to require only the deduction of costs incurred between importation and resale from CEP when the Agreement ''states that those expenses should be deducted in addition to any other expenses that affect price comparability.'' Finally, the petitioner contends that to allow a deduction from CEP of only those indirect selling expenses incurred in the United States permits respondents to avoid deduction of any selling expenses by shifting U.S.-related selling activities offshore. The petitioner also maintains that the Department must interpret section 772(d) according to its plain meaning, *citing Mitsubishi Heavy Industries, Ltd.* v. *United States,* 15 F.Supp.2d 807 (CIT 1998) (*Mitsubishi*). The CIT in *Mitsubishi,* the petitioner asserts, held that the plain language of section 772(d) of the Act requires the deduction, without limitation, of all expenses generally incurred in selling the subject merchandise in the United States, regardless of where or when paid.

CEMEX and CDC respond that the Department is correct in not deducting indirect selling expenses incurred in the home market from CEP calculations. CEMEX and CDC state that the petitioner raised the same argument unsuccessfully in the fifth and sixth administrative reviews. CEMEX argues further that the petitioner attempts to rewrite the legislative history of the URAA and that the Department rejected arguments similar to those advanced by the petitioner in the preamble to the Department's regulations. CDC refutes the petitioner's claim that *Mitsubishi* compels the Department to deduct from CEP expenses incurred in the home market by a foreign producer and distinguishes the facts in *Mitsubishi* from those in this case. Moreover, CDC believes that *Mitsubishi* reinforces the Department's position to limit acceptable deductions from CEP.

Department's Position: We agree with respondents that we calculated CEP correctly. Upon analysis, the Department determined that the indirect selling expenses at issue relate solely to respondents' sales to their affiliated importers and are not associated with economic activities in the United States. The Department does not deduct indirect expenses incurred in selling to the affiliated U.S. importer under section 772(d) of the Act. *See Certain Pasta From Italy,* 61 FR at 30352. Thus, we have used the same methodology for calculating CEP in the final results, as was done for the preliminary results.

Comment 2: The petitioner maintains that the Department neglected to include indirect selling expenses in the home market on sales to the United States in ''total U.S. expenses'' for purposes of calculating CEP profit under section 772(f) of the Act.

The petitioner argues that by including indirect selling expenses in total U.S. expenses in calculating total actual profit but excluding them from total U.S. expenses in determining the expense ratio renders the calculation of CEP profit inconsistent. The petitioner argues that this contradictory treatment of the same expenses cannot be reconciled with the statute. The petitioner also cites *U.S. Steel Group* v. *United States,* No. 97–05–00866, Slip Op. 98–96 (CIT 1998) (*U.S. Steel*), whereby the CIT rejected the Department's inconsistent treatment of movement expenses in the calculation of CEP. The petitioner concludes that if indirect selling expenses incurred in Mexico are properly attributable to U.S. sales for the purpose of calculating U.S. selling expenses in the computation of ''total actual profit'' they must be similarly attributable to U.S. sales for purposes of calculating ''total U.S. expenses'' for the purpose of applying the ''actual percentage.''

CEMEX and CDC argue that the Department calculated ''total U.S. expenses'' correctly in its ''total expenses'' calculations for CEP profit. CEMEX contends that the petitioner has not cited a determination supporting its argument that the Department excluded foreign indirect selling in ''total U.S. expenses'' incorrectly. CEMEX argues that the petitioner's citation to *U.S. Steel Group* is misplaced because the decision is not final and it does not give deference to the Department's statutory interpretation of the law that it is charged to administer.

CDC asserts that it was appropriate for the Department to include in total U.S. expenses for CEP profit only expenses related to U.S. operations. CDC cites section 772(f) of the Act, stating that it directs the Department to exclude HM indirect selling expenses associated with U.S. sales and corresponding inventory carrying costs from its definition of total U.S. expenses.

Department's Position: Pursuant to section 772(f) of the Act, CEP profit includes the total revenue and total actual expenses incurred in making the sale to the unaffiliated purchaser in the U.S. market. However, since the statute directs that profit be allocated only to expenses deducted under sections 772(d) (1) and (2) of the Act, we must exclude indirect selling expenses incurred in Mexico for U.S. sales from ''total U.S. expenses,'' the numerator of the expense ratio. Thus, we did not include indirect selling expenses incurred in Mexico for U.S. sales in ''total U.S. expenses'' in calculating CEP profit. This interpretation is consistent with the intent of the statute. With respect to the petitioner's reference to *U.S. Steel,* see our response to Comment 3, below. In preparing for these final results, however, we discovered a clerical error in the CEP calculation in our preliminary results. We inadvertently did not include indirect expenses for advertising in the calculation of profit to be allocated to expenses deducted pursuant to section 772(d) of the Act. We have corrected this clerical error for the final results.

Comment 3: The petitioner argues that the CIT's recent decision in *U.S. Steel* directs the Department to calculate CEP profit by excluding movement expenses from the denominator of the profit-allocation ratio. The petitioner notes that, in that case, the CIT rejected the Department's argument that the statute required the inclusion of ''all expenses,'' including movement expenses, in the ratio.

CEMEX and CDC respond that the Department's inclusion of movement expenses in its calculation of total expenses used to calculate CEP profit is a reasonable interpretation of section 772(f) of the Act and is consistent with the Department's past practice. CEMEX and CDC argue that the CIT's decision in *U.S. Steel* is not final and that the Department has not indicated its intention to abandon its prior policy and adopt the decision.

Department's Position: We agree with the respondents that our inclusion of movement expenses in the calculation of total expenses used to calculate CEP profit is proper. The CIT's decision in *U.S. Steel* is neither final nor binding. Accordingly, we have continued to include movement expenses in ''total expenses'' for calculating CEP profit for these final results. This is consistent with the Department's practice in accordance with section 772(d)(3) of the Act.

Comment 4: The petitioner argues that the Department should revise its calculation of CDC's U.S. indirect expenses because the Department inadvertently allowed a deduction from U.S. indirect selling expenses for the imputed costs of financing antidumping cash deposits. The petitioner notes that the Department denied such an adjustment in the sixth review and that this decision was consistent with past practice.

CDC responds that the Department's allowance of an offset for the cost of financing cash deposits is in accordance with past practice and CIT precedent. CDC argues that in the past the Department has not been consistent in its treatment of imputed interest payments on cash deposits. CDC contends that the Department has recognized that a company incurs a real expense whether it actually obtained loans or diverted funds from another investment activity to finance the antidumping cash deposits, citing *Tapered Roller Bearings, Four Inches or Less in Outside Diameter, and Components Thereof, From Japan,* 62 FR 11825, 11831 (March 13, 1997).

Department's Position: We agree that we have allowed CDC a deduction for the imputed costs of financing cash deposits inadvertently. For the final results, we have denied an adjustment to CDC for imputed expenses which CDC claims are related to financing cash deposits. This is consistent with the Department's treatment of such expenses in the sixth review and its practice as described in *Antifriction Bearings (Other Than Tapered Roller Bearings) and Parts Thereof from France, et al.,* 62 FR 54043, 54079 (October 17, 1997). As our position is unchanged from the prior review, we adopt the discussion with respect to this issue in our *Sixth Review Final Results* (63 FR at 1278).

10. Regional Assessment

CEMEX and CDC argue that the United States has not honored its obligations under Article 4.2 of the WTO Antidumping Agreement and its predecessor, Article 4.2 of the 1979 Tokyo Round Antidumping Code. CEMEX and CDC claim that the Department has not implemented the special antidumping duty assessment requirements for regional-industry cases set forth in Article 4.2 because it has imposed antidumping duties on all imports of subject merchandise, including those consigned for consumption outside the Southern Tier region as defined by the ITC in the original investigation. CDC argues that the Department did not give exporters an opportunity to cease exporting at dumped prices into the region prior to the assessment of duties and requests that the Department terminate this review and revoke the antidumping order or, alternatively, assess antidumping duties only on CDC's entries of merchandise consumed within the Southern Tier region. CEMEX requests only that the Department assess duties on its future entries consumed within the Southern Tier region.

CDC contends that, because the United States did not implement Article 4.2 until it adopted the Uruguay Round Agreement Act (URAA) in 1995, implementation was untimely because the regional assessment rules were absent from U.S. law during the original investigation and during the first several reviews of the antidumping order. CDC also asserts that, in adopting section 218 of the URAA, the United States implemented Article 4.2 inadequately. For instance, CDC asserts, Section 218 does not address producers/exporters who, like CDC, export merchandise both into and outside of the region. CDC proffers other examples of the inadequate U.S. implementation of Article 4.2, which are discussed below. If the Department does not terminate this review and revoke the order, CDC asserts, the Department should levy antidumping duties on a regional basis under Article 4.2.

CEMEX and CDC argue that the United States is obliged to comply with Article 4.2 of the Antidumping Agreement, which states:

> When the industry has been interpreted as referring to the producers in a certain area, *i.e.,* a market as defined in paragraph 1(ii), anti-dumping duties shall be levied only on the product in question consigned for final consumption to that area. When the constitutional law of the importing country does not permit the levying of anti-dumping duties on such a basis, the importing Member may levy the anti-dumping duties without limitation only if (a) the exporters shall have been given an opportunity to cease exporting at dumped prices to the area concerned or otherwise give assurances pursuant to Article 8 of this Agreement, and adequate assurances in this regard have not been promptly given, and (b) such duties cannot be levied only on products of specific producers which supply the area in question.

According to CEMEX and CDC, Article 4.2 compels the Department to refrain from assessing duties on its subject

merchandise destined for consumption outside the Southern Tier. CDC contends that the exception to Article 4.2 does not apply because none of the conditions necessary to justify an exception to Article 4.2 are satisfied in this case. First, both CEMEX and CDC assert that there is no U.S. Constitutional prohibition against levying antidumping duties on a regional basis. CEMEX and CDC contend that neither the port-preference clause of the Constitution, which prohibits Congress from regulating commerce or revenue of ports in a discriminatory manner that would confer preferential treatment for the ports of one state over the ports of another state, nor the uniformity clause, which requires the uniform imposition of taxes throughout the United States, render the regional assessment of antidumping duties unconstitutional, citing U.S. Const. Art. I, Sec. 9, cl. 6, and Art. I, Sec. 8, cl. 1. CDC argues further that the United States has never explained its theory that implementing the general assessment rule would result in a constitutional violation.

Next, CDC contends that the condition by which the Department would be exempted from assessing antidumping duties regionally has not been satisfied. CDC argues that the Department did not permit CDC to enter into a suspension agreement at the time of the original investigation because, at the time of the investigation, the Department's policy was one of refusal to enter into suspension agreements. Moreover, CDC maintains, the Department's decision to collapse CEMEX and CDC in the original investigation diminished CDC's opportunity further to enter into a suspension agreement. CDC also argues that the U.S. implementation included no provisions by which the regional-assessment rules could apply to cases predating the URAA. CDC argues the condition that duties cannot be levied only on products of specific producers which supply the area in question has not been met because the language of Section 218 of the URAA and the Department's regulations demonstrate that assessment on less than a national basis is possible. CDC contends that the fact that Congress enacted Section 218 with language calling for the regional assessment of duties attests to the absence of a U.S. constitutional prohibition against regional assessment.

The petitioner responds that the Department has assessed antidumping duties properly on all nationwide entries of the subject merchandise. First, the petitioner suggests that, since the Department has not yet assessed duties for the seventh review period, this issue is not ripe for the Department's consideration. However, assuming it is ripe for decision, the petitioner argues that the Department need only consider whether its assessment of antidumping duties under the order is consistent with the U.S. statute. The petitioner asserts that, because the Department's actions are consistent with the law, the Department need not consider respondents' remaining arguments. The petitioner contends that CEMEX, in referring only to Article 4.2, ignores the U.S. law on this issue.

The petitioner asserts that the Department must act within its authority under sections 736(d)(1)–(2) and 734(m)(1)–(2) of the Act, which were amended by the URAA to conform to the regional-industry provisions of the Antidumping Agreement. The petitioner contends that these provisions are inapplicable to respondents and thus confer no authority upon the Department to refrain from assessing antidumping duties outside the Southern Tier. The petitioner asserts that sections 736(d)(1) and 734(m)(1)–(2) of the Act only apply in investigations and not reviews. Second, the petitioner asserts that both CEMEX and CDC do not qualify for the regional assessment of duties under section 736(d)(2) of the Act because both respondents exported subject merchandise into the Southern Tier during the period of investigation (POI). Third, the petitioners contend, the Department has no obligation under sections 734(m)(1)–(2) of the Act to offer respondents a suspension agreement because the Department may only accept a suspension agreement during the pendency of an investigation or within 60 days after the publication of the antidumping order. For these reasons, the petitioner concludes, the Department complied fully with U.S. law.

In addition, the petitioner argues that the Department cannot ''implement'' its U.S. obligations under Article 4.2 because the Tokyo Round Antidumping Code is without legal force and only assumes binding character through implementing legislation enacted by Congress. Citing the legislative history of the Trade Agreements Act of 1979 and the URAA, the petitioner asserts that Congress intended U.S. law to prevail in the event of a conflict between U.S. law and these Agreements. Citing *inter alia, Suramerica* and *Footwear Distrib. And Retailers of Am.* v. *United States,* 852 F.Supp. 1078 (CIT 1994), *appeal dismissed,* 43 F.3d 1486 (Fed. Cir. 1994), the petitioner notes that courts have rejected the argument that U.S. law must be administered in conformity with the GATT.

The petitioner also argues that the Department lacks the statutory authority to terminate the antidumping order or assess duties regionally based on a claim that the Department did not offer respondents an opportunity to enter into a suspension agreement. Citing the *Sixth Review Final Results,* 63 FR at 12766, the petitioner notes that no respondent appealed the Department's final determination in 1990 based on an alleged lack of an opportunity for a suspension agreement and the Department's determination in the original investigation ''is final and binding on all persons, including the Department.'' The petitioner also asserts that neither the statute nor the Department's regulations authorize the Department to rescind a determination made in the original investigation and revoke the order in the context of an administrative review. The Department's authority in an administrative review is limited to calculating a margin and setting new cash deposit rates, the petitioner asserts, citing the NAFTA binational panel decision for the *Third Review Final Results.*

The petitioner also notes that CDC's claim that the Department neglected to offer an opportunity for a suspension agreement is barred by the statute of limitations, by *res judicata,* and because CDC failed to exhaust administrative remedies in the original investigation. Finally, the petitioner notes that, even if it were necessary to discuss the issue, Article 4.2 of the Antidumping Agreement does not require assessment of duties only on imports of subject merchandise consigned for consumption in the Southern Tier. The petitioner argues that the Constitution bars regional assessment of duties, the respondents had the opportunity to enter into a suspension agreement during the original investigation, and the Act complies with the requirement that antidumping duties be applied nationwide if they cannot be assessed only on the products of exporters in the region.

Department's Position: Before considering respondents' substantive arguments on this issue, we disagree with the petitioner's contention that this issue is not ripe for consideration since we have not yet assessed duties pursuant to the results of this administrative review. The purpose of an administrative review is to ''review and determine * * * the amount of any antidumping duty'' (section 751(a)(1)(B) of the Act) and the results of an administrative review ''shall be the

basis for the assessment of * * * antidumping duties on entries of merchandise covered by the determination and for deposits of estimated duties.'' Section 751(a)(2)(C) of the Act. Therefore, the Department's assessment procedures as they pertain to the antidumping duties determined in this review are an appropriate issue for the Department to consider for these final results.

Turning to arguments by CEMEX and CDC, we disagree that we should exempt entries of subject merchandise exported into regions other than the ''Southern Tier'' from antidumping duties and cash deposits. Respondents' argument focuses on the compatibility of the U.S. antidumping law with the United States' obligations under the URAA. Specifically, respondents suggest that the U.S. antidumping law, as amended by the URAA, does not implement the obligations contained in Article 4.2 of the Antidumping Agreement, which governs the assessment of antidumping duties in regional industry cases, properly.

The Department's determinations in an antidumping proceeding are governed by the U.S. antidumping statute—specifically, Title VII of the Tariff Act of 1930, as amended by the URAA in 1995. As numerous courts have recognized, in the event of a conflict between a GATT obligation and a statute, the statute must prevail. *See Federal Mogul Corp.* v. *United States*, 63 F.3d 1572, 1581 (Fed. Cir. 1995), *citing Suramerica DeAleaciones Laminadas* v. *United States*, 966 F.2d 660, 668 (Fed. Cir. 1992). Congress codified this principle in the URAA. Section 102 of the URAA states that ''[n]o provision of any of the Uruguay Round Agreements, nor the application of any such provision to any person or circumstance, that is inconsistent with any law of the United States shall have effect.'' *See also* SAA at 659 (''The WTO will have no power to change U.S. law. If there is a conflict between U.S. law and any of the Uruguay Round agreements * * * U.S. law will take precedence.''). Thus, even if respondents were correct in asserting that the statutory provisions relating to regional assessment of duties conflicted with the obligations contained in Article 4.2 of the Antidumping Agreement, the Department must act in conformity with the antidumping statute.

Sections 736(d)(1)–(2) and 734(m) of the Act govern the assessment of antidumping duties in regional-industry cases. To this extent, section 736(d)(1) of the Act provides that, in an investigation in which the ITC makes a regional-industry determination, the Department ''shall, to the maximum extent possible, direct that duties be assessed only on the subject merchandise of the specific exporters or producers that exported the subject merchandise for sale in the region during the period of investigation.'' Because the original Mexican cement antidumping investigation occurred in 1989–90 and the URAA applies only to investigations initiated on the basis of petitions filed after January 1, 1995, this provision does not apply to CEMEX's and CDC's exports. However, even if section 736(d)(1) of the Act did apply to this review, since CEMEX and CDC exported subject merchandise into the region during the POI, the Department directed properly that antidumping duties be assessed on all entries of merchandise produced by CEMEX and CDC. For the same reasons, contrary to CDC's argument, section 351.212(f) of the Department's regulations does not apply to CEMEX's and CDC's entries.

Moreover, section 736(d)(2) of the Act provides that, ''after publication of the antidumping order, if the administering authority finds that a new exporter or producer is exporting the subject merchandise for sale in the region concerned, the administering authority shall direct that duties be assessed on the subject merchandise of the new exporter or producer consistent with the provisions of section 751(a)(2)(B).'' Because neither CEMEX nor CDC is a new exporter or producer as described in this provision, section 751(a)(2)(B) of the Act is inapplicable to the assessment of antidumping duties on subject merchandise exported to the United States by CEMEX or CDC.

Finally, pursuant to section 734(m) of the Act, in an investigation in which the ITC makes a regional-industry determination, the Department ''shall offer exporters of the subject merchandise who account for substantially all exports of that merchandise for sale in the region concerned the opportunity to enter into (a suspension) agreement.'' Any such agreement is ''subject to all the requirements imposed under this section for other (suspension) agreements, except that if the Commission makes a regional industry determination * * * in its final determination * * * but not in the preliminary affirmative determination * * * any agreement * * * may be accepted within 60 days after the antidumping order is published under section 736.''

Under section 734(b) of the Act, we may only accept a suspension agreement during the pendency of an investigation. Because the Department cannot enter into a suspension agreement once the 60-day post-order period has passed (and, indeed, seven administrative reviews have passed), the Department's decision not to offer respondents an opportunity to enter into a suspension agreement in this review does not violate section 734(m) of the Act.

Moreover, although CEMEX argues that the posting of cash deposits should not be required of CEMEX's entries outside the Southern Tier, the Act contains no provision and describes no circumstances under which we may waive an importer's requirement to post cash deposits except when conducting new-shipper reviews under section 751(b) of the Act. Accordingly, for these final results, we will require the posting of cash deposits and assess antidumping duties on entries of CEMEX's and CDC's subject merchandise that have entered or will enter for consumption both inside and outside the Southern Tier.

As demonstrated above, the Department's decision to assess duties on all subject merchandise exported into the United States by CEMEX and CDC is consistent with the antidumping statute. Indeed, neither CEMEX nor CDC argue that the Department's actions fail to conform to these statutory provisions. For purposes of this administrative review, therefore, the Department need not consider respondents' arguments further concerning the United States' implementation of its obligations under the Antidumping Agreement.

Nonetheless, we disagree with respondents' contention that the antidumping statute does not fully implement the United States' obligations under the Antidumping Agreement. As the Federal Circuit in *Federal Mogul* explained: ''GATT agreements are international obligations, and absent express Congressional language to the contrary, statutes should not be interpreted to conflict with international obligations.'' *Federal Mogul*, 63 F.3d at 1581. Indeed, the U.S. Supreme Court elaborated on this canon of construction. ''It has also been observed that an act of Congress ought never to be construed to violate the law of nations, if any other possible construction remains * * *.'' *Murray* v. *Schooner Charming Betsy*, 6 U.S. (2 Cranch.) 64, 118 (1804). *See also Fundicao Tupy S.A.* v. *United States*, 652 F. Supp. 1538, 1543 (CIT 1987)(''An interpretation and application of the statute which would conflict with the GATT Codes would clearly violate the intent of Congress.''); *Footwear Dist. and Retailers of America* v. *United States*, 852 F. Supp. 1078, 1092–93 (CIT 1994), *quoting* Restatement (Third) of the

Foreign Relations Law of the United States, at 115, comment a, p. 64 (1987) (''Congress does not intend to repudiate an international obligation of the United States * * * Therefore, when an act of Congress and an international agreement * * * relate to the same subject, the courts, regulatory agencies, and the Executive Branch will endeavor to construe them so as to give effect to both.''). Because qualifying exporters are given an opportunity for exemption from the assessment of antidumping duties, the statutory scheme described above is consistent with Article 4.2 of the Antidumping Agreement. Thus, the United States has fully implemented its obligations with respect to the assessment of antidumping duties in regional industry cases.

We also disagree with CDC's contention that we must terminate the review and revoke the underlying antidumping duty order because U.S. implementation of its international obligations is allegedly untimely and inadequate. First, as we stated in the third, fourth, fifth and sixth administrative reviews and have reaffirmed in the ''Revocation of Underlying Order'' section, above, we have no authority to revoke the order. *Third Review Final Results. See also Fourth Review Final Results; Fifth Review Final Results*; and *Sixth Review Final Results.* Specifically, neither CEMEX nor CDC appealed the Department's final determination based upon the Department's alleged refusal to offer a suspension agreement. Thus, the antidumping duty order, based upon the Department's LTFV determination, is final and binding.

11. Bulk vs. Bag Sales

CEMEX argues that the Department should calculate NV based only on bulk sales rather than combining both bulk and bagged sales. CEMEX argues that the Department justified its use of bagged cement sales in its calculation incorrectly on the premise that, by excluding the cost of packing from NV, it made the price of cement in bags equal to the price of bulk cement. CEMEX argues that consumers are willing to pay a premium for the convenience of buying a bag of cement and that this fact is supported by record evidence. Additionally, CEMEX argues that, based on commercial realty, sales of cement in bags are at a different LOT than sales in bulk. CEMEX maintains that section 773(a)(7)(A) of the Act requires the Department to adjust the sale price in the comparison market to ''make due allowances'' for any difference in the comparison market shown to be ''wholly or partly'' due to differences in the LOT and that ''the amount of the adjustment shall be based on the price differences between the two levels of trade in the country in which NV is determined.'' Therefore, CEMEX argues, if the Department uses bagged cement sales in its calculation of NV for the final results, it must deduct the difference in average prices for bag and bulk cement from the net price of bagged cement.

CDC argues that the Department should compare bag sales in the United States to bag sales in the home market and bulk sales in the United States to bulk sales in the home market in order to make a fair comparison without distortions. CDC states that, in past segments of this and other cement proceedings, the Department made comparisons on a bag-to-bag and bulk-to-bulk basis, citing Original LTFV Investigation, 55 FR at 29245, and Concurrence Memorandum, *Preliminary Determination: Gray Portland Cement and Clinker from Venezuela* (October 28, 1991). CDC acknowledges that, in the fifth and sixth reviews of this order, when CDC made sales of bag and bulk cement in the home market and only bulk cement in the United States, the Department compared both bag and bulk sales made in the home market to bulk sales made in the United States. However, in this review, CDC argues, the Department should make comparisons on a bag-to-bag and bulk-to-bulk basis as it did in the original investigation under similar circumstances. CDC asserts that comparing bulk and bag separately in both markets ensures that no addition to HM price is necessary for the bulk HM sales and the Department need only subtract the HM packing from and add U.S. packing to NV for the HM bagged sale.

The petitioner responds that the Department compared both bulk and bagged sales to the United States with bulk and bagged sales in the home market in the preliminary results correctly. The petitioner maintains that, except for packaging, the cement sold in both bulk and bagged form is identical. The petitioner also argues that CDC has not established that the Department has a rule of comparing bulk sales only to bulk sales and bagged sales only to bagged sales which, the petitioner asserts, would be contrary to the statute. The petitioner states that sections 773(a)(1)(A)–(B) and section 771(16) of the Act require the Department to compare U.S. sales with sales of the ''foreign like product,'' which is defined as the identical merchandise sold in the home market or, if there is no identical HM merchandise, the most similar merchandise. The petitioner maintains that, in the fifth and sixth reviews, the Department found that bulk and bagged sales ''constitute identical merchandise,'' citing *Fifth Review Final Results* at 17165, and *Sixth Review Final Results* at 12777. The petitioner argues that CEMEX misinterpreted the Department's findings by stating that the Department was attempting to ''equalize'' the net prices of bagged and bulk cement by excluding the cost of packing from NV. In fact, the Department was making adjustments for packaging differences which, the petitioner asserts, accounted for the ''only difference between these products.''

The petitioner contends that the Department rejected CEMEX's argument that sales of bagged cement were at a different LOT than the HM sales of bulk cement in the fifth and sixth reviews and that CEMEX has not demonstrated that the facts in this review warrant a different result.

Finally, the petitioner claims that CEMEX has not satisfied the Department's two-step LOT analysis. First, the petitioner argues that CEMEX has not demonstrated that bagged and bulk cement are sold at different points in the chain of distribution. Second, the petitioner argues, CEMEX has not established differences in selling functions with respect to different customer classifications. In conclusion, the petitioner urges the Department to use bagged and bulk in its calculation of NV.

Department's Position: We agree with the petitioner and have included all Type I sales, bulk and bagged, in the calculation of NV. The only difference between these products is the packaging; therefore, we have made an adjustment downward to NV to account for packaging differences. In addition, as stated in the LOT section of this notice, we have determined that CEMEX sold at one LOT in the home market; therefore, distinguishing discrete channels of distribution is not warranted as there is only one LOT. Therefore, we have not calculated NV for each channel of distribution as CEMEX requested and have used our standard methodology for comparing NV to U.S. sales for purposes of the final results.

12. Rebates

The petitioner argues that the Department should deny CEMEX's claimed adjustment to NV for rebates. First, it claims that, prior to sale, CEMEX did not communicate the conditions to be fulfilled to qualify for the rebate and the amount of the rebate, which are requirements the Department

has established for granting rebate claims (citing *Certain Corrosion-Resistant Carbon Steel Flat Products And Certain Cut-To-Length Carbon Steel Plate From Canada*, 61 FR 13815, 13822–23 (1996), and *Certain Corrosion-Resistant Carbon Steel Flat Products And Certain Cut-To-Length Carbon Steel Plate From Canada*, 63 FR 12725, 12741 (1998)). The petitioner also asserts that CEMEX must establish that it granted the rebate pursuant to its standard business practice or under a pre-established program and cites *Antifriction Bearings (Other Than Tapered Roller Bearings) and Parts Thereof From The Federal Republic Of Germany*, 54 FR 18992, 19056 (1989), and *Portable Electric Typewriters From Japan*, 56 FR 14072, 14078 (1991).

Second, the petitioner argues that the allocation methodology CEMEX used for reporting certain rebates is distortive because the allocated rebates may include rebates on sales of non-subject merchandise. In this review, the petitioner contends, CEMEX used two different methods for reporting rebates on HM sales. The petitioner acknowledges that, in most instances, CEMEX reported rebates on a transaction-specific basis. However, the petitioner argues that CEMEX reported rebates in the REBALH field that it based on an allocation methodology, but it has not provided any information to demonstrate that this allocation is the most specific calculation feasible. Additionally, the petitioner claims that CEMEX has provided no information confirming that it paid allocated rebates on sales of subject merchandise.

CEMEX argues that the Department's preliminary results adjusted NV correctly for CEMEX's verified rebates. CEMEX argues that the Department has a long-standing practice of allowing a claimed rebate without documentary evidence if the rebates are consistent with a respondent's normal business practices and its past dealings with its customers. CEMEX notes that it provided detailed descriptive data of its rebate program in its response and adequate sample documentation. CEMEX rejects the petitioner's claim that CEMEX's customers were not aware of its rebate policies at the time they were purchasing cement from CEMEX. According to CEMEX, as all rebates were negotiated on a customer-specific basis, customers were aware of the discounts for which they were eligible.

Next, CEMEX rebuts the petitioner's claim that the Department has a long-standing policy to reject claims for a rebate adjustment unless they are reported on a transaction-specific basis. CEMEX argues that the Department recognizes that it is not unusual for price adjustments to be granted to customers on a specific basis.

Additionally, CEMEX claims that the petitioner mischaracterizes the record evidence by stating that CEMEX did not provide additional information regarding the rebates reported in the REBALH field. Contrary to the petitioner's argument, CEMEX asserts that, for the non-transaction-specific rebates, CEMEX identified where the allocated rebates were reported, the reasons why it allocated them, how it allocated them, and why the allocation methodology it used was not distortive. Therefore, CEMEX concludes, the Department's acceptance of the rebate claims was appropriate.

Department's Position: We allow adjustments to NV for rebates if we are satisfied that such rebates reflect the respondent's normal business practice and not an attempt by the respondent to eliminate dumping margins once we initiate an antidumping investigation or review. *See Certain Corrosion-Resistant Carbon Steel Flat Products From Japan*, 63 FR 47465, 47468 (1998). In this respect, based on CEMEX's response and our verification of the response, we are satisfied that rebates are a long-established business practice of CEMEX and that CEMEX's customers had a reasonable expectation of receiving such rebates based on their long-standing business relationships with CEMEX.

With respect to CEMEX's reporting methodology, we have allowed CEMEX's claimed rebate adjustments because the data was submitted in accordance with our methodology and was substantiated at verification. These rebates were reported in the same manner as the sixth review where we granted the adjustment. While the Department prefers that discounts, rebates, and other price adjustments be reported on a transaction-specific basis, the Department has long recognized that some price adjustments are not granted to customers on that basis and thus cannot be reported on that basis. Generally, ''we have accepted claims for discounts, rebates, and other billing adjustments as direct adjustments to price if we determined that the respondent, in reporting these adjustments, acted to the best of its ability and that its reporting methodology was not unreasonably distortive.'' *See Antifriction Bearings (Other than Tapered Roller Bearings) and Parts Thereof from France, et al., Final Results of Antidumping Duty Administrative Reviews*, 62 FR 2081 (1997). Based on CEMEX's responses to our questionnaire and our verification of those responses, and consistent with our *Sixth Review Final Results*, we have allowed adjustments for rebates.

13. Freight

Comment 1: The petitioner argues that the Department should deny CEMEX's reported HM freight adjustment. The petitioner argues that CEMEX did not demonstrate adequately that it is entitled to the adjustment on HM sales. The petitioner contends that movement expenses are allowable under the statute and under the Department's practice only if they are reported based on the actual, transaction-specific expense or on an allocation methodology that is not distortive. The petitioner argues that CEMEX did not report its HM freight expenses on a transaction-, customer-, point-of-sale- or even a plant-specific basis and has not demonstrated that it was not feasible to report these expenses on a such a basis. The petitioner notes specifically that CEMEX's record-keeping system compiles freight-cost data on a transaction-specific basis and thus CEMEX has failed to demonstrate why it cannot provide the Department with freight expense information on the same basis. The petitioner argues further that CEMEX's response demonstrates CEMEX either did not report freight on a type- and presentation (bulk vs. bag)-specific basis or failed to report a significant volume of Type II cement sold in the home market. The petitioner maintains that CEMEX provided an insufficient explanation for this discrepancy. The petitioner also argues that CEMEX has not demonstrated that its allocation methodology is not distortive of the actual, transaction-specific freight cost. The petitioner notes that, because cement costs vary widely depending upon transportation mode and shipment distances, CEMEX's company-average reporting methodology does not account for potentially significant variances in freight costs among sales. The petitioner also asserts that CEMEX has not demonstrated that freight provided by affiliated freight companies was at arm's length.

CEMEX argues that the Department deducted its reported HM freight expense from NV properly. CEMEX argues that it reported HM freight in the most specific manner permitted by its record-keeping system and that its methodology is not distortive. CEMEX observes that the Department rejected identical arguments made by the petitioner concerning HM freight expenses in the final results of the fifth and sixth administrative reviews. CEMEX also contends that it did present evidence that the expenses for freight

provided by affiliated parties were made at arm's length.

Department's Position: We disagree with the petitioner. Based on our findings at verification, we determine that CEMEX's reported freight costs for Type I cement are reported on as specific a basis as is feasible given CEMEX's accounting system, and that they provide a reasonable estimate of actual transaction-specific freight expenses. Thus, it would be inappropriate to apply adverse facts available to CEMEX's freight expense by rejecting the claimed adjustment. Furthermore, with regard to the petitioner's assertion that CEMEX did not demonstrate that the expense for freight provided by affiliated parties was at arm's length, we find that, based on data CEMEX submitted, the expense for freight provided by unaffiliated parties is generally higher than the expense for freight provided by affiliated parties. *See* Exhibit B–8–C of CEMEX's December 8, 1997, response. Based on this fact, we determine that the expense for freight provided by affiliated parties was at arm's length. Therefore, we have deducted CEMEX's claimed HM freight expense for Type I cement from NV for the final results.

Comment 2: The petitioner maintains that CDC has failed to demonstrate entitlement to a freight expense adjustment for sales by its affiliate Construcentro. Because CDC's responses demonstrate that CDC's freight-expense methodology for Construcentro results in commingled expenses for subject and non-subject merchandise, the petitioner argues, and because CDC has not demonstrated, in accordance with the preamble to the Department's regulations that its methodology is not distortive, the Department should deny CDC a freight-expense adjustment for sales by Construcentro.

CDC argues that the Department deducted its reported HM inland freight incurred by Construcentro from NV properly. CDC argues that its allocation is the most specific possible given its accounting system. CDC claims further that, because the majority of its total shipments were of subject cement, the freight expenses associated with its shipments is not inherently distortive. Finally, CDC observes that the Department made an adjustment for this expense in the fifth and sixth administrative reviews where CDC used the same methodology.

Department's Position: As in prior reviews, we find that CDC reported its freight expenses to the best of its ability given its accounting system. Furthermore, the record indicates that at least 70 percent of this particular affiliate's shipments are of subject merchandise and that at least another 10 percent of this affiliate's shipments are of nonsubject ''powder materials.'' *See* CDC's supplemental response dated May 8, 1998, at page B–6. Because the vast majority of the freight is for subject merchandise or for products sufficiently similar to subject merchandise, we can conclude the relative freight costs would be virtually identical so we find that CDC's methodology is not unreasonably distortive. Therefore, we have deducted the reported HM expense incurred by the affiliate from NV for the final results.

14. Other Adjustments

The petitioner argues that CDC is not entitled to a specific deduction included under certain other price adjustments in the OTHADJH field in its HM sales database. The petitioner claims that CDC did not provide documentation demonstrating a standard policy or any agreements communicated to its customers prior to sale and that the price adjustment benefits consumers of an out-of-scope product rather than subject merchandise.

CDC disagrees and asserts that the Department deducted CDC's OTHADJH from NV correctly. CDC states that in other cases the Department has allowed similar post-sale price adjustments where it was satisfied that the adjustments were not attributable to a company's attempt to lower or eliminate antidumping margins. CDC states that, in its case, there is no evidence on the record to suggest that these adjustments were an attempt to manipulate prices to lower its margin. On the contrary, it notes that the Department has accepted these types of adjustments in the fifth and sixth reviews. CDC also states that it provided sample credit memoranda to support its claim that customers were aware of the discount prior to sales. CDC also notes that the Department rejected in past administrative reviews the petitioner's argument that the discount is not awarded to cement customers.

Department's Position: Based on information CDC submitted and our verification of similar information in prior reviews, we are satisfied that the price adjustments in question are consistent with CDC's past business practices and that CDC's customers would be knowledgeable of these practices based on long-term business relationships with CDC. Also, no record evidence for this review indicates that we should not conclude, as we have in prior reivews, that the price adjustments covered by this item were paid to cement customers and not attributable to sales of non-subject merchandise. Since CDC was able to allocate the adjustment on a product-specific and customer-specific basis in the month in which the sale occurred, we conclude that such an allocation did not have a distortive effect. Thus, we have allowed CDC's claimed adjustment.

15. Pre-Sale Warehousing

CEMEX argues that the Department should have deducted pre-sale warehousing expenses in Mexico from NV. CEMEX cites section 773(a)(6)(B)(ii) of the Act which requires the Department to reduce NV if included in the price, by the amount of transportation and other expenses, including warehousing expenses, incurred in bringing the foreign like product from the original place of shipment to the place of delivery to the purchaser. As further support, CEMEX also cites the SAA at 827. CEMEX argues further that § 351.401(e)(2) of the Department's regulations provides that the warehousing expenses incurred after the subject merchandise leaves the original place of shipment are to be included in the adjustments for movement expenses. In addition, CEMEX cites section 773a(6)(B)(ii) of the Act, which recognizes that warehousing expenses incurred at facilities other than the production site are considered part of the movement expenses and should therefore be deducted from the sales price.

CEMEX disagrees with the Department's statement in its Calculation Memorandum of August 31, 1998, that it had reviewed the record of the instant review and found that there had been no change in the reporting methodology of this item from previous reviews. CEMEX claims that it provided the Department with new information such as the per-ton cost of pre-sale warehousing incurred in Mexico and that cost was calculated by company, by month, and reflects only the costs associated with the remote terminals.

The petitioner agrees with the Department's decision not to include CEMEX's HM pre-sale warehousing expenses as movement expenses. It asserts that, since the Department was not able to verify CEMEX's reported pre-sale warehousing expenses and no new information has been provided, the Department has no reason to change its treatment of these expenses. The petitioner contends that the expense figures CEMEX reported reflect warehouses at locations remote from CEMEX's production plants. In conclusion, the petitioner cites the Department's regulations, the statute, and legislative history to define

movement expenses as only those expenses incurred after the subject merchandise leaves the original place of shipment and that in CEMEX's case these expenses represent only factory warehousing.

Department's Position: We agree with the petitioner and have not deducted pre-sale warehousing expenses from NV. CEMEX did not, as in prior reviews, submit its data in accordance with the Department's instructions. Because there were no changes in CEMEX's reporting methodology from previous reviews, we again denied the adjustment (*see* Calculation Memorandum, dated August 31, 1998, located in Room B–009 of the Department's main building).

16. Advertising Expenses

CDC argues that the Department treated CDC's HM advertising expenses incorrectly as indirect rather than direct selling expenses. CDC maintains that it demonstrated, through sample documents, that it incurs these expenses directly in conjunction with sales of the product under review and the advertising is directed towards the customer's customer.

The petitioner disagrees and asserts that the Department treated these expenses as indirect selling expenses correctly. The petitioner maintains that the record evidence demonstrates that, as in the previous review, CDC's advertising is corporate-image advertising and is not related directly to sales of gray portland cement.

Department Position: As we have noted in prior reviews, we normally consider direct expenses as expenses that result from, and bear a direct relationship to, sales of products under review. With respect to advertising, the expense must be assumed on behalf of a customer and must be specifically associated with sales of subject merchandise for the Department to treat this expense as a direct selling expense. Although CDC argues that it submitted evidence to support its claim that the expenses were direct, we disagree. The advertising at issue is associated with sales of subject and non-subject cement and promotes the overall corporate image of CDC rather than promoting sales of gray portland cement. Therefore, consistent with our prior practice, we have treated these expenses as indirect selling expenses in the home market.

17. Ministerial Errors

Comment 1: CEMEX claims that the Department did not deduct certain rebates from NV inadvertently. The petitioner argues that, because the rebates in question were reported using a distortive methodology, an adjustment for these rebates should not be granted.

Department's Position: We agree with CEMEX. We have corrected this clerical error for the final results. With regard to the petitioner's argument that the methodology CEMEX used to report these rebates was distortive, *see* our position for comment 11, above.

Comment 2: CEMEX claims that the Department used the wrong month variable in recalculating credit for the arm's-length test. The petitioner agrees with CEMEX.

Department's Position: We agree and have corrected this clerical error for the final results.

Comment 3: CEMEX claims that, when the Department recalculated its home-market imputed expenses using its revised interest rates, the Department inadvertently used the cumulative average interest rate instead of the monthly interest rate although CEMEX used the monthly interest rates in its original submission. The petitioner argues that the Department apparently used a monthly average interest rate.

Department's Position: We agree with CEMEX and have corrected this clerical error for the final results.

Comment 4: CDC claims that the Department mismatched interest rates in recalculating its home-market credit expenses by using the rates that were off by one month. The petitioner agrees with CDC.

Department's Position: We agree and have corrected this clerical error for the final results.

Comment 5: CDC argues that the Department should use 360 days in recalculating HM credit expenses because that is the figure respondent used in its original credit calculation.

Department's Position: We agree with CDC. Because CDC used the same number of days in its U.S. credit expense calculation, we have changed our calculation of CDC's HM credit expenses to reflect a 360 day-credit calculation.

Comment 6: CDC argues that the Department should convert packing expenses from pesos to U.S. dollars before making the packing adjustment to NV. The petitioner agrees with CDC.

Department's Position: We agree with CDC and the petitioner and have corrected this ministerial error for the final results.

Comment 7: CDC argues that the Department should also add U.S. packing to NV rather than deduct it from U.S. price. The petitioner agrees with CDC.

Department's Position: We agree with CDC and the petitioner and have corrected this ministerial error for the final results.

Comment 8: CDC argues that the Department neglected to include U.S. packing expenses in its calculation of the CEP ratio. The petitioner agrees with CDC.

Department's Position: We agree with CDC and the petitioner and have corrected this ministerial error for the final results.

Comment 9: CEMEX claims that, in calculating the assessment rates, the Department should have included the entered value of cement used in CEMEX's further-manufactured sales. The petitioner agrees with CEMEX.

Department's Position: We agree with CEMEX and the petitioner and have corrected this error for the final results.

[FR Doc. 99–6402 Filed 3–16–99; 8:45 am]
BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–580–825]

Oil Country Tubular Goods from Korea: Final Results of Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, U.S. Department of Commerce.

ACTION: Notice of Final Results of the Antidumping Duty Administrative Review of Oil Country Tubular Goods From Korea.

SUMMARY: In response to a request from SeAH Steel Corporation (''SeAH''), the Department of Commerce (''the Department'') is conducting an administrative review of the antidumping duty order on oil country tubular goods from Korea. This review covers one manufacturer/exporter of the subject merchandise to the United States, SeAH, and the period August 1, 1996 through July 31, 1997, which is the second period of review (''POR'').

We have made a final determination that SeAH made sales below normal value (''NV''). We will instruct the U.S. Customs Service to assess antidumping duties based on the difference between the constructed export price (''CEP'') and the NV.

EFFECTIVE DATE: March 17, 1999.

FOR FURTHER INFORMATION CONTACT: Doug Campau, Steve Bezirganian, or Steven Presing, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, DC 20230; telephone: (202)

482–3964, –0162, or –0194, respectively.

SUPPLEMENTARY INFORMATION:

The Applicable Statute

Unless otherwise indicated, all citations to the Tariff Act of 1930, as amended (the Act), are to the provisions effective January 1, 1995, the effective date of the amendments made to the Act by the Uruguay Round Agreements Act (URAA). In addition, unless otherwise indicated, all citations to the Department's regulations are to 19 CFR part 351 (1998).

Background

On August 11, 1995, the Department published in the **Federal Register** (60 FR 41057) the antidumping duty order on oil country tubular goods from Korea. On August 4, 1997, the Department published in the **Federal Register** (62 FR 41925) a notice indicating an opportunity to request an administrative review of this order for the period August 1, 1996, through July 31, 1997, and on August 29, 1997, SeAH requested an administrative review for its entries during that period. On September 25, 1997, in accordance with section 751 of the Act, we published in the **Federal Register** a notice of initiation of an administrative review of this order for the period August 1, 1996 through July 31, 1997 (62 FR 50292).

Under section 751(a)(3)(A) of the Act, the Department may extend the deadline for completion of an administrative review if it determines that it is not practicable to complete the review within the statutory time limit of 365 days. On January 30, 1998, the Department published a notice of extension of the time limit for the preliminary results in the review to August 31, 1998. *See Oil Country Tubular Goods from Korea; Extension of Time Limit for Antidumping Duty Administrative Review,* 63 FR 4624. On December 21, 1998, the Department extended the deadline for determination of the final results in this case to March 8, 1999. *See Extension of Time Limit for Final Results of Antidumping Duty Administrative Review of Oil Country Tubular Goods from Korea,* 63 FR 70389.

The Department is conducting this review in accordance with section 751(a) of the Act.

Scope of Review

The merchandise covered by this order is oil country tubular goods (''OCTG''), hollow steel products of circular cross-section, including only oil well casing and tubing, of iron (other than cast iron) or steel (both carbon and alloy), whether seamless or welded, whether or not conforming to American Petroleum Institute (''API'') or non-API specifications, whether finished or unfinished (including green tubes and limited service OCTG products). This scope does not cover casing or tubing pipe containing 10.5 percent or more of chromium, or drill pipe. The OCTG subject to this order are currently classified in the Harmonized Tariff Schedule of the United States (''HTSUS'') under item numbers: 7304.29.10.10, 7304.29.10.20, 7304.29.10.30, 7304.29.10.40, 7304.29.10.50, 7304.29.10.60, 7304.29.10.80, 7304.29.20.10, 7304.29.20.20, 7304.29.20.30, 7304.29.20.40, 7304.29.20.50, 7304.29.20.60, 7304.29.20.80, 7304.29.30.10, 7304.29.30.20, 7304.29.30.30, 7304.29.30.40, 7304.29.30.50, 7304.29.30.60, 7304.29.30.80, 7304.29.40.10, 7304.29.40.20, 7304.29.40.30, 7304.29.40.40, 7304.29.40.50, 7304.29.40.60, 7304.29.40.80, 7304.29.50.15, 7304.29.50.30, 7304.29.50.45, 7304.29.50.60, 7304.29.50.75, 7304.29.60.15, 7304.29.60.30, 7304.29.60.45, 7304.29.60.60, 7304.29.60.75, 7305.20.20.00, 7305.20.40.00, 7305.20.60.00, 7305.20.80.00, 7306.20.10.30, 7306.20.10.90, 7306.20.20.00, 7306.20.30.00, 7306.20.40.00, 7306.20.60.10, 7306.20.60.50, 7306.20.80.10, and 7306.20.80.50. The HTSUS item numbers are provided for convenience and Customs purposes. The written description remains dispositive of the scope of this review.

Verification

We verified cost and sales information provided by SeAH, examining relevant accounting and financial records, production records, and original sales documentation. Our verification results are outlined in the verification report from Abdelali Elouaradia and Juanita H. Chen to The File, dated February 12, 1999 (''*Verification Report*'').

Analysis of Comments Received

We gave interested parties an opportunity to comment on the preliminary results. SeAH Steel Corporation, Ltd. (''respondent'') and Maverick Tube Corp., IPSCO Tubulars Inc., and Lone Star Steel Co. (''petitioners'') submitted case briefs on October 16, 1998. SeAH also submitted a rebuttal brief on October 23, 1998. None of the parties requested a public hearing.

Comment 1: Payment Date/Credit Expenses

Respondent argues the Department incorrectly concluded that SeAH extended credit to one of its customers beyond the reported payment date of February 20, 1997 for several sales where SeAH had not received payment. Respondent also believes the Department incorrectly imputed a payment date other than the date on which payment for the involved sales was actually made. Respondent claims that payment was in fact made for the involved sales, but that such payment was misdirected to and misappropriated by an unrelated third party.

For the involved sales, Panther Supply, Inc. (Panther), a sales division of State Pipe and Supply Co. (an affiliate of respondent), sold merchandise to an unaffiliated purchaser. According to respondent, the unaffiliated purchaser accidentally directed payment for these sales to the wrong party. This other party then wrongfully misappropriated the payment intended for Panther. Panther sued to secure payment, which in turn led to a June 24, 1998 summary judgment order awarding full payment to Panther, plus interest beginning February 20, 1997.

In its preliminary results, the Department did not take the court-ordered payments into account in determining dates of payment. Instead, the Department set the payment date for these sales equal to the date of the last submission made by SeAH prior to determination of the preliminary results (August 19, 1998), and recalculated credit expense accordingly.

According to respondent, the Department normally constructs imputed credit costs to represent credit that a seller extends to a customer for the time between shipment and payment. Respondent states that such costs are opportunity costs to the seller for not having possession of payment funds between the dates of shipment and actual payment. Respondent emphasizes that the basis for this theory rests on the concept that the seller incurs an opportunity cost because it voluntarily extends credit to the buyer until such time as payment is made.

In this case, respondent argues, the Department was incorrect in assigning August 19, 1998 as payment date and in concluding that the seller was extending credit to one of its customers for two reasons. First, respondent argues that assigning August 19, 1998 was incorrect because a court had already recognized February 20, 1997 as the date of full payment. Second, respondent argues that because the court also awarded

SeAH interest revenue on the late payments from February 20, 1997 forward, any opportunity costs that would arise from an extension of credit cease to exist.

Finally, respondent argues that if the Department uses any date other than February 20, 1997 as payment date for the sales in question, the Department must then conform the period used for calculation of the imputed credit expense with a comparable period for calculating an interest income offset. To do so, respondent believes the Department must add an additional day—for each day beyond February 20, 1997 that the Department extends the imputed credit periods—for which Panther is entitled to receive interest income.

Petitioners did not submit comments related to this issue.

Department's Position

Contrary to SeAH's claim, the Department normally calculates credit expense based on the time between shipment and actual payment to the seller, regardless of the credit terms given to a particular customer. For example, Appendix I at 4 of the Department's September 16, 1997 Questionnaire (''Questionnaire'') states that credit expense ''is the interest expense incurred (or interest revenue foregone) between shipment of merchandise to a customer and receipt of payment from the customer (emphasis added). Similarly, the Department asked SeAH to report interest revenue based on the per unit interest charges collected on each sale for late payment of the invoice (emphasis added) (see Questionnaire at C–23). In this case, while a court decision appears to indicate that State was entitled to receive payment and interest revenue, it did not in fact receive it. In a previous case involving unpaid U.S. sales, the Department clearly stated that the issue of concern for purposes of imputed credit was the receipt of payment: ''Prior to verification OAB had not indicated in its original questionnaire response or its subsequent supplemental responses that it had not yet received payment for certain of its U.S. sales'' (emphasis added). *See Brass Sheet and Strip From Sweden; Final Results of Antidumping Administrative Review*, 60 FR 3617, 3620 (January 18, 1995). This is also true for interest revenue. For example, in a recent case the Department ''made circumstance-of-sale adjustments for credit expenses (offset by interest revenue actually received by the respondent)...'' (emphasis added). *See Notice of Final Determination of Sales at Less Than Fair Value: Static Random Access Memory Semiconductors From Taiwan*, 63 FR 8909, 8915 (February 23, 1998). Furthermore, neither SeAH nor its U.S. affiliates appear to have had a practice of charging U.S. customers interest on late payments; in response to the aforementioned request that the respondent report collected interest revenue, the respondent indicated that ''{n}either SeAH nor State charged customers interest for late payment during the POR.'' *See* SeAH's November 12, 1997 Section C response at 31. Consequently, no adjustment for interest revenue is warranted.

It is the Department's current practice to calculate imputed credit for unpaid sales based on the last day of verification. However, in this case use of the last day of verification, January 27, 1999, would be inappropriate for several reasons. First, in administrative reviews verifications are typically conducted prior to the issuance of the Department's preliminary results. However, in this case verification was conducted several months after the issuance of the preliminary results; consequently, using the last day of verification as the basis for payment date extends the credit period several months beyond what is typical for unpaid sales, covering a period in which the respondent was unable to provide new information. Second, references to ''unpaid'' sales typically involve circumstances in which no payment has been made, rather than payment to the wrong party. While it is clear, as stated above, that imputed credit is based on the receipt of payment, the particular circumstances of this case (*i.e.*, payment made to the wrong party, court judgment in favor of the U.S. affiliate, and a credit period of approximately two years under the aforementioned Department practice) suggest that using the last day of verification as the payment date would be unwarranted. Consequently, we have decided to use as payment date the date of the last submission made by SeAH prior to determination of the preliminary results (August 19, 1998), the same date we utilized in our preliminary results.

Comment 2: Clerical Error in Treatment of CREDITU

Petitioners allege that the Department made a clerical error in the preliminary results by using outdated values for imputed U.S. credit expense (''CREDITU'') in the margin program. According to petitioners, the Department recalculated CREDITU to replace several negative credit values, but failed to use the recalculated figures for CREDITU in the margin calculation. Petitioners argue the Department should correct the margin program to properly utilize the recalculated figures for CREDITU. To this end, petitioners provide a replacement code for the margin program used in the Preliminary Results, which designated August 19, 1998 as payment date for the involved sales.

Respondent contends that the Department should not correct the clerical error identified by petitioners, but should instead determine that the date of payment for the sales at issue is February 20, 1997, the date of the aforementioned summary judgement. Respondent does not disagree with petitioners' suggested changes to the margin program, and concurs with petitioners' claim that the Department made a clerical error in its preliminary margin calculation. However, respondent disagrees with the need to use August 19, 1998 as the payment date for the sales at issue (those four sales which were the subject of the aforementioned litigation) for the same reasons articulated in Comment 1 above.

Department's Position

The Department acknowledges that it made a clerical error as described above. The Department has made a correction to the margin program and has properly utilized the recalculated figures for CREDITU, based on a payment date of August 19, 1998, as described in Comment 1 above.

Comment 3: Adding Duty Drawback to Third-Country Sales for Margin Analysis and Cost Test

Respondent argues that the Department should add duty drawback to third-country comparison market sales price for purposes of running both the margin analysis and cost test. For the preliminary determination, the Department used Myanmar as a comparison market. However, respondent points out that in doing so, the Department erroneously failed to account for duty drawback, as it was not added into third-country prices for use in the cost test and margin analysis. Respondent notes that the Department requested data on duty-inclusive costs, but not data on duty exclusive costs. As a result, in conducting the cost test and margin analysis, the Department compared duty-inclusive cost with duty-exclusive third-country sale price. To remedy this alleged error, respondent believes the Department must include duty drawback in third-country sales price, and then rerun the cost test and margin analysis.

Department's Position

We agree with the respondent. In a recent case involving use of third country sales as the basis for normal value, the Department made ''an adjustment to normal value for duty drawback'' for a respondent, Mares Australes. *See Notice of Final Determination of Sales at Less Than Fair Value: Fresh Atlantic Salmon from Chile*, 63 FR 31411 (June 9, 1998). The Department had determined that the home market was not viable for that respondent, and that sales to a third country, Japan, should be used as the basis of normal value. *See Notice of Preliminary Determination of Sales at Less Than Fair Value and Postponement of Final Determination: Fresh Atlantic Salmon From Chile*, 63 FR 2664, 2668–69. Furthermore, we note that the calculation of third country price for use in the cost test should also reflect an addition for duty drawback. It is the Department's current practice to request cost of production data inclusive of duty, as reflected at page D–12 of the Department's September 16, 1997 Section D Questionnaire: ''Direct materials costs should include transportation charges, import duties and other expenses normally associated with obtaining the materials that become an integral part of the finished product'' (emphasis added). As noted by respondent, the Department only requested duty-inclusive cost data for this review, and its reported costs include those duties. As a result, in order to effectuate an ''apples-to-apples'' comparison, the Department must add duty drawback to the third-country prices used for the cost test. Accordingly, the Department added duty drawback to both third-country net price for comparison to US price and to third-country price for comparison to cost of production in the cost test.

Comment 4: Duty Drawback when Normal Value is Constructed Value

Petitioners argue that where SeAH's CEP sales are compared to constructed value (CV), the Department must account for differences between the amount of duty included in CV and the amount of duty drawback adjustment claimed for CEP sales. Petitioners note that SeAH included duties in the raw material costs reported for cost of manufacture for CV. However, petitioners state, the duties respondent included in CV are not equivalent to the duty drawback adjustments claimed for U.S. sales. As a result, petitioners believe normal value and constructed export price are not being compared on the same basis. Petitioners state that this inequitable comparison is due to SeAH's improper calculation of raw material input costs. According to petitioners, SeAH calculated its raw material input costs based on the total average cost of domestic and imported steel for each product instead of on the cost of steel for the subject merchandise which only includes imported steel weighted by the relative amount of the duty drawback claimed on each sale. Petitioners note that according to 19 U.S.C. 1677b(e), ''the constructed value of imported merchandise shall be an amount equal to the sum of . . . the cost of materials . . . employed in producing the merchandise.'' Thus, petitioners assert, the statute requires that the cost of materials used in CV be the cost of materials for the product imported into the U.S. Petitioners argue that ignoring the resulting uneven treatment of duties in CV and Constructed Export Price distorts the dumping margin calculation. Thus, petitioners argue the Department must adjust for the difference.

In order to make this adjustment, petitioners argue that the Department should have respondent report material costs for CV without including duties, and then add the amount of duty drawback claimed on each sale to the reported cost of manufacture when calculating CV for each sale. If duty drawback is not claimed, petitioners argue that the average duty calculated by SeAH should be used.

Petitioners further argue that if the Department does not include the full amount of duties claimed in the drawback adjustment in CV, then it must make some other adjustment for the difference between normal value and CEP caused by the different values for duty by either limiting the drawback adjustment claimed by SeAH to the amount of duties included in CV, or by granting a circumstances of sale adjustment per 19 U.S.C. 1677b(a)(6)(C)(iii).

According to respondent, petitioners' arguments to add duty drawback to constructed value have been previously rejected by the Court of International Trade. *Laclede Steele Co. v. United States*, 18 CIT 965 (1994). Respondent argues that there is nothing in the statute, the regulations or the Department's practice to sanction petitioners' approach. According to respondent, the Department has a two-tiered test for determining the appropriateness of a duty drawback adjustment. Respondent cites *Final Determination of Sales at Less Than Fair Value: Circular Welded Non-Alloy Steel Pipe from Korea* in support of this assertion. 57 FR 42942, 42946 (September 17, 1992). Respondent claims that according to this case, a party must first demonstrate that import duty and rebate are directly linked to, and dependent upon, one another. *Id*. Second, a party must demonstrate that the company claiming the adjustment can demonstrate that there were sufficient imports of imported raw materials to account for the duty drawback received on the exports of the manufactured product. *Id*. Respondent argues that it has satisfied this two-tiered test. According to respondent, petitioners' argument that duty drawback and import duties included in CV should be the same is not supported by the law, regulations, or practice, and that previous arguments in favor of imposing such a requirement have been rejected in court (*e.g.*, in the *Laclede* case). Finally, respondent argues that the Department has deliberately not interpreted the relevant statutory language to limit such cost to the merchandise exported to the U.S.

Respondent also argues that petitioners' suggested alternative adjustments to account for the difference between normal value and CEP—either by limiting the drawback adjustment claimed by SeAH to the amount of duties included in CV, or by granting a circumstances of sale adjustment'would require that an entity prove that cost of manufacturing includes the same amount of duty as that claimed in the drawback. This, according to respondent, goes beyond the requirements of the Department's current two-tiered test. Respondent notes that prior attempts to add such criteria to the two-tiered test have been rejected by the court. Respondent also argues that none of the cases cited in the petitioners' brief override the aforementioned court decision of *Laclede*.

Department's Position

An upward adjustment to sale price for duty drawback is provided for in section 772(c)(1)(B) of the Act. The Department utilizes a two prong test to determine whether a party is entitled to a duty drawback adjustment: (1) The import duty and rebate must be directly linked to, and dependent upon, one another, and (2) the company claiming the adjustment must demonstrate that there were sufficient imports of imported raw materials to account for the duty drawback received on exports of the manufactured products. *See, e.g., Silicon Metal from Brazil: Notice of Final Results of Antidumping Duty Administrative Review*, 64 FR 6305, 6318 (February 9, 1999). This test was in *Far East Machinery Co.* v. *United*

States, 699 F. Supp. 309, 311 (CIT 1988).

The U.S. Court of International Trade has consistently held that there is no requirement that a specific input be traced from importation through exportation before allowing drawback on duties paid. *Laclede Steel Co.* v. *United States*, 18 CIT 965, 972 (1994). The only limit on the allowance for duty drawback is that the adjustment to U.S. sales price may not exceed the amount of import duty actually paid. *Id*.

Respondent satisfied both prongs of the aforementioned test, and was therefore entitled to claim a duty drawback adjustment. Respondent's duty drawback rebates are received under Korea's individual application system, which limits such rebates to actual duties paid. Duty drawback was reviewed at verification, and no inconsistencies with respondent's reported methodology were noted. *See Verification Report* at 13–14. Thus, duty drawback rebates received by respondent are not excessive.

It is the long standing-policy of the Department to require that respondents include import duties in constructed value. *See Offshore Platform Jackets and Piles from the Republic of Korea: Final Determination of Sales at Less Than Fair Value*, 51 FR 11795, 11796 (April 7, 1986). Requesting duty-exclusive constructed value data would add a new hurdle to the two prong drawback test that is not required under current Department regulations or policy.

Accordingly, the respondent was not required to report duty-exclusive constructed value data, nor otherwise make additional adjustments to the duty drawback claimed.

Comment 5: Duty Drawback Reported for CEP Sales

Petitioners argue that because duties were paid on an actual weight basis in Korea, and because duty drawback was paid on a theoretical weight basis, the Department should reduce duty drawback by multiplying the claimed drawback by the reported conversion. Petitioners cite *Final Results of Antidumping Duty Administrative Review and Partial Termination of Administrative Review; Circular Welded Non-Alloy Steel Pipe from the Republic of Korea* in support of this position. 62 FR 55574, 55577 (October 27, 1997).

Respondent argues that the circumstances leading to the adjustment in the case cited by petitioners are not applicable to the sales in this review. Respondent notes that the adjustment in the cited case was made because an entity was receiving duty drawback under a fixed rate system. However, according to respondent, there were only two observations in which merchandise was received under a fixed rate duty drawback system in the present review. Respondent also notes that in the fourth review of the cited case, the entity selling under the fixed rate system switched to an individual application system. *See Circular Welded Non-Alloy Steel Pipe from the Republic of Korea; Final Results of Antidumping Duty Administrative Review*, 63 FR 32833 (June 16, 1998). According to respondent, the Department determined that only the amounts received under the fixed rate system (received prior to the switch to the individual application system) warranted an adjustment. *Id*. at 32837. Respondent notes that in the present case, there is only one observation where duty drawback was received under the fixed rate system. Respondent notes that the drawback arguably should be adjusted for the difference between the theoretical and actual weight under the precedent cited by petitioners. Respondent notes, however, that the adjustment factor would be one, and thus have no effect, given that the product in question was produced and sold on a theoretical weight basis. In total, respondent argues that no additional adjustments to the reported duty drawback are warranted.

Department's Position

To the extent that duty drawback rebates exceed actual duties paid, the Department agrees with petitioners that adjustments to U.S. price should be limited to the amount of duties paid. However, with only one exception, the U.S. sales in this review, unlike those in the review cited by petitioners, were under the Korean individual application system, and the rebates received were limited to actual duties paid and were therefore not excessive. Again, duty drawback was reviewed at verification, and no inconsistencies with respondent's reported methodology were noted. As a result, the Department has used the full amount of duty drawback as reported in the analysis for the Final Results.

For the abovementioned single sale made under the Korean fixed rate system, the Department agrees with the respondent that the conversion factor would be one, and thus have no effect. Both the total costs for the product in question and the total duty drawback requested reflect a higher quantity of the imported material than would have been the case if the product had been produced and sold on an actual weight basis. As this sale was of a product produced on a theoretical weight basis, and because duty drawback is paid on a theoretical weight basis, no adjustment to the reported duty drawback is necessary.

Final Results of Review

These administrative reviews and notices are published in accordance with 751(a)(1) of the Act (19 U.S.C. 1675(a)(1)) and 19 CFR 351.213 and 19 CFR 351.221(b)(5).

Oil Country Tubular Goods

Producer/manufacturer/exporter	Weighted-average margin (percent)
SeAH	2.93

The Department shall determine, and the U. S. Customs Service shall assess, antidumping duties on all appropriate entries. We have calculated an importer-specific duty assessment rate based on the ratio of the total amount of antidumping duties calculated for the examined sales to the total entered value of the same sales. The rate will be assessed uniformly on all entries of that particular company made during the POR. The Department shall issue appraisement instructions directly to the Customs Service.

Furthermore, the following deposit requirements shall be effective upon publication of this notice of final results of review for all shipments of oil country tubular goods from Korea entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided for by section 751(a)(1) of the Act: (1) The cash deposit rates for the reviewed company named above will be the rate for that firm as stated above; (2) for previously investigated companies not listed above, the cash deposit rate will continue to be the company-specific rate published for the most recent period; (3) if the exporter is not a firm covered in these reviews, or the original LTFV investigations, but the manufacturer is, the cash deposit rate will be the rate established for the most recent period for the manufacturer of the merchandise; and (4) if neither the exporter nor the manufacturer is a firm covered in these reviews, the cash deposit rate will continue to be 12.17 percent, which was the ''all others'' rate in the LTFV investigations. 60 FR at 41058.

The deposit requirements, when imposed, shall remain in effect until publication of the final results of the next administrative review.

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f) to file a

certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

This notice also serves as a reminder to parties subject to administrative protective order (''APO'') of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with § 351.306 of the Department's regulations. Timely notification of return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

Dated: March 8, 1999.

Robert LaRussa,

Assistant Secretary for Import Administration.

[FR Doc. 99–6401 Filed 3–16–99; 8:45 am]

BILLING CODE 3510–DS–P

CONSUMER PRODUCT SAFETY COMMISSION

Sunshine Act Meeting

AGENCY: U.S. Consumer Product Safety Commission.

LOCATION: Room 410, East West Towers, 4330 East West Highway, Bethesda, Maryland.

TIME AND DATE: Thursday, March 25, 1999, 10:00 a.m.

STATUS: Closed to the Public

MATTERS TO BE CONSIDERED:

Compliance Status Report

The staff will brief the Commission on the status of various compliance matters.

For a recorded message containing the latest agenda information, call (301) 504–0709.

CONTACT PERSON FOR ADDITIONAL INFORMATION: Sadye E. Dunn, Office of the Secretary, 4330 East West Highway, Bethesda, MD 20207 (301) 504–0800.

Dated: March 15, 1999.

Sadye E. Dunn,

Secretary.

[FR Doc. 99–6659 Filed 3–15–99; 8:45 am]

BILLING CODE 6355–01–M

CONSUMER PRODUCT SAFETY COMMISSION

[CPSC Docket No. 99–C0005]

Nordstrom, Inc., a Corporation; Provisional Acceptance of a Settlement Agreement and Order

AGENCY: Consumer Product Safety Commission.

ACTION: Notice.

SUMMARY: It is the policy of the Commission to publish settlements which it provisionally accepts under the Flammable Fabrics Act in the **Federal Register** in accordance with the terms of 16 CFR 1605.13(d). Published below is a provisionally-accepted Settlement Agreement with Nordstrom, Inc., a corporation, containing a civil penalty of $150,000.

DATES: Any interested person may ask the Commission not to accept this agreement or otherwise comment on its contents by April 1, 1999.

ADDRESSES: Persons wishing to comment on this Settlement Agreement should send written comments to the Comment 99–C0005, Office of the Secretary, Consumer Product Safety Commission, Washington, D.C. 20207.

FOR FURTHER INFORMATION CONTACT: Dennis C. Kacoyanis, Trial Attorney, Office of Compliance and Enforcement, Consumer Product Safety Commission, Washington, D.C. 20207; telephone (301) 504–0626, 1346.

SUPPLEMENTARY INFORMATION: The text of the Agreement and order appears below.

Dated: March 11, 1999.

Sadye E. Dunn,

Secretary.

Settlement Agreement and Order

1. This Settlement Agreement and Order, entered into between Nordstrom, Inc., (hereinafter, ''Nordstrom'' or ''Respondent''), a corporation, and the staff of the Consumer Product Safety Commission (hereinafter, ''staff''), pursuant to the procedures set forth in 16 CFR 1118.20, is a compromise resolution of the matter described herein, without a hearing or a determination of issues of law and fact.

I. The Parties

2. The ''staff'' is the staff of the Consumer Product Safety Commission (hereinafter, ''Commission''), an independent regulatory commission of the United States government established pursuant to Section 4 of the Consumer Product Safety Act (CPSA), 15 U.S.C. 2053.

3. Respondent Nordstrom is a corporation organized and existing under the laws of the State Washington with principal corporate offices located in Seattle, WA. Respondent is a fashion specialty retailer selling a wide selection of apparel, shores, and accessories of women, men, and children.

II Allegations of the Staff

A. Children's Robes

4. In 1996, Respondent sold, or offered for sale, in commerce, approximately 900 style no. G26 100% cotton girls' terry cloth robes.

5s. On or about April 12, 1996, the Commission staff collected from a Nordstrom store in King of Prussia, PA, samples of 100% girls' terry cloth robes, style no. G26. The staff found the robes displayed for sale in the children's sleepwear section of the store.

6. Children's sleepwear means any product of wearing apparel sizes 7 through 14, such as robes intended to be worn primary for sleeping or activities relating to sleeping. Given the design and length of the robes identified above, they are suitable for use for activities related to sleeping. Accordingly, the robes identified above are items of children's sleepwear and, therefore, subject to the Standard for the Flammability of Children's sleepwear, (hereinafter, ''Sleepwear Standard''), 16 CFR part 1616, issued under Section 4 of the FFA, 15 U.S.C. 1193.

7. The staff tested samples of the robes identified in paragraphs 4 and 5 above for compliance with the requirements of the Sleepwear Standard. *See* 16 CFR 1616.3 and .4. The test results showed that the robes violated the requirements of the Sleepwear Standard.

8. On or about June 11, 1996, the staff informed Respondent that the robes identified in paragraphs 4 and 5 above failed to comply with the Sleepwear Standard and requested that it cease sale of the robes and correct future production.

9. Respondent knowingly sold, or offered for sale, in commerce, the robes identified in paragraphs 4 and 5 above, as the term ''knowingly'' is defined in Section 5(e)(4) of the FFA, 15 U.S.C. 1194(e)(4), in violation of Section 3 of the FFA, 15 U.S.C. 1192, for which a civil penalty may be imposed pursuant to section 5(e)(1) of the FFA, 15 U.S.C. 1194(e)(1).

B. Chenille Sweaters

10. In 1996, Respondent sold, or offered for sale, in commerce, approximately 8,900 style no. 3L89235P women's 90% rayon/10% nylon chenille sweaters.

11. On or about October 21, 1996, the staff collected from a Nordstrom store, in Bethesda, MD, samples of women's 90% rayon/10% chenille sweaters, style no. 3L89235P.

12. The sweaters identified in paragraphs 10 and 11 above are subject to the Clothing Standard for the Flammability of Clothing Textiles (hereinafter, ''Wearing Apparel Standard''), 16 CFR Part 1610, issued under section 4 of the FFA, 15 U.S.C. 1193.

13. The staff tested samples of the sweaters identified in paragraphs 10 and 11 above for compliance with the requirements of the Wearing Apparel Standard. *See* 16 CFR 1610.3 and .4. The test results showed that the sweaters violated the requirements of the Wearing Apparel Standard and, therefore, were dangerously flammable and unsuitable for clothing because of their rapid and intense burning.

14. On or about November 1, 1996, the staff informed Respondent that the sweaters identified in paragraphs 10 and 11 above failed to comply with the Wearing Apparel Standard and requested that it cease sale of the sweaters and conduct a consumer level recall.

15. Respondent knowingly sold, or offered for sale, in commerce, the sweaters identified in paragraphs 10 and 11 above, as the term ''knowingly'' is defined in section 5(e)(4) of the FFA, 15 U.S.C. 1194(e)(4), in violation of Section 3 of the FFA, 15 U.S.C. 1192, for which a civil penalty may be imposed pursuant to Section 5(e)(1) of the FFA, 15 U.S.C. 1194(e)(1).

III. Response of Nordstrom

16. Respondent denies the allegations of the staff set forth in paragraphs 4 through 15 above. Respondent Nordstrom specifically denies that the children's robes were subject to the Sleepwear Standard. Respondent Nordstrom also specifically denies that it knowingly sold or offered for sale the chenille sweaters described in paragraphs 10 and 11 above in violation of the requirements of the Wearing Apparel Standard.

17. Nordstrom purchased the robes identified in paragraphs 4 and 5 and the chenille sweaters identified in paragraphs 10 and 11 subject to a provision contained in Nordstrom's Purchase Order by which the vendor warranted and represented that such robes and chenille sweaters comply with all applicable governmental regulations, including expressly, the Flammable Fabrics Act and the Consumer Product Safety Act.

18. Respondent Nordstrom intended that the robes described in paragraphs 4 and 5 above be sold as beach cover-ups. The labels specifically noted that the cover-ups were not to be used as sleepwear. The robes did not constitute sleepwear as the term ''sleepwear'' is defined in 16 CFR 1616.2(a) and, therefore, were not subject to the Sleepwear Standard at 16 CFR Part 1616. Nevertheless, Nordstrom complied with the staff's request that the robes be further modified.

19. Upon notification by the Commission that the chenille sweaters described in paragraphs 10 and 11 above did not meet the requirements of the Wearing Apparel Standard, Respondent Nordstrom immediately ceased all sales of the garment, as well as those garments not identified by the Commission but which were composed of the same fiber content.

20. When notified by the Commission, Respondent Nordstrom promptly and diligently assisted the Commission staff in its efforts to implement recall of the sweaters described in paragraphs 10 and 11 above.

21. Respondent Nordstrom has received no reports of consumer injury resulting from the use of the robes described in paragraphs 4 and 5 above or from use of the sweaters described in paragraphs 10 and 11 above.

IV. Agreement of the Parties

22. The Commission has jurisdiction over Respondent and the subject mater of this Settlement Agreement and Order under the Consumer Product Safety Act (CPSA), 15 U.S.C. 2051 *et seq.*, the Flammable Fabrics Act (FFA), 15 U.S.C. 1191 *et seq.*; and the Federal Trade Commission Act (FTCA), 15 U.S.C. 41 *et seq.*

23. This Agreement is entered into for settlement purposes only and does not constitute an admission by Respondent or a determination by the Commission that Respondent knowingly violated the FFA and the Sleepwear and Wearing Apparel Standards.

24. Upon provisional acceptance of this Settlement Agreement and Order by the Commission, this Settlement Agreement and Order shall be placed on the public record and shall be published in the **Federal Register** in accordance with the procedures set forth in 16 CFR 1605.13(d). If the Commission does not receive any written request not to accept the Settlement Agreement and Order within 15 days, the Settlement Agreement and Order will be deemed to be finally accepted on the 20th day after the date it is published in the **Federal Register**.

25. Upon final acceptance of this Settlement Agreement by the Commission and issuance of the Final Order, Nordstrom knowingly, voluntarily, and completely waives any rights it may have in this matter (1) to an administrative or judicial hearing, (2) to judicial review or other challenge or contest of the validity of the Commission's actions, (3) to a determination by the Commission as to whether Nordstrom failed to comply with the FFA and the Sleepwear and Wearing Apparel Standards as aforesaid, (4) to a statement of findings of facts and conclusions of law, and (5) to any claims under the Equal Access to Justice Act.

26. In settlement of the staff's allegations, Nordstrom agrees to pay a civil penalty of $150,000.00 as set forth in the incorporated Order.

27. For purposes of section 6(b) of the CPSA, 15 U.S.C 2055(b), this matter shall be treated as if a complaint had issued, and the Commission may publicize the terms of the Settlement Agreement and Order.

28. Upon final acceptance by the Commission of this Settlement Agreement and Order, the Commission shall issue the attached Order incorporated herein by reference.

29. A violation of the attached Order shall subject Respondent to appropriate legal action.

30. Agreements, understandings, representations, or interpretations made outside this Settlement Agreement and Order may not be used to vary or contradict its terms.

31. The provisions of this Settlement Agreement and Order shall apply to Nordstrom and each of its successors and assigns.

Dated: January 20, 1999.

Erik B. Nordstrom,

Co-President Nordstrom, Inc., 1617 Sixth Avenue, Seattle, Washington 98101.

Respondent Nordstrom, Inc.

Dated: January 20, 1999.

D. Wayne Gittinger, Esq.,

Lane Powell Spears Lubersky LLP, 1420 Fifth Avenue, Suite 4100, Seattle, Washington 98101–2338.

Commission Staff

Alan H. Schoem,

Assistant Executive Director, Office of Compliance, Consumer Products Safety Commission, Washington, DC 20207–0001.

Eric L. Stone,

Director, Legal Division, Office of Compliance.

Dated: January 21, 1999.

Dennis C. Kacoyanis,

Trial Attorney.

Ronald G. Yelenik,

Trial Attorney, Legal Division, Office of Compliance.

Order

Upon consideration of the Settlement Agreement entered into between Respondent Nordstrom, Inc., (hereinafter, ''Respondent''), a corporation, and the staff of the Consumer Product Safety Commission (''Commission''); and the Commission having jurisdiction over the subject matter and Respondent; and it appearing that the Settlement Agreement and Order is in the public interest, *it is*

Ordered, that the Settlement Agreement and Order be and hereby is accepted, as indicated below; *and it is*

Further ordered, that Respondent pay to the United States Treasury a civil penalty of *one hundred fifty thousand dollars* ($150,000.00) within twenty (20) days after service upon Respondent of the Final Order.

Provisionally accepted and Provisional Order issued on the 11th day of March, 1999.

By Order of the Commission.

Sadye E. Dunn,

Secretary, Consumer Product Safety Commission.

[FR Doc. 99–6398 Filed 3–16–99; 8:45 am]

BILLING 6355–01–M

DEPARTMENT OF DEFENSE

Defense Logistics Agency

Cost Sharing Cooperative Agreement Applications

AGENCY: Defense Logistics Agency (DLA).

ACTION: Notice of solicitation for cost sharing cooperative agreement applications.

SUMMARY: The Defense Logistics Agency (DLA) has issued a solicitation for cooperative agreement applications (SCAA) to assist state and local governments and other nonprofit eligible entities in establishing or maintaining procurement technical assistance centers (PTACs). These centers help business firms market their goods and services to the Department of Defense (DoD), other federal agencies, and state and/or local government agencies. This solicitation applies to all applications from all eligible entities, including Indian Economic Enterprises and Indian Tribal Organizations. Contrary to previous notices, no separate solicitation will be issued for cooperative agreement proposals to assist Indian Economic Enterprises and Indian Tribal Organizations. This solicitation will govern the submission of applications for calendar years 1999, 2000, 2001, and 2002.

DATES: The closing date for the submission of applications is April 30, 1999. The SCAA is available for review on the Internet Website:

http://www.dla.mil/ddas/scaa

Printed copies are not available for distribution.

Eligible entities may only submit an application as outlined in Section IV of the SCAA. In order to comply with the electronic portion of the submission, applicants must obtain a log in account and password from DLA. To obtain these, applicants must furnish the Grants Officer written evidence that they meet the criteria of an eligible entity as set forth in paragraph 14 of Section II of the SCAA. This information should be mailed or otherwise delivered to: HQ, Defense Logistics Agency, Small & Disadvantaged Business Utilization Office (DDAS Room 1127), 8725 John J. Kingman Road, Ft. Belvoir, VA 22060–6221.

Two pre-solicitation conferences will be held; the first is 1:00 P.M., on the March 23, 1999 at the Camberley Gunther Hotel, San Antonio, Texas. The second conference will be held at 9:30 A.M., Tuesday, March 30, 1999 at Ft. Belvoir, VA. If you plan to attend the Ft. Belvoir conference please notify DLA not later than March 24, 1999, of your intentions by mailing, faxing (703–767–1670) or e-mailing (pta__administrator@hq.dla.mil) your name, organization, and the number of people planning to attend.

FOR FURTHER INFORMATION CONTACT: If you have any questions or need additional information please contact Mr. Kenneth G. Dougherty at (703) 767–1657 or Ms. Diana Maykowskyj at (703) 767–1656.

Anthony J. Kuders,

Deputy Director, Small and Disadvantaged Business Utilization.

[FR Doc. 99–6451 Filed 3–16–99; 8:45 am]

BILLING CODE 3620–01–M

DEPARTMENT OF EDUCATION

Notice of Proposed Information Collection Requests

AGENCY: Department of Education.

SUMMARY: The Acting Leader, Information Management Group, Office of the Chief Information Officer, invites comments on the proposed information collection requests as required by the Paperwork Reduction Act of 1995.

DATES: Interested persons are invited to submit comments on or before May 17, 1999.

ADDRESSES: Written comments and requests for copies of the proposed information collection requests should be addressed to Patrick J. Sherrill, Department of Education, 400 Maryland Avenue, SW, Room 5624, Regional Office Building 3, Washington, DC 20202–4651, or should be electronically mailed to the internet address *Pat Sherrill@ed.gov*, or should be faxed to 202–708–9346.

FOR FURTHER INFORMATION CONTACT: Patrick J. Sherrill (202) 708–8196. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern time, Monday through Friday.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that the Office of Management and Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. The Acting Leader, Information Management Group, Office of the Chief Information Officer, publishes that notice containing proposed information collection requests prior to submission of these requests to OMB. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, e.g. new, revision, extension, existing or reinstatement; (2) Title; (3) Summary of the collection; (4) Description of the need for, and proposed use of, the information; (5) Respondents and frequency of collection; and (6) Reporting and/or Recordkeeping burden. OMB invites public comment at the address specified above. Copies of the requests are

available from Patrick J. Sherrill at the address specified above.

The Department of Education is especially interested in public comment addressing the following issues: (1) is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology.

Dated: March 11, 1999.

Patrick J. Sherrill,

Acting Leader, Information Management Group, Office of the Chief Information Officer.

Office of Elementary and Secondary Education

Type of Review: New.

Title: Consolidated State Performance Report and State Self-Review.

Frequency: Annually.

Affected Public: State, local or Tribal Gov't, SEAs or LEAs.

Reporting and Recordkeeping Hour Burden:

Responses: 53.

Burden Hours: 207,514.

Abstract: This information collection package contains two related parts: the Consolidated State Performance Report and State Self-Review. The Elementary and Secondary Education Act (ESEA), in general, and its provision for submission of consolidated plans, in particular (see section 14302 of the ESEA), emphasize the importance of cross-program coordination and integration of federal programs into educational activities carried out with State and local funds. States would use both instruments for reporting on activities that occur during the 1999–2000 school year and, if the ESEA when reauthorized does not become effective for the 2000–2001 school year, for that year as well. The documents allow State and local officials and educators to see at one time the full scope of their general reporting (and corresponding data collection) responsibilities, and promotes the Department's interests in (1) receiving essential information on how States have implemented their approved consolidated State plans and (2) promoting the Department's ability to provide assistance to States on how they may be able to use federal funds most effectively. The State Self-Review would be completed by those States (approximately 18 per year) that are the object of an Office of Elementary and Secondary Education integrated program review. The information States provide will complement their responses to the Consolidated Performance Report, but also will provide specific information on program implementation that is needed for an effective integrated review. The Department intends that, once the ESEA is reauthorized, it will work actively with the public to revise their content so that they support an integrated information collection system that responds to the new law and better reflects how federal programs help to promote State and local reform efforts.

[FR Doc. 99–6425 Filed 3–16–99; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Notice of Proposed Information Collection Requests

AGENCY: Department of Education.

ACTION: Notice of proposed information collection requests.

SUMMARY: The Acting Leader, Information Management Group, Office of the Chief Information Officer, invites comments on the proposed information collection requests as required by the Paperwork Reduction Act of 1995.

DATES: An emergency review has been requested in accordance with the Act (44 U.S.C. Chapter 3507 (j)), since public harm is reasonably likely to result if normal clearance procedures are followed. Approval by the Office of Management and Budget (OMB) has been requested by March 25, 1999. A regular clearance process is also beginning. Interested persons are invited to submit comments on or before May 17, 1999.

ADDRESSES: Written comments regarding the emergency review should be addressed to the Office of Information and Regulatory Affairs, Attention: Danny Werfel, Desk Officer: Department of Education, Office of Management and Budget; 725 17th Street, NW, Room 10235, New Executive Office Building, Washington, DC 20503. Comments regarding the regular clearance and requests for copies of the proposed information collection request should be addressed to Patrick J. Sherrill, Department of Education, 400 Maryland Avenue, SW , Room 5624, Regional Office Building 3, Washington, DC 20202–4651, or should be electronically mailed to the internet address *Pat—Sherrill@ed.gov*, or should be faxed to 202–708–9346.

FOR FURTHER INFORMATION CONTACT: Patrick J. Sherrill (202) 708–8196. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern time, Monday through Friday.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that the Director of OMB provide interested Federal agencies and the public an early opportunity to comment on information collection requests. The Office of Management and Budget (OMB) may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. The Acting Leader, Information Management Group, Office of the Chief Information Officer, publishes this notice containing proposed information collection requests at the beginning of the Departmental review of the information collection.

Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, e.g., new, revision, extension, existing or reinstatement; (2) Title; (3) Summary of the collection; (4) Description of the need for, and proposed use of, the information; (5) Respondents and frequency of collection; and (6) Reporting and/or Recordkeeping burden. ED invites public comment at the address specified above. Copies of the requests are available from Patrick J. Sherrill at the address specified above.

The Department of Education is especially interested in public comment addressing the following issues: (1) is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner, (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected, and (5) how might the Department minimize the burden of this collection on respondents, including through the use of information technology.

Dated: March 11, 1999.

Patrick J. Sherrill,

Acting Leader, Information Management Group, Office of the Chief Information Officer.

Office of Elementary and Secondary Education

Type of Review: New.

Title: Guidance to State Educational Agencies (SEAs) Seeking to Use an Alternative Method to Distribute Title I Funds to Local Educational Agencies (LEAs) with Fewer Than 20,000 Total Residents.

Abstract: Guidance to SEAs seeking to use an alternative method to distribute Title I funds to LEAs with fewer than 20,000 total residents.

Additional Information: The Department of Education has developed guidance on the use of an alternative method to distribute Title I funds to local educational agencies (LEAs) with fewer than 20,000 total residents, and supporting justification materials, including a copy of the relevant parts of the Title I of the Elementary and Secondary Education Act (ESEA) as amended by Pub. L. 103–382.

We are requesting that this package be reviewed and cleared on an emergency basis. ED did not make a decision about allocating Title I Basic and Concentration Grant funds to LEAs until recently.

Frequency: Guidance issued on as needed basis.

Affected Public: State, local or Tribal Gov't, SEAs or LEAs.

Reporting and Recordkeeping Hour Burden:

Responses: 25.

Burden Hours: 25.

[FR Doc. 99–6426 Filed 3–16–99; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

[FE Docket Nos. 99–08–NG, 89–69–NG et al.]

Office of Fossil Energy; Orders Granting, Amending and Vacating Authorizations To Import and/or Export Natural Gas

AGENCY: Office of Fossil Energy, DOE.

ACTION: Notice of Orders.

SUMMARY: The Office of Fossil Energy (FE) of the Department of Energy gives notice that it has issued Orders granting, amending and vacating various natural gas import and export authorizations. These Orders are summarized in the attached appendix.

These Orders may be found on the FE web site at http://www.fe.doe.gov., or on the electronic bulletin board at (202) 586–7853.

They are also available for inspection and copying in the Office of Natural Gas & Petroleum Import & Export Activities, Docket Room 3E–033, Forrestal Building, 1000 Independence Avenue, SW, Washington, DC 20585, (202) 586–9478. The Docket Room is open between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

Issued in Washington, DC, on March 9, 1999.

John W. Glynn,

Manager, Natural Gas Regulation, Office of Natural Gas & Petroleum Import & Export Activities, Office of Fossil Energy.

APPENDIX—ORDERS GRANTING, AMENDING AND VACATING IMPORT/EXPORT AUTHORIZATION

[DOE/FE Authority]

Order No.	Date issued	Importer/exporter FE docket no.	Two-year maximum		Comments
			Import volume	Export volume	
1458	02/02/99	Cogen Energy Technology L.P. 99–08–NG	.....	10 Bcf	Import from Canada, beginning on July 1, 1999, and ending on June 30, 2000.
429–B	02/02/99	Cogen Energy Technology L.P. 89–69–NG	.....	.....	Vacating long-term import authority.
1459	02/02/99	Coast Energy Group A Division Of Cornerstone Propane L.P. 99–07–NG.	100 Bcf	100 Bcf	Import combined total from Canada and Mexico, and to export combined total to Canada and Mexico, beginning January 1, 1999, and ending December 31, 2000.
1460	02/05/99	CanWest Gas Supply U.S.A., Inc. 99–10–NG.	400 Bcf		Import and export combined total from and to Canada, beginning on March 1, 1999, and ending on February 28, 2001.
494–E	02/08/99	Sumas Cogeneration Company, L.P. 90–92–NG.	.....	.....	Amending long-term import authority to increase volumes.
1461	02/08/99	Boundary Gas, Inc. 99–09–NG	67.5 Bcf		Import and export combined total from and to Canada, beginning on date of first delivery after February 24, 1999.
1462	02/11/99	Portland Natural Gas Transmission System 99–11–NG.	0.8 Bcf	.....	Import from Canada, beginning on date of first delivery.
1463	02/23/99	Stampeder Energy (U.S.) Inc. 99–14–NG ..	100 Bcf 10 Bcf (LNG).	100 Bcf	Import combined total from Canada and Mexico, and to export combined total to Canada and Mexico, and to import LNG from any country beginning March 1, 1999, through February 28, 2001.
1464	02/24/99	British Columbia Power Exchange Corporation 99–12–NG.	14 Bcf		Import and export combined total from and to Canada, beginning on March 1, 1999, through February 28, 2001.
1465	02/24/99	Wisconsin Gas Company 99–13–NG	200 Bcf	.....	Import from Canada, beginning on the date of first delivery.
1466	02/26/99	Cabot Oil & Gas Marketing Corporation 99–15–NG.	10 Bcf	.....	Import from Canada, beginning on the date of first delivery after March 31, 1999.

[FR Doc. 99–6476 Filed 3–16–99; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Office of Arms Control and Nonproliferation Policy; Proposed Subsequent Arrangement

AGENCY: Department of Energy.

ACTION: Subsequent Arrangement.

SUMMARY: This notice is being issued under the authority of Section 131 of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2160). The Department is providing notice of a proposed ''subsequent arrangement'' under the Agreement for Cooperation in the Peaceful Uses of Nuclear Energy Between the Government of the United States of America and the European Atomic Energy Community (EURATOM).

This subsequent arrangement concerns the approval of RTD/RS(EU)–2 which involves the retransfer of U.S.-origin nuclear components including 632 pieces of stainless steel fuel guard, 649,690 meters of zircaloy fuel cladding tubes, 7,296 pieces of zircaloy spacers, and 1,480 kilograms of zircaloy end-plug from Germany to the Elektrostal Nuclear Fuel Fabrication Facility in Moscow, Russia for fabrication of fuel assemblies. Siemens AG will then sell the fuel assemblies to nuclear power plants in western Europe.

This request is the commercial phase of a three-part cooperation between Siemens AG and Elektrostal. DOE approved the qualification phase and test phase in January 1995 and April 1998, respectively. The Russian government has confirmed that the assurances it gave in 1994 for the transfer of zircaloy fuel cladding tubes, confirming no nuclear explosive or other military use and no retransfer except to Western European countries without prior U.S. consent, would apply equally to the transfer of fuel guards, spacers, and end-plugs.

In accordance with Section 131 of the Atomic Energy Act of 1954, as amended, we have 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.

Dated: March 9, 1999.

For the Department of Energy.

Terry Tyborowski,

Acting Director, International Policy and Analysis Division, Office of Arms Control and Nonproliferation.

[FR Doc. 99–6477 Filed 3–16–99; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

DOE Response to Recommendation 98–2 of the Defense Nuclear Facilities Safety Board, Safety Management at the Pantex Plant

AGENCY: Department of Energy.

ACTION: Notice.

SUMMARY: The Defense Nuclear Facilities Safety Board published Recommendation 98–2, concerning the safety management at the Pantex plant, on October 7, 1998 (63 FR 53884). Under section 315(e) of the Atomic Energy Act of 1954, as amended, 42 U.S.C. 2286d(e), the Department of Energy must transmit an implementation plan on Recommendation 98–2 to the Defense Nuclear Facilities Safety Board by March 10, 1999, or submit a notification of extension for an additional 45 days. The Secretary's notification of extension for an additional 45 days follows.

ADDRESSES: Send comments, data, views, or arguments concerning the Secretary's notification to: Defense Nuclear Facilities Safety Board, 625 Indiana Avenue, NW, Suite 700, Washington, DC 20004.

FOR FURTHER INFORMATION CONTACT: Mr. Gene Ives, Deputy Assistant Secretary for Military Application and Stockpile Management, Defense Programs, Department of Energy, 1000 Independence Avenue, SW, Washington DC, 20585.

Issued in Washington, DC, on March 11, 1999.

Mark B. Whitaker, Jr.,

Departmental Representative to the Defense Nuclear Facilities Safety Board.

March 10, 1999.

The Honorable John T. Conway,
Chairman
Defense Nuclear Facilities Safety Board 624 Indiana Avenue, NW, Suite 700, Washington, DC 20004.

Dear Mr. Chairman: This is to notify you, pursuant to 42 U.S.C. 2286d(e), that the Department of Energy will require an additional 45 days to transmit the implementation plan for addressing the issues raised in the Defense Nuclear Facilities Safety Board (DNFSB) Recommendation 98–2, ''Safety Management at the Pantex Plant.'' The additional time will be beneficial for both the Department and the DNFSB to assure the implementation plan represents a comprehensive approach to this complex issue.

Mr. Gene Ives, Deputy Assistant Secretary for Military Application and Stockpile Management, will further discuss the implementation plan with you on March 9, 1999. Together, we can then determine the appropriate commitments for incorporation into the implementation plan. The implementation plan will be provided to the DNFSB by April 23, 1999.

Yours sincerely,

Bill Richardson,

[FR Doc. 99–6478 Filed 3–16–99; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Site-Wide Environmental Impact Statement (SWEIS); Oak Ridge Y–12 Plant

AGENCY: U.S. Department of Energy (DOE).

ACTION: Notice of Intent (NOI).

SUMMARY: Pursuant to the National Environmental Policy Act (NEPA), DOE announces its intent to prepare a Site-Wide Environmental Impact Statement (SWEIS) for the Oak Ridge Y–12 Plant (Y–12), DOE's primary site for enriched uranium operations and storage related to the nation's nuclear weapons program. The SWEIS will analyze current levels of Y–12 operations and foreseeable new operations and facilities for approximately the next ten years. The alternatives to be analyzed in the SWEIS include: an extensive upgrade/retrofit of existing processes and facilities; construction of new facilities to replace existing processes and facilities; a combination of upgrades of existing processes and facilities and new construction; and the No Action alternative. The No Action alternative is to continue current facility operations throughout Y–12 in support of assigned missions. There is no preferred alternative at this time. The purpose of this notice is to invite public participation in the process and to encourage public dialogue on the alternatives that should be considered.

DATES: The DOE invites other federal agencies; state, local and tribal governments; and the general public to comment on the scope of this SWEIS. The public scoping period starts with the publication of this Notice in the **Federal Register** and will continue until May 17, 1999. DOE will consider all comments received or postmarked by that date in defining the scope of this SWEIS. Comments received or postmarked after that date will be considered to the extent practicable. Public scoping meetings will be held in the Oak Ridge area and their dates, times, and locations will be published in local newspapers and other appropriate media.

The DOE is requesting, by separate correspondence and this Notice, that federal and state government agencies desiring to be designated as cooperating

agencies on the Y–12 SWEIS inform DOE by April 30, 1999.

ADDRESSES: Written comments or suggestions to assist the DOE in identifying the appropriate scope of the Y–12 SWEIS should be directed to: Gary S. Hartman, SWEIS Document Manager, U.S. Department of Energy, Oak Ridge Operations Office, Post Office Box 2001, Oak Ridge, Tennessee 37831, or by facsimile at (423) 576–1237, or by E-Mail at Y12EIS@oro.doe.gov.

For general information on the DOE NEPA process, please contact: Carol M. Borgstrom, Director, Office of NEPA Policy and Assistance, EH–42, U.S. Department of Energy, 1000 Independence Avenue SW, Washington, D.C. 20585.

Ms. Borgstrom can also be reached at (202) 586–4600, or by leaving a message at 1–800–472–2756.

Additional information regarding DOE NEPA activities and access to many NEPA documents is available on the Internet through the NEPA Home Page at http://www.eh.doe.gov/nepa.

SUPPLEMENTARY INFORMATION:

Background

The DOE is the federal agency responsible for providing the nation with nuclear weapons and ensuring that those weapons remain safe and reliable. As one of the DOE major production facilities, Y–12 has been DOE's primary site for enriched uranium processing and storage, and one of the primary manufacturing facilities for maintaining the U.S. nuclear weapons stockpile. Y–12 is located on the Oak Ridge Reservation (ORR), approximately 40 km (25 mi) west of Knoxville, Tennessee. For purposes of the SWEIS, the Y–12 Site is defined as approximately 5,000 acres of the 34,516 acre ORR, bounded by the DOE Boundary and Pine Ridge to the north, Scarboro Road to the east, Bethel Valley Road to the south, west to Mount Vernon Road, and then extending west down Bear Creek Valley to the security fence-line near the Roane/Anderson County boundary. Y–12 has a current annual budget of approximately $460 million and houses approximately 5,000 employees on site.

Nondefense-related activities at the Y–12 Plant include environmental monitoring, remediation, and deactivation and decontamination activities of the Environmental Management Program; management of waste materials from past and current operations; research activities operated by the Oak Ridge National Laboratory; support of other federal agencies through the Work-for-Others Program; and the transfer of highly specialized technologies to support the capabilities of the U.S. industrial base.

In response to the end of the Cold War and changes in the world's political regimes, the emphasis of the U.S. weapons program has shifted dramatically over the past few years from developing and producing new weapons to dismantlement and maintenance of a smaller, enduring stockpile. Even with these significant changes, however, DOE responsibilities for the nuclear weapons stockpile continue, and the President and Congress have directed DOE to continue to maintain the safety and reliability of the nuclear weapons stockpile.

In order to meet the challenges of the post-Cold War era, DOE has prepared several Programmatic Environmental Impact Statements (PEISs) to determine how best to carry out its national security requirements. The Stockpile Stewardship and Management PEIS (SSM PEIS, DOE/EIS–0236), which was completed in September 1996, evaluated alternatives for maintaining the safety and reliability of the nuclear weapons stockpile without underground nuclear testing or production of new-design weapons. The Storage and Disposition of Weapons-Usable Fissile Material PEIS (S&D PEIS, DOE/EIS–0229), which was completed in December 1996, evaluated alternatives for the long-term storage of fissile material, and the disposition of surplus fissile material. The Records of Decision (RODs) from these two PEISs form a starting point for the scope of actions that are contemplated in this Y–12 SWEIS.

In the SSM PEIS ROD, DOE decided to maintain the national security missions at Y–12, but to downsize the plant consistent with reduced requirements. These national security missions include: (1) maintaining the capability to fabricate uranium and lithium components and parts for nuclear weapons, (2) evaluating components and subsystems returned from the stockpile, (3) storing enriched uranium that is designated for national security purposes (also referred to as non-surplus enriched uranium), (4) storing depleted uranium and lithium materials and parts, (5) dismantling nuclear weapon secondaries returned from the stockpile, (6) processing uranium (which includes chemical recovery, purification, and conversion of enriched uranium to a form suitable for long-term storage and/or further use), and (7) providing support to weapons laboratories. In the S&D PEIS ROD, DOE decided that Y–12 would also store surplus enriched uranium pending disposition.

The DOE NEPA strategy for both the SSM and the S&D programs consists of multiple phases. The first phase was to prepare PEISs (now completed) to support program-wide decisions. In the second phase, DOE would prepare any necessary site-wide and/or project-specific NEPA documents required to implement any programmatic decisions. This Y–12 SWEIS is the next step for DOE's NEPA strategy for the Y–12 Plant. As such, the proposals in this NOI are consistent with previous decisions of the DOE in the PEIS RODs to downsize the Y–12 Plant and store non-surplus and surplus enriched uranium. As described in the ''alternatives'' section of this NOI, DOE is proposing several different approaches to carrying out these missions.

Public scoping meetings held in the Oak Ridge area will facilitate dialogue between DOE and the public and provide an opportunity for individuals to provide written or oral statements. In addition to providing comments at the public scoping meetings, all interested parties are invited to record their comments, ask questions concerning the Y–12 SWEIS, request time to speak, request assistance for special needs at the public meetings (e.g., an interpreter for the hearing impaired or special access), or request to be placed on the Y–12 SWEIS mailing or document distribution list. This may be done by contacting the SWEIS Document Manager at the address given above.

Proposed Action

DOE proposes to continue to provide the capability and capacity to maintain the nation's stockpile, in support of the U.S. Nuclear Weapons Program. Further, DOE proposes to continue the processing and storage of enriched and depleted uranium, lithium compounds, and other materials; and the manufacturing and assembly/disassembly mission assigned to the Y–12 Plant in the safest and most efficient manner practicable. The SWEIS will provide a baseline of impacts associated with current activities, analyze the potential impacts of constructing a new enriched uranium storage facility, and address siting issues associated with other possible modernization projects.

Alternatives to be Analyzed

As described below, DOE will analyze three broad alternatives involving upgrades of existing facilities, construction of new facilities, and a combination of these two approaches. Analysis will be performed at a level of detail sufficient to enable DOE to make

decisions regarding approach (i.e., upgrade or construct) and location (i.e., where on the site) for each function or activity. Environmental considerations will be addressed for footprint reduction activities as Y–12 surplus facilities are transitioned into the Environmental Management program consistent with the SSM PEIS and the Department's Lifecycle Asset Management Order. For most major functions or activities, additional NEPA evaluations would be required as more detailed information becomes available in order to make subsequent decisions regarding construction and operation. However, as an exception to this general approach, DOE will analyze the potential impacts of designing, constructing, and operating a new enriched uranium storage facility, for which conceptual design has begun and sufficient information is available.

Under the Upgrade Alternative, the SWEIS will assess impacts from extensive upgrade/retrofit of existing processes and facilities, such as: enriched uranium manufacturing, depleted uranium manufacturing, lithium manufacturing, assembly/disassembly, general manufacturing, office facilities, and other support facilities.

Under the Construction Alternative, the SWEIS will assess the impacts of replacing existing processes and facilities with newly designed and constructed processes and facilities, such as: enriched uranium manufacturing, depleted uranium manufacturing, lithium manufacturing, assembly/disassembly, general manufacturing, office facilities, and other support facilities.

Under the Upgrade/Construction Alternative, the SWEIS will assess the impacts of the combination of extensive upgrades to certain existing processes and facilities and the design and construction of certain new processes and facilities. This alternative will include a combination of both existing upgraded/new processes and facilities, such as: enriched uranium manufacturing, depleted uranium manufacturing, lithium manufacturing, assembly/disassembly, general manufacturing, office facilities, and other support facilities.

The No Action Alternative would continue current facility operations throughout Y–12 in support of assigned missions. NEPA regulations require analysis of the No Action alternative to provide a benchmark for comparison with environmental effects of the other alternatives. This alternative reflects the current nuclear weapons program missions at Y–12, and includes the manufacture and assembly/disassembly of weapons components, and the continued processing and storage of enriched uranium materials in existing facilities. As specified in the SSM PEIS and the S&D PEIS, these operations would continue in a reduced footprint of consolidated operations. This alternative also includes environmental considerations of footprint reduction activities as Y–12 surplus facilities are transitioned into the Environmental Management program consistent with the SSM PEIS and the Department's Lifecycle Asset Management Order. Limited upgrades of existing facilities are underway and their completion would be included in the No Action alternative.

Other Alternatives Considered

Members of the public have in the past expressed interest in shutting down all operations at Y–12 and deactivating some or all facilities. As discussed in the Background section above, DOE has considered these suggestions in previous PEIS documents. DOE recognizes that Y–12 has unique capabilities and diverse roles supporting a variety of national programs, and that there is an essential near-term need to manage and maintain the safety and stability of the existing nuclear materials inventory. In addition, the *National Security Strategy for a New Century,* issued by The White House in October 1998, emphasizes the need to ''ensure the continued viability of the infrastructure that supports U.S. nuclear forces and weapons.'' Accordingly, the DOE view at this time is that a decision to shut down or further reduce Y–12 missions within the time frame of the SWEIS would be highly unlikely. Therefore, DOE does not plan to analyze an alternative involving an orderly shutdown or further reduction during this period.

The Role of the SWEIS in the DOE NEPA Compliance Strategy

The SWEIS will be prepared pursuant to the NEPA of 1969, 42 USC 4321 et seq., the Council on Environmental Quality (CEQ) NEPA regulations (40 CFR Parts 1500–1508) and the DOE NEPA regulations (10 CFR Part 1021). The DOE has a policy (10 CFR 1021.330) of preparing SWEISs for certain large, multiple-facility sites such as Y–12. The purpose of a SWEIS is to: (1) provide DOE and its stakeholders with an analysis of the individual and cumulative environmental impacts resulting from ongoing and reasonably foreseeable new operations and facilities (and reasonable alternatives) at a DOE site; (2) provide a basis for site-wide decision making; and (3) improve and coordinate agency plans, functions, programs, and resource utilization. A SWEIS can be used to efficiently and effectively analyze multiple proposals and help establish an efficient, environmentally sound, and cost-effective plan for operating the site and its facilities. Additionally, a SWEIS provides an overall NEPA baseline for a site that is useful as a reference when project-specific NEPA documents are prepared. The NEPA process allows for federal, state, tribal, county, municipal, and public participation in the environmental review process.

In accordance with 10 CFR 1021.330(d), DOE will evaluate the SWEIS at least every five years after its completion to determine whether it remains adequate, should be supplemented, or should be replaced with a new SWEIS.

The Y–12 Site-Wide Analysis

The SWEIS will address operations and activities that DOE foresees at Y–12 for the ten years following the publication of the ROD. The SWEIS is expected to facilitate and streamline subsequent NEPA reviews at Y–12 by allowing DOE to focus on project-specific issues and narrow and simplify the scope of later reviews. This process is called ''tiering'' (40 CFR 1508.28). DOE believes that the SWEIS analysis will provide adequate NEPA analysis for impacts related to existing and reasonably foreseeable activities and projects covered within the SWEIS.

Preliminary Environmental Analysis

The following issues have been identified for analysis in the SWEIS. The list is tentative and intended to facilitate public comment on the scope of this SWEIS. It is not intended to be all-inclusive, nor does it imply any predetermination of potential impacts. The DOE specifically invites suggestions for the addition or deletion of items on this list.

1. Potential effects on the public and workers from exposures to radiological and hazardous materials during normal operations, construction, and credible accident scenarios.
2. Impacts on surface and groundwater, floodplains and wetlands, and on water use and quality.
3. Impacts on air resources.
4. Impacts to plants and animals and their habitat, including species which are federal- or state-listed as threatened or endangered, of special concern, or economically/recreationally important.
5. Impacts on physiography, topography, geology, and soil characteristics.

6. Impacts to cultural resources such as historic, archaeological, scientific, or culturally important sites.

7. Socioeconomic impacts to affected communities.

8. Environmental Justice, particularly whether or not activities at Y–12 have a disproportionately high and adverse effect on minority and low-income populations.

9. Potential impacts on land use plans, policies, and controls.

10. Transportation of radiological and hazardous materials on and off the Y–12 Plant.

11. Pollution prevention and waste management practices and activities.

12. Impacts on aesthetics and noise levels of the Y–12 facilities on the surrounding communities and ambient environment.

13. Unavoidable adverse impacts due to natural phenomena (e.g., floods, earthquakes, etc.).

14. Cumulative effects of past, present, and future operations within the Y–12 region of influence.

15. Reasonably foreseeable impacts associated with the shutdown of excess facilities.

16. Status of compliance with all applicable federal, state, and local statutes and regulations; required federal and state environmental consultations and notifications; and DOE orders on environmental protection and waste management.

Related NEPA Reviews

The following is a list of recent NEPA and other documentation related to the scope of this SWEIS. The summaries below are intended to familiarize the reader with the purpose of these other NEPA reviews and how Y–12 is considered in them.

Programmatic NEPA Reviews

Stockpile Stewardship and Management PEIS (DOE/EIS–0236). A ROD was issued on December 19, 1996 (61 FR 68014, December 26, 1996). The DOE decided to maintain, but downsize, the weapons secondary and case component fabrication capability at Y–12.

Storage and Disposition of Weapons-Usable Fissile Materials PEIS (DOE/EIS–0229). A ROD was issued on January 14, 1997 (62 FR 3014, January 21, 1997). Oak Ridge, in particular Y–12, will continue to store non-surplus highly enriched uranium and surplus highly enriched uranium pending disposition in upgraded and consolidated facilities.

Waste Management PEIS (DOE/EIS–0200). The Final PEIS was issued in May 1997. Multiple RODs are being prepared for various categories of waste. A ROD for the Treatment of Non-Wastewater Hazardous Waste was issued on July 30, 1998 (63 FR 41810, August 5, 1998). The DOE decided to continue to use off-site facilities for the treatment of major portions of the non-wastewater hazardous waste generated at DOE sites. The ORR will treat some of its own non-wastewater hazardous waste on site, where capacity is available in existing facilities and where this is economically favorable. A ROD for Transuranic Waste was issued on January 20, 1998 (63 FR 3629, January 23, 1998). Transuranic waste at the ORR will be packaged to meet waste acceptance criteria for the Waste Isolation Pilot Plant (WIPP) in New Mexico and then stored on site for eventual disposal at the WIPP. Decisions for managing low-level radioactive waste, low-level radioactive and hazardous mixed waste, and high-level radioactive waste are still pending.

Project-Specific NEPA Reviews

Disposition of Surplus Highly Enriched Uranium EIS (DOE/EIS–0240). A ROD was issued on August 5, 1996 (61 FR 40619, August 5, 1996). The ORR, particularly Y–12, is one of four DOE sites selected for implementing blending technologies for highly enriched uranium.

Interim Storage of Enriched Uranium Environmental Assessment (EA) (DOE/EA–0929). A Finding of No Significant Impact (FONSI) was issued on September 14, 1995. This allowed for the continued interim storage of enriched uranium at Y–12, with an increase in the amount of material stored above the historical maximum level. The S&D PEIS, discussed above, confirmed and extended this mission beyond the ten years assessed in the EA.

Replacement and Operation of the Anhydrous Hydrogen Fluoride (AHF) Supply and Fluidized-Bed Chemical Processing Systems EA (DOE/EA–1049). A FONSI was issued on September 20, 1995. This allowed for replacement of the AHF supply and fluidized-bed reactor systems at Y–12 to meet operational and safety requirements and extend the life of the process by approximately 20 years.

ORR Related NEPA Reviews

Spallation Neutron Source (SNS) EIS (DOE/EIS–0247). The draft EIS was issued for review in December 1998. This document evaluates four alternative DOE sites for construction and operation of a new SNS facility. The preferred alternative is a site at the Oak Ridge National Laboratory (ORNL) on the ORR.

Lease of Land and Facilities Within the East Tennessee Technology Park (ETTP) EA (DOE/EA–1175). A FONSI was issued on December 1, 1997. The EA evaluated impacts of alternatives on future use and/or disposition of surplus facilities at the former K–25 Site on the ORR, and allowed for the lease of some facilities and land to commercial entities.

Long-Term Management and Use of Depleted Uranium Hexafluoride PEIS (DOE/EIS–0269). The final PEIS and ROD are scheduled to be issued in 1999. The ETTP is an alternative site for management and storage of this material.

Receipt and Storage of Uranium Materials from the Fernald Environmental Management Project Site EA (DOE/EA–1291). The draft EA was issued for review in February 1999. Y–12 and ETTP are among the candidates for storage of materials being removed in the cleanup effort at the Fernald site in Ohio.

Transuranic Waste Treatment Facility EIS (DOE/EIS–030J). An NOI was published in January 1999. DOE proposes to treat wastes at ORNL at a new facility to be constructed near the Melton Valley Storage Tanks, where the material is currently being stored.

Other Documents

Environmental, Safety and Health Vulnerabilities Associated with the Storage of Highly Enriched Uranium (HEU) (DOE/EH0525). This report was issued in December 1996; the related Management Plan (DOE/DP–0139) was issued in April 1997. In this report, the DOE evaluated 22 sites that handle and store HEU materials in a variety of forms, including disassembled weapons parts, reactor fuels, solids, solutions, and scrap and residues. Most of the HEU vulnerabilities identified at those sites, including Y–12, are associated with poor facility conditions and institutional weaknesses. Further analyses are being conducted on particular facilities and issues presented in the Vulnerability Assessment Report.

Report on the Remedial Investigation (RI) of the Upper East Fork Poplar Creek Characterization Area at the Oak Ridge Y–12 Plant (DOE/OR/01–1641/D2). The RI was issued in August 1998. The feasibility study that accompanies the RI is still in draft form. A ROD on remediation of the Upper East Fork Poplar Creek watershed will be issued in the future.

The SWEIS Preparation Process

After the scoping period, DOE will prepare the draft Y–12 SWEIS. Additional public meetings or

workshops may be scheduled during this time based on stakeholder interest. The DOE intends to complete the draft SWEIS in early 2000 and will announce its availability in the **Federal Register** and through local media. The DOE will hold public hearings to solicit comments on the draft SWEIS from the public, organizations, and other agencies, and will consider all comments in the preparation of the final SWEIS. The DOE intends to complete the final SWEIS in August 2000, and issue a ROD in October 2000, but at least 30 days after the Environmental Protection Agency's Notice of Availability of the final SWEIS is published in the **Federal Register**.

Classified Material

DOE will review classified material while preparing this SWEIS. Within the limits of classification, DOE will provide to the public as much information as possible to assist public understanding and comment. Any classified material DOE needs to use to explain the purpose and need for the action, or the uses, materials, or impacts analyzed in this SWEIS, will be segregated into a classified appendix or supplement, which will not be available for general public review. However, all unclassified results of calculations using classified data will be reported in the unclassified section of the SWEIS, to the extent possible in accordance with federal classification requirements.

Availability of Scoping Documents

Copies of all written comments and transcripts of all oral comments related to the Y–12 SWEIS will be available at the following locations:

The DOE Public Reading Room, 230 Warehouse Road, Building 1916–T–2, Suite 300, Oak Ridge, Tennessee 37831.

Oak Ridge Public Library, 1401 Oak Ridge Turnpike, Oak Ridge, Tennessee 37831.

Issued in Washington, D.C., this 11th day of March 1999, for the United States Department of Energy.

Peter N. Brush,

Principal Deputy Assistant Secretary, Environment, Safety and Health.

[FR Doc. 99–6481 Filed 3–16–99; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Rocky Flats

AGENCY: Department of Energy.

ACTION: Notice of Open Meeting.

SUMMARY: This notice announces a meeting of the Environmental Management Site-Specific Advisory Board (EM SSAB), Rocky Flats. The Federal Advisory Committee Act (Public Law 92–463, 86 Stat. 770) requires that public notice of these meetings be announced in the **Federal Register**.

DATES: Thursday, April 1, 1999: 6:00 p.m.–9:30 p.m.

ADDRESSES: College Hill Library, (Front Range Community College), 3705 West 112th Avenue, Westminster, CO.

FOR FURTHER INFORMATION CONTACT: Ken Korkia, Board/Staff Coordinator, EM SSAB-Rocky Flats, 9035 North Wadsworth Parkway, Suite 2250, Westminster, CO 80021, phone: (303) 420–7855, fax: (303) 420–7579.

SUPPLEMENTARY INFORMATION: Purpose of the Board: The purpose of the Board is to make recommendations to DOE and its regulators in the areas of environmental restoration, waste management, and related activities.

Tentative Agenda

1. Follow-up discussion on low-level waste disposition issues; responses to questions, comments, and inquiry requests from the Board.
2. Review and approve the Request for Proposal (RFP) and contract for the Community Radiation Monitoring (COMRAD) program.
3. Other Board business will be conducted as necessary.

Public Participation: The meeting is open to the public. Written statements may be filed with the Committee either before or after the meeting. Individuals who wish to make oral statements pertaining to agenda items should contact Ken Korkia at the address or telephone number listed above. Requests must be received 5 days prior to the meeting and reasonable provision will be made to include the presentation in the agenda. The Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Each individual wishing to make public comment will be provided a maximum of 5 minutes to present their comments at the beginning of the meeting.

Minutes: The minutes of this meeting will be available for public review and copying at the Freedom of Information Public Reading Room, 1E–190, Forrestal Building, 1000 Independence Avenue, SW, Washington, DC 20585 between 9:00 a.m. and 4 p.m., Monday–Friday, except Federal holidays. Minutes will also be available at the Public Reading Room located at the Board's office at 9035 North Wadsworth Parkway, Suite 2250, Westminster, CO 80021; telephone (303) 420–7855. Hours of operation for the Public Reading Room are 9:00 a.m. and 4:00 p.m. on Monday through Friday. Minutes will also be made available by writing or calling Deb Thompson at the Board's office address or telephone number listed above.

Issued at Washington, DC on March 11, 1999.

Rachel M. Samuel,

Deputy Advisory Committee Management Officer.

[FR Doc. 99–6479 Filed 3–16–99; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

International Energy Agency Meeting

AGENCY: Department of Energy.

ACTION: Notice of Meeting.

SUMMARY: The Industry Advisory Board (IAB) to the International Energy Agency (IEA) will meet March 25, 1999 at the headquarters of the International Energy Agency in Paris, France.

FOR FURTHER INFORMATION CONTACT: Samuel M. Bradley, Acting Assistant General Counsel for International and Legal Policy, Department of Energy, 1000 Independence Avenue, S.W., Washington, D.C. 20585, 202–586–6738.

SUPPLEMENTARY INFORMATION: In accordance with section 252(c)(1)(A)(i) of the Energy Policy and Conservation Act (42 U.S.C. 6272(c)(1)(A)(i)), the following meeting notice is provided:

A meeting of the Industry Advisory Board (IAB) to the International Energy Agency (IEA) will be held on March 25, 1999, at the headquarters of the IEA, 9 rue de la Federation, Paris, France, beginning at approximately 9:00 a.m. The purpose of this meeting is to permit attendance by representatives of U.S. company members of the IAB at a meeting of the IEA's Standing Group on Emergency Questions (SEQ) scheduled to be held at the IEA's offices on March 25, including a preparatory encounter among company representatives from approximately 9:00 a.m. to 9:30 a.m. The Agenda for the preparatory encounter among company representatives is to elicit views regarding items on the SEQ's Agenda. The Agenda for the SEQ meeting is under the control of the SEQ. It is expected that the SEQ will adopt the following Agenda:

1. Adoption of the Agenda
2. Approval of the Summary Records of the 93rd and 94th Meetings
3. SEQ Work Program
   - The 1999 SEQ Work Program
   - First Elements of the Year 2000

Work Program
4. Appraisal of Emergency Response Exercise 98 (ERE 98)
   - Draft Appraisal of ERE 98 by the Secretariat
   - Appraisal of ERE 98 by Administrations
   - Appraisal of ERE 98 by Reporting Companies
   - Appraisal of ERE 98 by Industry Supply Advisory Group (ISAG)
   - Appraisal of ERE 98 by the IAB
5. Policy and Legislative Developments in Member Countries
   - Recent Strategic Petroleum Reserve Developments
   - Developments in other IEA countries
6. SEQ Issues for the IEA Ministerial Meeting
   - Security Issues in the Transport Sector
   - Spare Oil Production Capacity in OPEC Countries
7. Current IAB Activities
8. Emergency Reserve Situation of IEA Countries
   - Emergency Reserve and Net Import Situation of IEA Countries on 1 October 1998
9. Emergency Reserve Issues
   - Seminar on IEA Oil Stock Strategy
10. Emergency Response Simulation
   - Proposal for Disruption Simulation Exercise
11. Emergency Response Issues of IEA Candidate Countries
   - Emergency Reserve Situation of IEA Candidate Countries
12. Emergency Data System and Related Questions
   - Base Period Final Consumption Q497-Q398
   - Monthly Oil Statistics (MOS) October 1998
   - MOS November 1998
   - Quarterly Oil Forecast Q298-Q199
13. Emergency Response Reviews of IEA Countries
   - Emergency Response Review of Finland
   - Emergency Response Review of Greece
   - Emergency Response Review of New Zealand
   - Updated Schedule of Emergency Response Reviews
14. Emergency Reference Guide—Update of Emergency Contact Points List
15. Dispute Settlement Center—Panel of Arbitrators
16. Other Business
   - Discussion of possible event to mark 25 years of SEQ work on energy security
   - Emergency oil stocks and Asia Pacific Economic Cooperation energy security (APERC Study)
   - The year 2000 problem (the millennium bug)

As provided in section 252(c)(1)(A)(ii) of the Energy Policy and Conservation Act (42 U.S.C. 6272(c)(1)(A)(ii)), this meeting is open only to representatives of members of the IAB and their counsel, representatives of members of the SEQ, representatives of the Departments of Energy, Justice, and State, the Federal Trade Commission, the General Accounting Office, Committees of the Congress, the IEA, and the European Commission, and invitees of the IAB, the SEQ, or the IEA.

Issued in Washington, D.C., March 11, 1999.

Mary Anne Sullivan,

General Counsel.

[FR Doc. 99–6480 Filed 3–16–99; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP99–233–000]

Florida Gas Transmission Company; Notice of Application

March 11, 1999.

Take notice that on March 3, 1999, Florida Gas Transmission Company (FGT) 1400 Smith Street, Houston, Texas 77002, filed, in Docket No. CP99–233–000, an application pursuant to Section 7(b) of the Natural Gas Act and Part 157 of the Commission's Regulations for an order permitting and approving the abandonment by sale to Copano Pipelines/South Texas, L.P., a Texas Limited Partnership (Copano), of its South of MOPS facilities located in San Patricio, Refugio, and Nueces Counties, Texas, as more fully set forth in the application which is on file with the Commission and open to public inspection. This filing may be viewed on the web at http://www.ferc.fed.us/online/rims.htm (call 202–208–2222 for assistance).

Specifically, FGT explains that the South of MOPS facilities consist of 70.25 miles of 20-inch diameter pipeline, FGT's Compressor Station No. 2, consisting of two units for a total of 4,000 horsepower, and various measurement facilities, with appurtenances.

FGT further requests that the Commission find that, upon abandonment and sale of such facilities, the South of MOPS facilities will be intrastate transportation facilities under Section 2(16) of the NGPA, and exempt from jurisdiction of the Commission under the NGA. FGT states that when conveyed to Copano, the South of MOPS facilities would be integrated with other Copano facilities and be operated as a non-jurisdictional intrastate pipeline.

Any person desiring to be heard or to make any protest with reference to said application should on or before April 1, 1999, file with the Federal Energy Regulatory Commission, 888 First Street, NE, Washington, D.C. 20426, a motion to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) and the regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken, but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party in the proceeding herein must file a motion to intervene in accordance with the Commission's rules.

Take further notice that, pursuant to the authority contained in and subject to the jurisdiction conferred upon the Commission by Sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission or its designee on this application if no motion to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that permission and approval for the proposed abandonment are required by the public convenience and necessity. If a motion for leave to intervene is timely filed, or if the Commission on its own motion believes that formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for FGT to appear or to be represented at the hearing.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 99–6416 Filed 3–16–99; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP99–237–000]

Williston Basin Interstate Pipeline Company; Notice of Request Under Blanket Authorization

March 11, 1999.

Take notice that on March 5, 1999, Williston Basin Interstate Pipeline Company (Williston Basin), 200 North Third Street, Suite 300, Bismarck, North Dakota 58501, filed in Docket No. CP99–237–000 a request pursuant to Sections 157.205 and 157.216 of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205 and 157.216) for authorization to abandon the South Byron supply lateral pipeline located in Big Horn County, Wyoming. Williston Basin makes such request under its blanket certificate issued in Docket Nos. CP82–487–000, *et al.*, pursuant to Section 7 of the Natural Gas Act, all as more fully set forth in the request on file with the Commission. The filing may be viewed on the web at http://www.ferc.fed.us/online/rims.htm (call 202–208–2222 for assistance).

Specifically, Williston Basin proposes to abandon the 3.77 mile South Byron supply lateral pipeline that consists of 3.16 mile of 4-inch pipeline .07 mile of 7-inch pipeline and .54 mile of 8-inch pipelines. It is stated that the South Byron supply lateral pipeline consists of various vintage sections of pipeline, which are deteriorated and prone to leaks.

It is indicated that the South Byron supply lateral pipeline was previously used to transport gas received from a producer in the South Byron Field, but that the producer no longer delivers gas into the South Byron supply lateral pipeline. Williston Basin avers that the shipper who previously purchased the gas received through the South Byron supply pipeline has informed Williston Basin that its gas purchase contract with this producer was terminated, effective March 1, 1999.

Any person or the Commission's staff may, within 45 days after issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and pursuant to Section 157.205 of the Regulations under the Natural Gas Act (18 CFR 157.205) a protest to the request. If no protest is filed within the time allowed therefor, the proposed activity shall be deemed to be authorized effective the day after the time allowed for filing a protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to Section 7 of the Natural Gas Act.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 99–6417 Filed 3–16–99; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT 0F ENERGY

Federal Energy Regulatory Commission

Notice of Application Tendered for Filing With the Commission and Soliciting Additional Study Requests

March 11, 1999.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Type of Application:* Minor License.

b. *Project No.:* P–11541–001.

c. *Date filed:* February 26, 1999.

d. *Applicant:* Atlanta Power Company, Inc.

e. *Name of Project:* Atlanta Power Station Hydroelectric Project.

f. *Location:* On the Middle Fork Boise River in Elmore County, Idaho, near the town of Atlanta within the Boise National Forest (T5N, R11E, sections 5, 4, 3, 2, and 11, Boise Meridian).

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Lynn E. Stevenson, President, Atlanta Power Company, Inc., Box 100, Fairfield, ID, (208) 352–4692; Michael C. Creamer, Esq., Givens Pursley LLP, 277 N. 6th Street, Suite 200, P.O. Box 2720, Boise, ID 83701, (208) 388–1200.

i. *FERC Contact:* Gaylord W. Hoisington (202) 219–2756.

j. *Deadline for filing additional study requests:* April 27, 1999.

All documents (original and eight copies) should be filed with: David P. Boergers, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

The Commission's Rules of Practice and Procedure require all intervenors filing documents with the Commission to serve a copy of that document on each person whose name appears on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. Status of environmental analysis: This application is not ready for environmental analysis at this time.

l. Brief Description of the Project: The proposed project would consist of the existing Atlanta Power Station facilities, located at the Forest Service's Kirby Dam, consisting of: (1) a penstock intake structure; (2) a powerhouse located at the dam, containing a single generating unit with a capacity of 187 kilowatts; (3) 4.8 miles of 3-phase, 2,400-volt transmission line; and (4) related facilities.

m. Locations of the application: A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street, NE., Room 2A, Washington, DC 20426, or by calling (202) 208–1371. This filing may be viewed on the web at http://www.ferc.fed.us/online/rims.htm (call 202–208–2222 for assistance). A copy is also available for inspection and reproduction at the address in item h above.

n. With this notice, we are initiating consultation with the *IDAHO STATE HISTORIC PRESERVATION OFFICER (SHPO),* as required by § 106, National Historic Preservation Act, and the regulations of the Advisory Council on Historic Preservation, 36 CFR 800.4.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 99–6418 Filed 3–16–99; 8:45 am]

BILLING CODE 6717–01–M

ENVIRONMENTAL PROTECTION AGENCY

[FRL–6311–2]

Agency Information Collection Activities: Submission for OMB Review; Comments Request: Used Oil Management Standards Recordkeeping and Reporting Requirements

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this notice announces that the following Information Collection Request (ICR) has been forwarded to the Office of Management and Budget (OMB) for review and approval: Used Oil Management Standards Recordkeeping and Reporting Requirements, OMB Control Number 2050–0124, expires 3/31/99. The ICR describes the nature of the information collection and its expected burden and

cost; where appropriate, it includes the actual data collection instrument.

DATES: Comments must be submitted on or before [Insert date 30 days after publication in the **Federal Register**].

FOR FURTHER INFORMATION OR A COPY CALL: Contact Sandy Farmer at EPA by phone at (202) 260–2740, by email at farmer.sandy@epamail.epa.gov, or download off the Internet at http://www.epa.gov/icr and refer to EPA ICR No. 1286.05.

SUPPLEMENTARY INFORMATION: *Title:* Used Oil Management Standards Recordkeeping and Reporting Requirements, ICR No. 1286.05, OMB No. 2050–0124, expires 3/31/99. This is a request for extension of a currently approved collection.

Abstract: The Used Oil Management Standards, which include information collection requests, were developed in accordance with section 3014 of the Resource Conservation and Recovery Act (RCRA), as amended by the Hazardous and Solid Waste Amendments of 1984 (HSWA), which directs EPA to ''promulgate regulations * * * as may be necessary to protect public health and the environment from the hazards associated with recycled oil'' and, at the same time, to not discourage used oil recycling. In 1985 and 1992, EPA established mandatory regulations that govern the management of used oil (see 40 CFR part 279). To document and ensure proper handling of used oil, these regulations establish notification, testing, tracking and recordkeeping requirements for used oil transporters, processors, re-refiners, marketers, and off-specification burners. They also set standards for the prevention and cleanup of releases to the environment during storage and transit, and for the safe closure of storage units and processing and re-refining facilities to mitigate future releases and damages. EPA believes these requirements minimize potential hazards to human health and the environment from the potential mismanagement of used oil by used oil handlers, while providing for the safe recycling of used oil. Information from these information collection requirements is used to ensure compliance with the Used Oil Management Standards.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR Part 9 and 48 CFR Chapter 15. The **Federal Register** Notice required under 5 CFR 1320.8(d), soliciting comments on this collection of information was published on 10/14/98 (63 FR 55115); seven comments were received.

Burden Statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to range from six minutes to 23 hours per response depending on the type of response. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

Respondent/Affected Entities: business.

Estimated Number of Respondents: 732.

Frequency of Response: biennially.

Estimated Total Annual Hour Burden: 363,664 hours.

Estimated Total Annualized Cost Burden: $0.

Send comments on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques to the following addresses. Please refer to EPA ICR No. 1286.05 and OMB Control No. 2050–0124 in any correspondence.

Ms. Sandy Farmer, U.S. Environmental Protection Agency, Office of Policy, Regulatory Information Division (2137), 401 M Street, SW., Washington, DC 20460.

and

Office of Information and Regulatory Affairs; Office of Management and Budget, *Attention:* Desk Officer for EPA, 725 17th Street, NW., Washington, DC 20503.

Dated: March 11, 1999.

Joseph Retzer,

Director, Regulatory Information Division.

[FR Doc. 99–6501 Filed 3–16–99; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–6310–3]

Agency Information Collection Activities: Submission for OMB Review; Comment Request; Pesticide Registration Application, Notification and Report for Pesticide-Producing Establishments

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3507 (a)(1)(D)), this document announces that the Information Collection Request (ICR) for the Application for Registration of Pesticide-Producing Establishments, and the Pesticides Report for Pesticide-Producing Establishments described below has been forwarded to the Office of Management and Budget (OMB) for review and comment. The ICR describes the nature of the information collection and its expected burden and cost; and it includes the forms. Also included is the Notification of Registration of Pesticide-Producing Establishments, which EPA uses to notify the company of their newly registered pesticide-producing establishments, and the assignment of their Establishment Number(s).

DATES: Comments must be submitted on or before April 16, 1999.

FOR FURTHER INFORMATION CONTACT: Contact Sandy Farmer at EPA by phone at (202) 260–2740, by email at farmer.sandy@epamail.epa.gov, or download off the Internet at http://www.epa.gov/icr and refer to EPA ICR No. 0160.06.

SUPPLEMENTARY INFORMATION: *Title:* Pesticide Registration Application, Notification and Report for Pesticide-Producing Establishments; (OMB Control No. 2070–0078; EPA ICR No. 0160.06).

Abstract: The U.S. Environmental Protection Agency (EPA) must collect information on pesticide-producing establishments in order to meet the statutory requirements of Section 7 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). FIFRA requires producers of pesticide products, active ingredients, and devices to register their establishments with EPA and to submit an initial report, and thereafter, annually report on the types and amounts of products produced. The purpose of this notice is to request renewal of the collection process and reporting processes for the

Application for Registration of Pesticide-Producing Establishments (EPA Form 3540–8), the Notification of Registration of Pesticide-Producing Establishments (EPA Form 3540–8A), and the Pesticides Report for Pesticide-Producing Establishments (EPA Form 3540–16).

Application for Registration of Pesticide-Producing Establishments information, collected on EPA Form 3540–8, is a one-time requirement for all pesticide-producing establishments. The reporting of pesticide production information collected on the Pesticides Report for Pesticide-Producing Establishments, EPA Form 3540–16, is required within 30 days of receipt of the Notification of Registration of Pesticide-Producing Establishments (EPA Form 3540–8A); and then annually thereafter, on or before March 1. The information is entered and stored in EPA's Office of Enforcement and Compliance Assurance (OECA)/Office of Compliance (OC) Section Seven Tracking System (SSTS), a computerized data processing and record-keeping system.

The Office of Compliance/OECA collects the establishment and pesticide production information for compliance oversight and risk assessment. The information is used by EPA Regional pesticide enforcement and compliance staffs, OECA, and the Office of Pesticide Programs (OPP) within the Office of Prevention, Pesticides and Toxic Substances (OPPTS), as well as the U.S. Department of Agriculture (USDA), the Food and Drug Administration (FDA), other Federal agencies, States under Cooperative Enforcement Agreements, and the public.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR part 9 and 48 CFR Chapter 15. The **Federal Register** document required under 5 CFR 1320.8(d), soliciting comments on this collection of information was published on 01/05/99 (64 FR 499), and no comments were received.

Burden Statement: The annual public reporting and record keeping burden for this collection of information is estimated to be an average of 18 minutes for a one time response for the Application for Registration of Pesticide-Producing Establishments (EPA Form 3540–8), and 1 hour and 26 minutes for the annual yearly response for the Pesticides Report for Pesticide-Producing Establishments (EPA Form 3540–16). There is no public burden associated with the Notification of Registration of Pesticide-Producing Establishments (EPA Form 3540–8A) because EPA completes this form. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information. The burden associated with this ICR is described below:

Respondents/Affected Entities: Pesticide producing establishments.

Estimated Number of Respondents: 13,262.

Frequency of Response: One time and yearly.

Estimated Total Annual Hour Burden: 18,173 hours.

Estimated Total Annualized Cost Burden: $0

Send comments on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques to the following addresses. Please refer to EPA ICR No. 0160.06 and OMB Control No. 2070–0078 in any correspondence.

Ms. Sandy Farmer, U.S. Environmental Protection Agency, Office of Policy, Office of Regulatory Management, Regulatory Information Division (2137), 401 M Street, SW, Washington, DC 20460;

and

Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for EPA, 725 17th Street, NW, Washington, DC 20503.

Dated: March 8, 1999.

Richard T. Westlund,

Acting Director, Regulatory Information Division.

[FR Doc. 99–6509 Filed 3–16–99; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–6311–4]

Formation of a Task Force on Innovative Approaches to Environmental Protection and a Public Meeting on draft recommendations for innovative actions by the Agency

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

ACTION: Notice of formation of the Task Force on Innovative Approaches to Environmental Protection and notice of a public meeting on draft recommendations for innovative actions by the Environmental Protection Agency.

SUMMARY: On January 28, 1999, Administrator Browner formed a Task Force on Innovative Approaches to Environmental Protection to assess the Agency's progress on reinvention activities designed to achieve improved environmental protection at lower cost, with greater efficiency, and with less burden on the regulated community. The Task Force will review the effectiveness of innovative activities designed to achieve compliance with environmental requirements and to encourage broader environmental stewardship. The Task Force will submit recommendations to the Administrator on May 15, 1999 that include practical actions that can be implemented over the next 12 to 18 months to further our progress toward compliance and stewardship. Involvement from EPA's State partners, the regulated community, the environmental community and the public, as well as EPA staff will be essential to identifying the best opportunities for successful action with the greatest environmental benefit. In order to obtain this input, EPA program offices and regional offices are holding a series of focus group sessions to develop a broad range of ideas. In addition, input received in recent stakeholder meetings conducted by the Office of Enforcement and Compliance Assistance will be integrated into the input that the Task Force considers in developing draft recommendations for public comment, before preparing final recommendations to submit to the Administrator. There are two opportunities for comment in this process. The Office of Reinvention has established a web site at *http://www.epa.gov/reinvent/taskforce.* Users may provide comment directly at the web site with initial suggestions as well as comments on draft recommendations when they are available. The Office of

Reinvention is also convening a one-day public meeting of stakeholders and State Partners to discuss draft recommendations, with a time allotted for public comments.

DATES: The public meeting will be on April 15, 1999 from 9 AM until 4:30 PM in room 6208 of the Ariel Rios Building, 1200 Pennsylvania Ave. NW, Washington, DC 20004. The Ariel Rios Building is located at the Federal Triangle Metro stop. If you plan to attend, please inform one of the contacts listed below, as seating is limited.

FOR FURTHER INFORMATION CONTACT: Cynthia Nolt (telephone 202–260–9642) or Patricia Cohn (202–260–9643) of the Office of Reinvention (MC1801), U. S. Environmental Protection Agency, 401 M St. SW, Washington, DC 20460. Also see http://www.epa.gov/reinvent/taskforce.

SUPPLEMENTARY INFORMATION: Scope and Objectives of the Innovations Task Force: EPA's leadership, at the direction of Vice President Gore and with the support of the National Partnership for Reinventing Government (NPR), has formed the Task Force on Innovative Approaches to Environmental Protection to take stock of EPA's reinvention work and find new approaches to improve environmental compliance and performance. The Task Force is charged with developing a set of proposals that can be promptly implemented to improve or expand the Agency's reinvention activities with input from employees, EPA's state partners and stakeholders.

Innovative efforts are underway in all parts of EPA—the media-based program offices, the regional offices, and the cross-cutting offices—and state environmental programs. Through various reinvention initiatives, the Agency has streamlined regulatory requirements, tested innovative regulatory approaches through programs such as Project XL and the Common Sense Initiative, initiated voluntary programs to encourage environmental improvement, and launched new programs and policies to assist businesses in complying with environmental laws.

It is now time to take stock of these efforts: to identify ''what's working'' and to integrate successful approaches more broadly into day-to-day operations. The task force will look for specific, concrete and readily implementable ideas, focusing on innovative ways to:

- achieve the baseline of regulatory compliance, and
- encourage environmental improvements beyond that baseline.

The Task Force is soliciting feedback on these topics from EPA staff, state partners and external stakeholders in March and April 1999. The task force, chaired by Deputy Administrator Peter Robertson, will submit its final report to the Administrator by May 15.

Key Issues and Questions

I. Achieving the Compliance Baseline.

Full compliance with environmental laws is the baseline standard of environmental performance. A wide variety of EPA activities, in addition to enforcement actions, address this issue. These activities include:

1. *New approaches in regulatory requirements.* EPA is testing regulatory approaches that establish clear standards, while providing flexibility in how those standards are achieved. In one program, the Agency has consolidated scattered rules that apply to a single industry into a clearer and more understandable package. We are also writing new regulations in ''plain language'' to reduce confusion about what is expected of regulated parties. These efforts should promote improved compliance. Are there additional steps that EPA can take to make regulatory requirements easier to understand and comply with?

2. *Results-oriented permitting and reporting.* Unnecessarily complicated permit conditions and reporting requirements can be sources of non-compliance. EPA has carried out a number of pilots to test simplified or consolidated environmental reporting and has experimented with many approaches for getting better results from permits, such as watershed trading. Can EPA use this experience to make broader changes that will reduce the frequency of non-compliance associated with complex permit and reporting requirements?

3. *Compliance assistance.* EPA and other regulators are using a number of innovative approaches to help regulated parties comply, ranging from compliance assistance centers, to compliance manuals, to onsite technical assistance and hotlines. Should EPA expand the use of these strategies? What is EPA's role versus the role of state agencies in providing compliance assistance? Based on the experience of the past five years, are there ways that compliance assistance strategies can be adjusted to get the maximum benefit? Are there new strategies that should be adopted?

II. Encouraging Environmental Stewardship:

The work of the the Task Force also includes identifying incentives to stimulate environmentally beneficial behavior beyond what is legally required. Included in this effort may be reductions in emissions below the levels required by regulations and permits, helping to solve environmental problems that are not regulated by EPA, such as energy or water use, or actions which support broadly desirable goals such as sustainability. There are an increasing number of companies and communities which are demonstrating leadership through pollution prevention, product stewardship, providing others with guidance about environmental responsibilities, and developing other creative ways to achieve environmental results.

1. *Encouraging top performance.* Some companies consistently perform well above required levels environmentally—not only meeting the compliance baseline, but going well beyond it in addressing environmental issues. Is EPA doing enough to reward and encourage this kind of outstanding environmental performance? What specific opportunities are there to employ other incentive approaches to promote these objectives? What types of incentives are likely to be most effective?

2. *Encouraging voluntary improvements.* An increasing number of companies are interested in improving their environmental performance beyond minimum regulatory requirements—e.g., by participating in targeted voluntary programs. Similarly, communities are working to solve local environmental problems such as habitat loss, traffic congestion, and loss of open space. There is widespread interest in actions individuals can take to reduce their impact on the environment. Are there additional steps EPA should be taking to encourage improvement by these parties? Are there unaddressed problems, or problems not fully addressed by regulatory approaches, that present promising opportunities for using voluntary approaches? Is there a particular industry or set of pollution sources that presents opportunities? Should EPA develop more comprehensive strategies for encouraging continuous improvement by companies and communities?

3. *Integrating environmental and business decisions.* New business tools have been developed that incorporate environmental considerations into traditional business systems. For example, some companies now use

robust accounting systems that track environmental costs and benefits thereby providing information necessary for the organization to achieve greater economic efficiencies and improved environmental performance. Are there additional opportunities to accelerate the adoption of these new practices in related areas such as capital budgeting, design, materials management, underwriting, and finance?

Dated: March 11, 1999.

Jay Benforado,

Acting Associate Administrator, Office of Reinvention.

[FR Doc. 99–6513 Filed 3–16–99; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–6311–6]

Notice of Oxygenate Use in Gasoline Panel Meeting

AGENCY: Environmental Protection Agency.

ACTION: Notice.

SUMMARY: On November 30, 1998, U.S. Environmental Protection Agency Administrator Carol M. Browner announced the creation of a blue-ribbon panel of leading experts from the public health and scientific communities, automotive fuels industry, water utilities, and local and State government to review the important issues posed by the use of MTBE and other oxygenates in gasoline. EPA created the panel to gain a better understanding of the public health concerns raised by the discovery of MTBE in some water supplies. The panel will be chaired by Mr. Daniel Greenbaum, President of the Health Effects Institute (HEI) of Cambridge, Massachusetts, and Mr. Robert Perciasepe, Assistant Administrator for Air and Radiation, US EPA.

This notice announces the time and place for the third meeting of the panel.

DATES: The blue-ribbon panel reviewing the use of oxygenates in gasoline will conduct its third meeting on Thursday and Friday, March 25 and 26, 1999, in Sacramento, CA beginning at 8:30 a.m.

ADDRESSES: The meeting will be held from 8:30 a.m. to possibly 8:30 p.m. on Thursday, March 25th and from 8:30 a.m.–12:00 p.m. on Friday, March 26th at the Sacramento Convention Center, 1030 15th Street, Room 202, Sacramento, CA.

FOR FURTHER INFORMATION CONTACT: Karen Smith at U.S. Environmental Protection Agency Office of Air and Radiation, 401 M Street, SW (6406J), Washington, D.C. 20460, (202) 564–9674, or John Brophy at (202) 564–9068. Information can also be found at www.epa.gov/oms/consumer/fuels/oxypanel/blueribb.htm.

SUPPLEMENTARY INFORMATION: This is the third in a series of meetings at locations around the country to hear from regional and national experts on the facts concerning oxygenate use in fuel. While in Sacramento, the panel will focus on understanding oxygenate and water issues in California. A number of presenters have been invited to offer a variety of perspectives regarding oxygenate issues. The panel will also be accepting written public comment submissions. Written submissions can be mailed to US EPA, 401 M Street, SW, Mail Code 6406J (Attn: Blue-Ribbon Panel), Washington, DC 20460. Panel members will be provided with copies of all written submissions.

Dated: March 12, 1999.

Margo T. Oge,

Director, Office of Mobile Sources.

[FR Doc. 99–6619 Filed 3–16–99; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–6311–1]

Science Advisory Board; Notification of Public Advisory Committee Meetings

Pursuant to the Federal Advisory Committee Act, Public Law 92–463, notice is hereby given that two Committees of the Science Advisory Board (SAB) will meet on the dates and times described below. All times noted are Eastern Time. All meetings are open to the public, however, seating is limited and available on a first come basis. Documents that are the subject of SAB reviews are normally available from the originating U.S. Environmental Protection Agency (EPA) office and are *not* available from the SAB Office. Public drafts of SAB reports are available to the Agency and the public from the SAB office. Details on availability are noted below.

1. Ecological Processes and Effects Committee

The Ecological Processes and Effects Committee (EPEC) of the Science Advisory Board (SAB) will hold a public meeting on April 6–7, 1999 in Washington, DC. The meeting will be held in Room 1103 West Tower of the EPA Waterside Mall Complex, 401 M Street, SW, Washington, DC 20460, beginning at 8:30 am and ending no later than 5:30 pm on each day. The purpose of the meeting is to offer advice to the Agency on the following topics: (a) review of a proposed methodology for establishing sediment guidelines for metals mixtures; (b) review of a Biotic Ligand Model (BLM) for establishing aquatic life criteria for metals; and (c) review of a proposed approach for setting Ecological Soil Screening Levels (Eco-SSLs) for use at Superfund sites.

Background (a) Bioavailability and Toxicity of Metals in Surface Waters and Sediments: The Office of Water and the Office of Research and Development have been working over the past several years to refine Agency approaches to developing criteria and guidance for metals levels that are protective of benthic organisms, aquatic life in the water column, and wildlife that consume aquatic organisms. A focus of this recent work has been on improving the understanding of factors that influence metals bioavailability, and thus toxicity, in the environment. The Office of Water is asking the SAB to review its integrated approach to assessing bioavailability and toxicity of metals in surface waters and sediments by evaluating proposed modifications to the approaches used to develop sediment metals guidelines and aquatic life criteria for metals. The Charge to the Committee is as follows:

Overall Charge

Does the integrated metals methodology improve our ability to make both protective and predictive assessments of toxicity due to copper, silver and other selected metals in the water column and sediment?

Biotic Ligand Model Questions:

(1) Does the BLM improve our ability to predict toxicity to water column organisms due to metals (copper and silver) in comparison to the currently applied dissolved metal concentration criterion?

(2) Is the scientific and theoretical foundation of the model sound?

(3) In comparison to the current Water Effects Ration (WER) adjustment for aquatic life criteria, will the application of the BLM as a site-specific adjustment reduce uncertainty associated with metals bioavailability and toxicity?

(4) Are the data presented for the validation of the BLM sufficient to support the incorporation of the BLM directly into copper and silver criteria documents?

Equilibrium Sediment Guidelines for Metals Mixtures Questions

(1) By incorporating the fraction organic carbon into the bioavailability

equation, have we retained the protective features of the guidelines and improved its predictiveness of toxic effects?

(2) If the BLM is used to derive or adjust a water quality criterion, is the revised criterion appropriate for use in the interstitial water component of the Metals Mixtures ESG?

(3) Are the data presented from lab and field experiments with chromium and silver sufficient to support their addition to the Metals Mixtures ESG?

(b) Ecological Soil Screening Levels (Eco-SSLs):

The Office of Emergency and Remedial Response (i.e., the Superfund Program) has asked the SAB to provide an advisory on ongoing work to develop Ecological Soil Screening Levels (Eco-SSLs) that will be protective of the terrestrial environment. The Agency has formed a multi-stakeholder workgroup to develop Eco-SSLs. Members include scientists and risk assessors from EPA, Environment Canada, Department of Energy, Army, Navy, Air Force, states, industry, academia, and consulting firms. This collaborative project is expected to result in a Superfund guidance document that includes a look-up table of generic Eco-SSLs for up to 24 chemicals or groups of chemicals that are frequently of ecological concern at Superfund sites. The charge to the Committee includes the following questions:

(1) Will the proposed procedures for evaluating mammalian and avian toxicity data result in the selection and use of the most appropriate data for generating wildlife Eco-SSL?

(2) Will the proposed procedures for evaluating soil biota toxicity data result in the selection and use of the most appropriate available data for generating plant, invertebrate, and microbial Eco-SSLs?

(3) Do the models and exposure factors used in the wildlife food chain model reflect the state of the practice?

(4) Do the proposed approaches for selecting single Eco-SSL values for the five receptor groups reflect a reasoned balance between conservativeness and reasonableness?

(5) Do the proposed efforts for modifying the Eco-SSLs in Tier 2 consider the factors of greatest concern (e.g., soil chemistry and bioavailability issues, unit area of exposure, probablilistic approaches)?

For Further Information:

The briefing and review materials prepared by the Agency for this meeting are *NOT* available from the Science Advisory Board. Single copies of the background information for the sediment metals and Biotic Ligand Model reviews can be obtained by contacting Jennifer Mitchell, Office of Water's Health and Ecological Criteria Division, Mail Code 4304, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; by e-mail at: <mitchell.jennifer@epa.gov>; or by telephone at (202) 260–6101. Single copies of the background material for the Eco-SSL advisory can be obtained by contacting Steve Ells, Office of Emergency and Remedial Response, Mail Code 5204G, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; by e-mail at: <ells.steve@epa.gov>; or by telephone at (703) 603–8822.

Additional information about the meeting, or the meeting agenda, can be obtained by contacting Ms. Mary Winston, Committee Operations Staff, Science Advisory Board (1400), U.S. EPA, 401 M Street, SW, Washington, DC 20460; by telephone at (202) 260–2554; by fax at (202) 260–7118 or via e-mail at: <winston.mary@epa.gov>. Anyone wishing to make an oral presentation to the Committee must contact Ms. Stephanie Sanzone, Designated Federal Official for EPEC, in writing to the address or fax above, or via e-mail at: <sanzone.stephanie@epa.gov> no later than 4:00 pm on March 31, 1999, in order to be included on the Agenda. The request should identify the name of the individual who will make the presentation and an outline of the issues to be addressed. At least 35 copies of any written comments to the Committee are to be given to Ms. Sanzone no later than the time of the presentation for distribution to the Committee and the interested public.

2. Executive Committee

The Science Advisory Board's (SAB) Executive Committee, will conduct a public teleconference meeting on Thursday, April 8, 1999, between the hours of 12:00 noon and 2:00 pm, Eastern Time. The meeting will be coordinated through a conference call connection in Room M3709 of the Mall at the U.S. Environmental Protection Agency, 401 M Street SW, Washington, DC 20460. The public is welcome to attend the meeting physically or through a telephonic link. Additional instructions about how to participate in the conference call can be obtained by calling Ms. Priscilla Tillery-Gadson at (202) 260–4126.

During this meeting the Executive Committee plans to review draft reports from its Committees. *Anticipated* drafts include: (a) Executive Committee (EC) Subcommittee: Data from Testing of Human Subjects; (b) Ecological Processes and Effects Committee (EPEC): Review of the Agency's Index of Watershed Indicators (IWI); and (c) Environmental Engineering Committee: Commentary on the Need to Address Source Reduction and Control Technology in PM2.5 Research Plan. It is possible that other draft reports may be available for review at this meeting as well. Please check with Ms. Tillery-Gadson prior to the meeting to confirm any changes in the planned review schedule.

For Further Information:

Any member of the public wishing further information concerning the meeting or wishing to submit comments should contact Dr. Donald G. Barnes, Designated Federal Officer for the Executive Committee, Science Advisory Board (1400), U.S. Environmental Protection Agency, Washington DC 20460; telephone (202) 260–4126; FAX (202) 260–9232; and via e-mail at: <barnes.don@epa.gov>. Copies of the draft reports are available from the same source, or from the SAB Website (http://www.epa.gov/sab) at least one week prior to the meeting.

Providing Oral or Written Comments at SAB Meetings

The Science Advisory Board expects that public statements presented at its meetings will not be repetitive of previously submitted oral or written statements. In general, each individual or group making an oral presentation will be limited to a total time of ten minutes. For teleconference meetings, opportunities for oral comment will usually be limited to no more than three minutes per speaker and no more than fifteen minutes total. Written comments (at least 35 copies) received in the SAB Staff Office sufficiently prior to a meeting date (usually one week before the meeting), may be mailed to the relevant SAB committee or subcommittee; comments received too close to the meeting date will normally be provided to the committee at its meeting, or mailed soon after receipt by the Agency. Written comments may be provided to the relevant committee or subcommittee up until the time of the meeting.

Additional information concerning the Science Advisory Board, its structure, function, and composition, may be found on the SAB Website (http://www.epa.gov/sab) and in The Annual Report of the Staff Director which is available from the SAB Publications Staff at (202) 260–4126 or via fax at (202) 260–1889.

Individuals requiring special accommodation at SAB meetings, including wheelchair access, should contact the appropriate DFO at least five business days prior to the meeting so that appropriate arrangements can be made.

Dated: March 10, 1999.

Donald G. Barnes,

Staff Director, Science Advisory Board.

[FR Doc. 99–6502 Filed 3–16–99; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[OPP–66265; FRL–6067–8]

Oxythioquinox; Voluntary Termination of Uses

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of receipt of request to terminate uses.

SUMMARY: In accordance with section 6(f)(1) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, EPA is issuing a notice of receipt of requests by Bayer Corporation to voluntarily cancel products containing oxythioquinox (Morestan), 6-methyl-1,3-dithiolo [4,5-b] quinoxalin-2-one or chinomethionate, to terminate uses.

DATES: Unless the request is withdrawn by September 13, 1999, orders will be issued canceling these registrations.

FOR FURTHER INFORMATION CONTACT: By mail: Jamil Mixon, Reregistration Branch I, (7508C), Special Review and Reregistration Division, Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20046. Office location for commercial courier, Reregistration Branch I, 3rd floor, 2800 Crystal Drive, Arlington, VA; telephone number: (703) 308–8032.

SUPPLEMENTARY INFORMATION:

I. Background Information

Oxythioquinox (trade name Morestan) is an insecticide/miticide/fungicide first registered in 1968, to control mites, mite eggs on ornamental plants in green houses, nurseries and landscapes. On October 17, 1996, Bayer requested voluntary cancellation of all food uses but citrus. Bayer also requested cancellation of all but two of the 24(c) registrations (California and Louisiana). Subsequently, on June 4, 1997, the Agency received a request from Bayer to cancel registration of the remaining food-use products: Morestan 25WP (3125–117) and Morestan Solupak 25 WP 9 (3125–302). These cancellations were announced in the **Federal Register** of August 27, 1997 (62 FR 45416) (FRL–5737–4), and became final March 9, 1998. Initiation of the exiting stocks period began when the Agency received the request for cancellations and ran for 18 months. On February 1, 1999, Bayer requested cancellation of its remaining oxythioquinox registrations. After cancellation orders for these products are issued, there will be no remaining registered products containing oxythioquinox.

II. Terminations Pursuant to Voluntary Requests

Under section 6(f)(1) of FIFRA, registrants may request at any time that ''a pesticide registration of the registrant be canceled or amended to terminate one or more pesticide uses.'' (7 U.S.C. 136d(f)(1)). Consistent with 6(f)(1) of FIFRA, EPA is issuing a notice of receipt of the request.

III. Termination Intent to Cancel

This notice announces receipt of request for voluntary cancellation of EPA registrations listed in Table 1 below. Unless this request is withdrawn, oxythioquinox (Morestan) will no longer appear in any registered products.

Table 1.—6(F) Notice for Voluntary Cancellation

Product Name	EPA Registration Number
Morestan 4 Ornamental Miticide	3125-381
Morestan 4 Nursery Miticide	3125-437
Morestan 4 Technical	3125-205

IV. Procedures for Withdrawal of Request

For Bayer to withdraw a request for use termination the company must submit such withdrawal in writing to Jamil Mixon, at the address given above, postmarked before September 13, 1999. This written withdrawal of the request for use termination will apply only to the applicable 6(f)(1) request listed in this notice. The notice must include a commitment to pay any maintenance fees and to fulfill any unsatisfied data requirements.

V. Existing Stocks Provision

EPA proposes to accept the registrants' request for amendment to terminate all products listed in Table 1 in Unit III. of this notice. It is EPA's general practice to accept registrant's requests for cancellation of registrations or specific registered uses.

Notice of the request for cancellation is published primarily for the purpose of alerting affected parties so that they may either attempt to convince the registrant to maintain the registration or apply to register the product themselves. EPA proposes to approve these cancellations expeditiously after the close of the comment period unless the registrant withdraws its request or a compelling reason opposing termination is presented in public comments. If the requests are granted, any use of the above mentioned chemicals would be permitted only if the products are used in accordance with the terms and conditions specified on the label.

EPA also proposes to accept the registrants' requests for existing stocks provisions. Under FIFRA section 6(a)(1), EPA may permit the continued sale and use of a canceled pesticide if such sale or use ''is not inconsistent with the purposes of this Act.'' For each of the chemicals listed in this notice: Morestan 4 Ornamental Miticide, Morestan 4 Nursery Miticide, and Morestan Technical, the Agency has concluded that the limited short-term continued use of these pesticides, when used in accordance with the label, will not result in unreasonable risk or adverse effects to human health or the environment.

If EPA grants any or all of the requested cancellations, it is likely that the Agency will establish an existing stocks provision consistent with the following schedule. The distributors of products containing the active ingredients, as listed in Table 1 in Unit III. of this notice, have requested an 18–month existing stocks provision from the effective date of cancellation as a condition of its termination, so that existing supplies of oxythioquinox (Morestan) can be exhausted. EPA agrees to registrant's request and will permit sale and distribution of these products for 18 months after the effective date of cancellation. The end-users will then be allowed an additional year (for a total of 2 years beyond the registrant requested date) for the use of existing stocks for each of these chemicals.

Dated: March 3, 1999.

Jack E. Housenger,

Acting Director, Special Review and Reregistration, Office of Pesticide Programs.

[FR Doc. 99–6182 Filed 3–16–99; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[PF–864; FRL–6066–7]

ICI Surfactants; Pesticide Tolerance Petition Filing

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of pesticide petitions proposing the establishment of regulations for residues of certain pesticide chemicals in or on various food commodities.

DATES: Comments, identified by the docket control number PF–864, must be received on or before April 16, 1999.

ADDRESSES: By mail submit written comments to: Information and Records Integrity Branch, Public Information and Services Divison (7502C), Office of Pesticides Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person bring comments to: Rm. 119, CM #2, 1921 Jefferson Davis Highway, Arlington, VA.

Comments and data may also be submitted electronically by following the instructions under ''SUPPLEMENTARY INFORMATION.'' No confidential business information should be submitted through e-mail.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as ''Confidential Business Information'' (CBI). CBI should not be submitted through e-mail. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 119 at the address given above, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: Bipin Gandhi, Registration Support Branch, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW, Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 707A, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703) 308–8380; e-mail: gandhi.bipin@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA has received a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Comestic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set forth in section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

The official record for this notice of filing, as well as the public version, has been established for this notice of filing under docket control number [PF–864] (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The official record is located at the address in ''ADDRESSES'' at the beginning of this document.

Electronic comments can be sent directly to EPA at:

opp-docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comment and data will also be accepted on disks in Wordperfect 5.1/6.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket control number [PF–864] and appropriate petition number. Electronic comments on this notice may be filed online at many Federal Depository Libraries.

List of Subjects

Environmental protection, Agricultural commodities, Food additives, Feed additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: March 3, 1999.

Peter Caulkins, Acting

Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

The petitioner summary of the pesticide petition is printed below as required by section 408(d)(3) of the FFDCA. The summary of the petition was prepared by the petitioner and represents the views of the petitioner. EPA is publishing the petition summaries verbatim without editing them in any way. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

1. ICI Surfactants

PP 6E4987

EPA has received a pesticide petition (PP 6E4987) from ICI Surfactants, 3411 Silverside Road, Wilmington, DE 19803-8340, proposing pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 346a(d), to amend 40 CFR 180.1001(c), and (e) to establish an exemption from the requirement of a tolerance for methyl methacrylate-methacrylic acid-monomethoxypolyethylene glycol methacrylate copolymer when used as an inert ingredient in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest or to animals. EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

Magnitude of residues. No residue chemistry data or environmental fate data are presented in the petition as the Agency does not generally require some or all of the listed studies to rule on the exemption from the requirement of a tolerance for an inert ingredient.

B. Toxicological Profile

1. *Acute toxicity*. The Agency has established a set of criteria which identifies categories of polymers that present low risk. These criteria (described in 40 CFR 723.250) identify polymers that are relatively unreactive and stable compared to other chemical substances as well as polymers that typically are not readily absorbed. ICI believes that methyl methacrylate-methacrylic acid-monomethoxypolyethylene glycol methacrylate copolymer conforms to the definition of a polymer given in 40 CFR 723.250 and meet the criteria used to identify a low risk polymer. We also believe that based on this substance conformance to the above mentioned criteria, no mammalian toxicity is anticipated from dietary, inhalation or

dermal exposure to methyl methacrylate-methacrylic acid-monomethoxypolyethylene glycol methacrylate copolymer and that methyl methacrylate-methacrylic acid-monomethoxypolyethylene glycol methacrylate copolymer will present minimal or no risk.

i. This polymer is not a cationic substance.

ii. It contains as an integral part of it's composition the atomic elements carbon, hydrogen, and oxygen.

iii. It does not contain as an integral part of it's composition, except as impurities, any elements other than those listed in 40 CFR 723.250(d)(2)(ii).

iv. This polymer is not designed or reasonably anticipated to substantially degrade, decompose, or depolymerize.

v. It is not manufactured or imported from monomers and/or other reactants that are not already on the TSCA Chemical Substance Inventory or manufactured under an applicable TSCA Section 5 exemption.

vi. It is not a water absorbing polymer.

vii. The minimum average molecular weight of the above mentioned polymer is greater than 1,000. Substances with molecular weights greater than 400 are generally not readily absorbed through the intact skin, and substances with molecular weights greater than 1,000 are generally not absorbed through the intact gastrointestinal (GI) tract. Chemicals not absorbed through the GI tract are generally incapable of eliciting a toxic response.

viii. This polymer has an oligomer content less than 10% below MW 500, and less than 25% MW 1,000. ICI believes sufficient information was submitted in the petition to assess the hazards of methyl methacrylate-methacrylic acid-monomethoxypolyethylene glycol methacrylate copolymer. No toxicology data were presented in the petition as the Agency does not generally require some or all of the listed studies to rule on the exemption from the requirement of a tolerance for an inert ingredient. Based on this polymer conforming to the definition of a polymer and meeting the criteria of a polymer under 40 CFR 723.250 ICI believes there are no concerns for risks associated with toxicity.

2. *Endocrine disruption*. ICI has no information to suggest that methacrylate-methacrylic acid-monomethoxypolyethylene glycol methacrylate copolymer will have an effect on the immune and endocrine systems. EPA is not requiring information on the endocrine effects of this substance at this time; Congress has allowed 3 years after August 3, 1996, for the Agency to implement a screening program with respect to endocrine effects.

C. Cumulative Effects

ICI believes sufficient information was submitted in the petition to assess the hazards of methacrylate-methacrylic acid-monomethoxypolyethylene glycol methacrylate copolymer. Based on this polymer confirming to the definition of a polymer and meeting the criteria of a polymer under 40 CFR 723.250 ICI believes there are no concerns for risks associated with cumulative effects.

D. Safety Determination

1. *U.S. population*. ICI believes sufficient information was submitted in the petition to assess the hazards of methacrylate-methacrylic - acid-monomethoxypolyethylene glycol methacrylate copolymer. Based on this polymer conforming to the definition of a polymer and meeting the criteria of a polymer under 40 CFR 723.250, ICI believes there are no concerns for risks associated with any potential exposure to adults.

2. *Infants and children*. ICI believes sufficient information was submitted in the petition to assess the hazards of methacrylate-methacrylic - acid-monomethoxypolyethylene glycol methacrylate copolymer. Based on this polymer conforming to the definition of a polymer and meeting the criteria of a polymer under 40 CFR 723.250, ICI believes there are no concerns for risks associated with any potential exposure to infants and children.

2. ICI Surfactants

PP 8E4988

EPA has received a pesticide petition (PP 8E4988) from ICI Surfactants, 3411 Silverside Road, Wilmington, DE 19803-8340, proposing pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 346a(d), to amend 40 CFR 180.1001(c) and (e) to establish an exemption from the requirement of a tolerance for 12-hydroxystearic acid-polyethylene glycol copolymer (CAS Reg. No. 70142-34-6) when used as an inert ingredient in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest or to animals. EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

Magnitude of residues. No residue chemistry data or environmental fate data are presented in the petition as the Agency does not generally require some or all of the listed studies to rule on the exemption from the requirement of a tolerance for an inert ingredient.

B. Toxicological Profile

1. *Acute toxicity*. The Agency has established a set of criteria which identifies categories of polymers that present low risk. These criteria (described in 40 CFR 723.250) identify polymers that are relatively unreactive and stable compared to other chemical substances as well as polymers that typically are not readily absorbed. ICI believes that 12-hydroxystearic acid-polyethylene glycol copolymer (CAS Reg. No. 70142-34-6) conforms to the definition of a polymer given in 40 CFR 723.250 and meet the criteria used to identify a low risk polymer. We also believe that based on this substances conformance to the above mentioned criteria, no mammalian toxicity is anticipated from dietary, inhalation or dermal exposure to 12-hydroxystearic acid-polyethylene glycol copolymer and that 12-hydroxystearic acid-polyethylene glycol copolymer will present minimal or no risk.

i. This polymer is not a cationic substance.

ii. It contains as an integral part of it's composition the atomic elements carbon, hydrogen, and oxygen.

iii. It does not contain as an integral part of it's composition, except as impurities, any elements other than those listed in 40 CFR 723.250 (d)(2)(ii).

iv. This polymer is not designed or reasonably anticipated to substantially degrade, decompose, or depolymerize.

v. It is not manufactured or imported from monomers and/or other reactants that are not already on the TSCA Chemical Substance Inventory or manufactured under an applicable TSCA Section 5 exemption.

vi. It is not a water absorbing polymer.

vii. The minimum average molecular weight of the above mentioned polymer is greater than 1,000. Substances with molecular weights greater than 400 are generally not readily absorbed through the intact skin, and substances with molecular weights greater than 1,000 are generally not absorbed through the intact gastrointestinal (GI) tract. Chemicals not absorbed through the GI tract are generally incapable of eliciting a toxic response.

viii. This polymer has an oligomer content less than 10% below MW 500, and less than 25% MW 1,000. ICI

believes sufficient information was submitted in the petition to assess the hazards of 12-hydroxystearic acid-polyethylene glycol copolymer (CAS Reg. No. 70142-34-6). No toxicology data were presented in the petition as the Agency does not generally require some or all of the listed studies to rule on the exemption from the requirement of a tolerance for an inert ingredient. Based on this polymer conforming to the definition of a polymer and meeting the criteria of a polymer under 40 CFR 723.250 ICI believes there are no concerns for risks associated with toxicity.

2. *Endocrine disruption*. ICI has no information to suggest that 12-hydroxystearic acid-polyethylene glycol copolymer (CAS Reg. No. 70142-34-6) will have an effect on the immune and endocrine systems. EPA is not requiring information on the endocrine effects of this substance at this time; Congress has allowed 3 years after August 3, 1996, for the Agency to implement a screening program with respect to endocrine effects.

C. Cumulative Effects

ICI believes sufficient information was submitted in the petition to assess the hazards of 12-hydroxystearic acid-polyethylene glycol copolymer (CAS Reg. No. 70142-34-6). Based on this polymer conforming to the definition of a polymer and meeting the criteria of a polymer under 40 CFR 723.250 ICI believes there are no concerns for risks associated with cumulative effects.

D. Safety Determination

1. *U.S. population*. ICI believes sufficient information was submitted in the petition to assess the hazards of 12-hydroxystearic acid-polyethylene glycol copolymer (CAS Reg. No. 70142-34-6). Based on this polymer conforming to the definition of a polymer and meeting the criteria of a polymer under 40 CFR 723.250 ICI believes there are no concerns for risks associated with any potential exposure to adults.

2. *Infants and children*. ICI believes sufficient information was submitted in the petition to assess the hazards of 12-hydroxystearic acid-polyethylene glycol copolymer (CAS Reg. No. 70142-34-6). Based on this polymer conforming to the definition of a polymer and meeting the criteria of a polymer under 40 CFR 723.250 ICI believes there are no concerns for risks associated with any potential exposure to infants and children.

3. ICI Surfactants

PP 8E4989

EPA has received a pesticide petition (PP 8E4989) from ICI Surfactants, 3411 Silverside Road, Wilmington, DE 19803-8340, proposing pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 346a(d), to amend 40 CFR 180.1001(c), and (e) to establish an exemption from the requirement of a tolerance for polyethylene glycol-polyisobutenyl anhydride-tall oil fatty acid copolymer when used as an inert ingredient in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest or to animals. EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

Magnitude of residues. No residue chemistry data or environmental fate data are presented in the petition as the Agency does not generally require some or all of the listed studies to rule on the exemption from the requirement of a tolerance for an inert ingredient.

B. Toxicological Profile

1. *Acute toxicity*. The Agency has established a set of criteria which identifies categories of polymers that present low risk. These criteria (described in 40 CFR 723.250) identify polymers that are relatively unreactive and stable compared to other chemical substances as well as polymers that typically are not readily absorbed. ICI believes that polyethylene glycol-polyisobutenyl anhydride-tall oil fatty acid copolymer conforms to the definition of a polymer given in 40 CFR 723.250 and meet the criteria used to identify a low risk polymer. We also believe that based on this substances conformance to the above mentioned criteria, no mammalian toxicity is anticipated from dietary, inhalation or dermal exposure to polyethylene glycol-polyisobutenyl anhydride-tall oil fatty acid copolymer and that polyethylene glycol-polyisobutenyl anhydride-tall oil fatty acid copolymer will present minimal or no risk.

i. This polymer is not a cationic substance.

ii. It contains as an integral part of it's composition the atomic elements carbon, hydrogen, and oxygen.

iii. It does not contain as an integral part of it's composition, except as impurities, any elements other than those listed in 40 CFR 723.250(d)(2)(ii).

iv. This polymer is not designed or reasonably anticipated to substantially degrade, decompose, or depolymerize.

v. It is not manufactured or imported from monomers and/or other reactants that are not already on the TSCA Chemical Substance Inventory or manufactured under an applicable TSCA Section 5 exemption.

vi. It is not a water absorbing polymer.

vii. The minimum average molecular weight of the above mentioned polymer is greater than 1,000. Substances with molecular weights greater than 400 are generally not readily absorbed through the intact skin, and substances with molecular weights greater than 1,000 are generally not absorbed through the intact gastrointestinal (GI) tract. Chemicals not absorbed through the GI tract are generally incapable of eliciting a toxic response.

viii. This polymer has an oligomer content less than 10% below MW 500, and less than 25% MW 1,000. ICI believes sufficient information was submitted in the petition to assess the hazards of polyethylene glycol-polyisobutenyl anhydride-tall oil fatty acid copolymer. No toxicology data were presented in the petition as the Agency does not generally require some or all of the listed studies to rule on the exemption from the requirement of a tolerance for an inert ingredient. Based on this polymer conforming to the definition of a polymer and meeting the criteria of a polymer under 40 CFR 723.250 ICI believes there are no concerns for risks associated with toxicity.

2. *Endocrine disruption*. ICI has no information to suggest that polyethylene glycol-polyisobutenyl anhydride-tall oil fatty acid copolymer will have an effect on the immune and endocrine systems. EPA is not requiring information on the endocrine effects of this substance at this time; Congress has allowed 3 years after August 3, 1996, for the Agency to implement a screening program with respect to endocrine effects.

C. Cumulative Effects

ICI believes sufficient information was submitted in the petition to assess the hazards of polyethylene glycol-polyisobutenyl anhydride-tall oil fatty acid copolymer. Based on this polymer conforming to the definition of a polymer and meeting the criteria of a polymer under 40 CFR 723.250 ICI believes there are no concerns for risks associated with cumulative effects.

D. Safety Determination

1. *U.S. population*. ICI believes sufficient information was submitted in the petition to assess the hazards of polyethylene glycol-polyisobutenyl anhydride-tall oil fatty acid copolymer. Based on this polymer conforming to the definition of a polymer and meeting the criteria of a polymer under 40 CFR 723.250 ICI believes there are no concerns for risks associated with any potential exposure to adults.

2. *Infants and children*. ICI believes sufficient information was submitted in the petition to assess the hazards of polyethylene glycol-polyisobutenyl anhydride-tall oil fatty acid copolymer. Based on this polymer conforming to the definition of a polymer and meeting the criteria of a polymer under 40 CFR 723.250 ICI believes there are no concerns for risks associated with any potential exposure to infants and children.

[FR Doc. 99–6184 Filed 3–16–99; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[PF–863; FRL–6065–5]

Notice of Filing; Pesticide Petitions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of pesticide petitions proposing the establishment of regulations for residues of certain pesticide chemicals in or on various food commodities.

DATES: Comments, identified by the docket control number PF–863, must be received on or before April 16, 1999.

ADDRESSES: By mail submit written comments to: Information and Records Integrity Branch, Public Information and Services Divison (7502C), Office of Pesticides Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person bring comments to: Rm. 119, CM #2, 1921 Jefferson Davis Highway, Arlington, VA.

Comments and data may also be submitted electronically by following the instructions under ''SUPPLEMENTARY INFORMATION.'' No confidential business information should be submitted through e-mail.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as ''Confidential Business Information'' (CBI). CBI should not be submitted through e-mail. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 119 at the address given above, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: Bipin Gandhi, Registration Support Branch, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW, Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 707A, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703) 308–8380; e-mail: gandhi.bipin@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA has received a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Comestic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set forth in section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

The official record for this notice of filing, as well as the public version, has been established for this notice of filing under docket control number [PF–863] (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The official record is located at the address in ''ADDRESSES'' at the beginning of this document.

Electronic comments can be sent directly to EPA at:

opp-docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comment and data will also be accepted on disks in Wordperfect 5.1/6.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket control number [PF–863] and appropriate petition number. Electronic comments on this notice may be filed online at many Federal Depository Libraries.

List of Subjects

Environmental protection, Agricultural commodities, Food additives, Feed additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: March 3, 1999.

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

The petitioner summary of the pesticide petition is printed below as required by section 408(d)(3) of the FFDCA. The summary of the petition was prepared by the petitioner and represents the views of the petitioner. EPA is publishing the petition summaries verbatim without editing them in any way. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

1. Rhodia Inc.

PP 8E4956

EPA has received a pesticide petition (PP 8E4956) from Rhodia Inc., CN 7500 Cranbury, NJ 08512-7500, proposing pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 346a(d), to amend 40 CFR part 180 to request exemption from the requirements of a tolerance for a-alkyl (C8-C16)-w-hydroxy poly(oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters and the corresponding ammonium, calcium, isopropylamine, magnesium, monoethanolamine, potassium, sodium and zinc salts of the phosphate esters; the poly(oxyethylene) content averages 3 - 20 moles, in or on raw agricultural commodities. EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

The **Federal Register** of July 7, 1995 (60 FR 35396) announced the reclassification of a number of inert ingredients from List 3 to List 4B (minimal risk). The EPA included octyloxypoly(ethyleneoxy)ethyl phosphate (C8 ethoxylated phosphate ester) among the inerts of minimal risk indicating:

1. ''On behalf of the Office of Pesticide Programs, these substances were reviewed by the Structure Activity Team of EPA's Office of Pollution Prevention and Toxics with each judged to be of low concern for potential human health and/or environmental effects.''

2. ''These inert ingredients were evaluated by the Office of Pesticide Program's Inert Review Group and determined to be of minimal risk.''

3. ''A list of these inert ingredients proposed for reclassification was provided to EPA's Office of Water and to the FDA's Center for Food Safety and Applied Nutrition for comment; no adverse comments were received.''

Additionally, EPA has already exempted from the requirements of a tolerance under 40 CFR 180.1001(d): a-alkyl (C10-C16)-w-hydroxy poly(oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters and the corresponding ammonium, calcium, magnesium, monoethanolamine, potassium, sodium and zinc salts of the phosphate esters; the poly(oxyethylene) content averages 3 - 20 moles.

The extension of the alkyl range to include the C8 analog will not alter the residue profile of the phosphate esters and their salts. In fact, a number of exemptions including the C8 alkyl moiety are found in 40 CFR 180.1001, including n-octyl alcohol, alkyl amine acetates, alkyl ethoxylates and alkyl sulfate isopropylamine salts. Further, it is widely acknowledged that alcohol ethoxylates of the C10 - C16 range contain minor amounts of the C8 and lower alkyl analogs, as well as C18 and higher analogs. This petition merely requests expansion of the existing exemption from tolerance for the C10 - C16 range to include C8 alkyl ethoxylate phosphates and their salts.

The addition of the isopropylamine salts of these phosphate esters acknowledges the fact that isopropylamine is a common counterion in water-soluble herbicides.

B. Toxicological Profile

1. *Acute toxicity*. As part of the EPA policy statement on inert ingredients published in the **Federal Register** of April 22, 1987 (52 FR 13305) (FRL-3190-1), the Agency set forth a list of studies which would generally be used to evaluate the risks posed by the presence of an inert ingredient in a pesticide formulation. However, where it can be determined without the data that the inert ingredient will present minimal or no risk, the Agency generally does not require some or all of the listed studies to rule on the proposed tolerance or exemption from the requirement of a tolerance for an inert ingredient. Rhodia Inc. believes that the data and information described below is adequate to ascertain the toxicology and characterize the risk associated with the use of a-alkyl (C8-C16)-w-hydroxy poly(oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters and the corresponding ammonium, calcium, isopropylamine, magnesium, monoethanolamine, potassium, sodium and zinc salts of the phosphate esters; the poly(oxyethylene) content averages 3 - 20 moles.

While not highly acutely toxic, alkyl ethoxylate phosphate esters are known to be severely irritating to skin and eyes. However, their corresponding salts have a reduced irritation potential. For the specific alkylethoxylate phosphate ester salt blend that Rhodia Inc. petitions for exemption from the requirements of a tolerance, the acute oral LD_{50} (rat) is greater than 2,000 milligram kilogram (mg/kg), and the acute dermal LD_{50} (rat) is greater than 2,000 mg/kg. The product is considered to be an eye irritant. The product is non-irritating to rabbit skin and is negative for skin sensitization.

2. *Genotoxicity*. An Ames test conducted on the product (blended alkyl ethoxylate phosphates, isopropylamine salts) was negative.

3. *Reproductive and developmental toxicity*. The broad range of structurally similar products which are presently approved for use in pesticide formulations has not been reported to cause reproductive or developmental toxicity.

4. *Subchronic toxicity*. Similar compounds are not known to exert significant subchronic toxic effects.

5. *Chronic toxicity*. Similar compounds are not known to exert significant chronic toxic effects.

6. *Metabolite toxicology*. Alcohol ethoxylates are already exempted from the requirements of a tolerance under 40 CFR 180.1001 (c).

7. *Endocrine disruption*. There is no evidence that this product has endocrine disruptor effects, individually or in combination with any other chemical. Further, this product is not part of a class of compounds that has previously been alleged to cause endocrine effects.

C. Aggregate Exposure

1. *Food*. As noted above, a-alkyl (C10 - C16)-w-hydroxypoly(oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters and the corresponding ammonium, calcium, magnesium, monoethanolamine, potassium, sodium,and zinc salts of the phosphate esters; the poly(oxyethylene) content averages 3-20 moles have already been exempted from the requirements of a tolerance under 40 CFR 180.1001(d). The expansion of the alkyl range to include the C8 alkyl moiety is not expected to significantly affect the dietary exposure to these compounds. The inclusion of the isopropylamine salts of these phosphate esters merely acknowledges the fact that isopropylamine is a common counterion in water-soluble herbicides, and thus approval of this petition would not be expected to substantially increase the dietary intake of these compounds.

2. *Drinking water*. This class of products have been shown to readily biodegrade and are therefore, not likely to be present in potable water supplies.

3. *Non-dietary exposure*. Phosphate esters of alkyl ethoxylates, and their salts are extensively used industrially as water-soluble lubricants, as detergents and household cleaners, and in personal care products in addition to their use as emulsifiers, dispersants and suspending agents in pesticide formulations. The slight contribution to total exposure resulting from granting the petition is not expected to significantly alter the risk profile.

D. Cumulative Effects

As stated above, there are a wide range of structurally similar compounds that are used in many products to which the U.S. population is exposed. Rhodia Inc. is unaware of any cumulative effects occurring from such uses. Further, the use of the product that is the subject of the tolerance exemption petition is not likely to significantly increase daily exposure to this class of similar compounds.

E. Safety Determination

1. *U.S. population*. In its notice **Federal Register**, July 7, 1995, (60 FR 35396) which reclassified octyloxypoly(ethyleneoxy)ethyl phosphate from List 3 to List 4B (inerts of minimal risk), the Agency has stated :

i. ''On behalf of the Office of Pesticide Programs, these substances were reviewed by the Structure Activity Team of EPA's Office of Pollution

Prevention and Toxics with each judged to be of low concern for potential human health and/or environmental effects.''

ii. ''These inert ingredients were evaluated by the Office of Pesticide Program's Inert Review Group and determined to be of minimal risk.''

iii. ''A list of these inert ingredients proposed for reclassification was provided to EPA's Office of Water and to the FDA's Center for Food Safety and Applied Nutrition for comment; no adverse comments were received.''

Expansion of the uses of the product to food uses is not likely to significantly increase the U.S. population's exposure to the product and related compounds. Therefore, there is a reasonable certainty that no harm to the U.S. population will result from the use described.

2. *Infants and children*. FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for pre- and postnatal toxicity and the completeness of the data base unless EPA concludes that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through the use of margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. There is no available data to indicate any additional sensitivity of infants and children to this product or to other similar products which have been in use for many years and for numerous uses. There is no data which suggests that there is a basis to require an additional margin of safety to be applied.

F. International Tolerances

Rhodia Inc. has demonstrated to the satisfaction of the Australian Environmental Protection Authority and the Australian National Registration Authority that certain formulations of blended alkyl ethoxylate phosphate esters and salts are safe for use in and near aquatic environments. Further, because of its enhanced properties, use of this blend allows reduction of the total chemical burden of the pesticide inert ingredients on the environment.

The alkyl ethoxylate phosphate monohydrogen and dihydrogen esters and their salts, including the isopropylamine salts are being used as inert ingredients in registered pesticide formulations applied to food crops in 14 nations including European, African, South American and Pacific Rim nations. These include: United Kingdom, France, Italy, Spain, Japan, Australia, New Zealand, Brazil and Argentina.

Rhodia Inc. therefore respectfully requests that an exemption from the requirements of a tolerance be established for a-alkyl (C8-C16)-w-hydroxy poly(oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters and the corresponding ammonium, calcium, isopropylamine, magnesium, monoethanolamine, potassium, sodium and zinc salts of the phosphate esters; the poly(oxyethylene) content averages 3 - 20 moles, in or on raw agricultural commodities.

2. Rhodia Inc.

PP 8E4990

EPA has received a pesticide petition (PP 8E4990) from Rhodia Inc., CN 7500, Cranbury, NJ 08512-7500, proposing pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 346a(d), to amend 40 CFR part 180 to request exemption from the requirement of a tolerance for butoxytriethyleneglycol phosphate and the corresponding ammonium, calcium, isopropylamine, magnesium, monoethanolamine, potassium, sodium and zinc salts of the phosphate esters, and to include use with water-soluble herbicide formulations in or on raw agricultural commodities. EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

The **Federal Register** of July 7, 1995 (60 FR 35396) announced the reclassification of a number of inert ingredients from List 3 to List 4B (minimal risk). The EPA included butylpolyethoxyethanol esters of phosphoric acid among those substances on List 4B, indicating:

1. ''On behalf of the Office of Pesticide Programs, these substances were reviewed by the Structure Activity Team of EPA's Office of Pollution Prevention and Toxics with each judged to be of low concern for potentialhuman health and/or environmental effects.''

2. ''These inert ingredients were evaluated by the Office of Pesticide Program's Inert Review Group and determined to be of minimal risk.''

3. ''A list of these inert ingredients proposed for reclassification was provided to EPA's Office of Water and to the FDA's Center for Food Safety and Applied Nutrition for comment; no adverse comments were received.''

Additionally, EPA has already exempted from the requirements of a tolerance under 40 CFR 180.1001(d) the residues of butoxytriethyleneglycol phosphate when used as a surfactant for arsenical herbicides.

The addition of the isopropylamine salts of this phosphate ester to the list of substances considered exempt from the requirements of a tolerance merely acknowledges the fact that isopropylamine is a common counterion in water-soluble herbicides.

B. Toxicological Profile

1. *Acute toxicity*. As part of the EPA policy statement on inert ingredients published in the **Federal Register** of April 22, 1987 (52 FR 13305) (FRL 3190-1), the Agency set forth a list of studies which would generally be used to evaluate the risks posed by the presence of an inert ingredient in a pesticide formulation. However, where it can be determined without the data that the inert ingredient will present minimal or no risk, the Agency generally does not require some or all of the listed studies to rule on the proposed tolerance or exemption from the requirement of a tolerance for an inert ingredient. Rhodia Inc. believes that the data and information described below is adequate to ascertain the toxicology and characterize the risk associated with the use of butoxytriethyleneglycol phosphate and the corresponding ammonium, calcium, isopropylamine, magnesium, monoethanolamine, potassium, sodium and zinc salts of the phosphate esters.

Alkyl ethoxylate phosphate esters are known to be severely irritating to skin and eyes. However, their corresponding salts have a reduced irritation potential. For the specific alkyl ethoxylate phosphate ester blend that Rhodia Inc. petitions for exemption from the requirements of a tolerance, acute oral LD_{50} (rat) is greater than 2,000 milligram kilogram (mg/kg), and the acute dermal LD_{50} (rat) is greater than 2,000 mg/kg. The product is non-irritating to rabbit skin and is negative for skin sensitization. The product is considered to be an eye irritant.

2. *Genotoxicity*. An Ames test conducted on the blended alkyl ethoxylate phosphate salts was negative.

3. *Reproductive and developmental toxicity*. The broad range of structurally similar compounds has not been reported to produce reproductive or developmental toxicity.

4. *Subchronic toxicity*. Similar compounds are not know to exert significant subchronic toxic effects.

5. *Chronic toxicity*. Similar compounds are not know to exert significant chronic toxic effects.

6. *Metabolite toxicology*. Alcohol ethoxylates are already exempted from the requirements of a tolerance under 40 CFR 180.1001(c). Diethyleneglycol monobutyl ether, ethyleneglycol monobutyl ether and n-butanol are specifically exempted from the requirements of a tolerance under 40 CFR 180.1001(d). Triethylene glycol monobutyl ether, a likely metabolite, has been reported Patty's Industrial Hygiene and Toxicology, Fourth Edition, Volume II, Part D, ed. George D. Clayton, and Florence E. Clayton (New York: John Wiley & Sons, 1994), 2,860 to exhibit low acute toxicity by oral and dermal routes, to be non-toxic by the inhalation route, and to cause eye irritation and slight skin irritation.

7. *Endocrine disruption*. There is no evidence that this product has endocrine disruptor effects, individually or in combination with any other chemical. Further, this product is not part of a class of compounds that has previously been alleged to cause endocrine effects.

C. Aggregate Exposure

1. *Food*. As noted above, butoxytriethyleneglycol phosphate has already been exempted from the requirements of a tolerance under 40 CFR 180.1001(d). The addition of the expanded use to include use with water-soluble herbicides is not expected to significantly affect the dietary exposure to these compounds. The inclusion of the isopropylamine salts of these phosphate esters merely acknowledges the fact that isopropylamine is already a common counterion in water-soluble herbicides. Thus approval of this petition would not be expected to substantially increase the dietary intake of these compounds.

2. *Drinking water*. The product has been shown to readily biodegrade and therefore is not likely to be present in potable water supplies.

3. *Non-dietary exposure*. Phosphate esters of alkyl ethoxylates are widely used industrially as water-soluble lubricants, as detergents and household cleaners, and in personal care products in addition to their use as emulsifiers, dispersants and suspending agents in pesticide formulations. Given the widespread use of this group of compounds, the additional exposure resulting from granting the petition is not expected to significantly alter the risk profile.

D. Cumulative Effects

As stated above, there are a wide range of structurally similar compounds that are used in many products to which the U.S. population is exposed. Rhodia Inc. is unaware of any cumulative effects occurring from such uses. Further, the use of the product that is the subject of the tolerance exemption petition is not likely to significantly increase daily exposure to this class of similar compounds.

E. Safety Determination

1. *U.S. population*. In its notice of July 7, 1995 (60 FR 35396); which moved butylpolyethoxyethanol esters of phosphoric acid from List 3 to List 4B (inerts of minimal risk), EPA stated :

i. ''On behalf of the Office of Pesticide Programs, these substances were reviewed by the Structure Activity Team of EPA's Office of Pollution Prevention and Toxics with each judged to be of low concern for potential human health and/or environmental effects.''

ii. ''These inert ingredients were evaluated by the Office of Pesticide Program's Inert Review Group and determined to be of minimal risk.''

iii. '' List of these inert ingredients proposed for reclassification was provided to EPA's Office of Water and to the FDA's Center for Food Safety and Applied Nutrition for comment; no adverse comments were received.''

Expansion of the uses of the product to food uses is not likely to significantly increase the U.S. population's exposure to the product and related compounds. Therefore, there is a reasonable certainty that no harm to the U.S. population will result from the use described.

2. *Infants and children*. FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for pre- and postnatal toxicity and the completeness of the data base unless EPA concludes that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through the use of margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. There is no available data to indicate any additional sensitivity of infants and children to this product or to other similar products which have been in use for many years and for numerous uses. There is no data which suggests that there is a basis to require an additional margin of safety to be applied.

F. International Tolerances

Rhodia Inc. has demonstrated to the satisfaction of the Australian Environmental Protection Authority and the Australian National Registration Authority that certain formulations of blended alkyl ethoxylate phosphate esters and salts are safe for use in and near aquatic environments. Further, because of its enhanced properties, use of this blend allows reduction of the total chemical burden on the environment.

The alkyl ethoxylate phosphate monohydrogen and dihydrogen esters and their salts, including the isopropylamine salts are being used as inert ingredients in registered pesticide formulations applied to food crops in 14 nations including European, African, South American and Pacific Rim nations. These include: United Kingdom, France, Italy, Spain, Japan, Australia, New Zealand, Brazil and Argentina.

Rhodia Inc. therefore, respectfully requests that an exemption from the requirements of a tolerance be established for butoxytriethyleneglycol phosphate and the corresponding ammonium, calcium, isopropylamine, magnesium, monoethanolamine, potassium, sodium and zinc salts of the phosphate esters, and to include use with water-soluble herbicide formulations in or on raw agricultural commodities under 40 CFR 180.1001(d).

[FR Doc. 99–6183 Filed 3–16–99; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[NCEA–CD–99–1015; FRL–6310–4]

Air Quality Criteria for Carbon Monoxide (External Review Draft); Estimation of Carbon Monoxide Exposures and Associated Carboxyhemoglobin Levels in Denver Residents Using pNEM/CO (Version 2.0) (Draft)

AGENCY: Environmental Protection Agency.

ACTION: Notice of two drafts for public review and comment.

SUMMARY: The U.S. Environmental Protection Agency (EPA), National Center for Environmental Assessment, is announcing the availability of an external review draft of the document, Air Quality Criteria for Carbon Monoxide. Required under sections 108 and 109 of the Clean Air Act, the purpose of this document is to provide an assessment of the latest, relevant

scientific information that may have an impact on the next periodic review of the National Ambient Air Quality Standards (NAAQS) for carbon monoxide (CO).

The EPA's Office of Air Quality Planning and Standards (OAQPS) is announcing the availability of a draft carbon monoxide exposure analysis methodology report, Estimation of Carbon Monoxide Exposures and Associated Carboxyhemoglobin Levels in Denver Residents Using pNEM/CO (Version 2.0). This document is part of the technical support work that will be summarized in the OAQPS staff paper on carbon monoxide.

DATES: Anyone who wishes to comment on the draft document, Air Quality Criteria Document for Carbon Monoxide, may do so in writing by May 15, 1999. Send the written comments to the Project Manager for Carbon Monoxide, National Center for Environmental Assessment-RTP Office (MD–52), U.S. Environmental Protection Agency, Research Triangle Park, NC 27711.

The OAQPS draft report will be available by March 15, 1999. A letter that will be included with copies of the draft will discuss the length of time that OAQPS is allowing the public for comment and will provide mailing information for the comments.

ADDRESSES: To obtain a copy of the Air Quality Criteria for Carbon Monoxide (External Review Draft) 1999, EPA/600/P–99/001, contact the National Service Center for Environmental Publications. Request a copy by telephoning 1–800–490–9198 and provide the title and the EPA number for the document. Internet users may obtain a copy from the EPA's National Center for Environmental Assessment (NCEA's) home page. The URL is http://www.epa.gov/ncea/.

To obtain a copy of the Estimation of Carbon Monoxide Exposures and Associated Carboxyhemoglobin Levels in Denver Residents Using pNEM/CO (Version 2.0), Internet users can go to the EPA's OAR Policy and Guidance page on the OAQPS TTNWeb. The URL is http://www.epa.gov/ttn/caa/t1sp.html. A limited number of paper copies of this document will be available and can be obtained from: U.S. Environmental Protection Agency Library, MD–35, Research Triangle Park, NC 27711, telephone (919) 541–2777.

FOR FURTHER INFORMATION CONTACT: Mr. James Raub, National Center for Environmental Assessment-RTP Office (MD–52), U.S. Environmental Protection Agency, Research Triangle Park, NC 27711; telephone: 919–541–4157; facsimile: 919–541–1818; E-mail: *raub.james@epa.gov*. Mr. Raub will provide information on the draft document, Air Quality Criteria for Carbon Monoxide.

For further information related to the draft exposure analysis methodology report for Denver, contact Mr. Harvey Richmond, Office of Air Quality Planning and Standards (MD–15), U.S. Environmental Protection Agency, Research Triangle Park, NC 27711; telephone: 919–541–5271; facsimile: 919–541–0840; E-mail: *richmond.harvey@epa.gov*.

SUPPLEMENTARY INFORMATION: The U.S. Environmental Protection Agency (EPA) is updating and revising, where appropriate, the EPA's Air Quality Criteria for Carbon Monoxide (CO). Sections 108 and 109 of the Clean Air Act require that the EPA carry out a periodic review and revision, where appropriate, of the criteria and the National Ambient Air Quality Standards (NAAQS) for the ''criteria'' air pollutants such as carbon monoxide.

After the completion of the comment period, the EPA will present the external review draft of the Air Quality Criteria for Carbon Monoxide and, as supporting documentation for the OAQPS staff paper on carbon monoxide, the Estimation of Carbon Monoxide Exposures and Associated Carboxyhemoglobin Levels in Denver Residents Using pNEM/CO (Version 2.0) for review before the Clean Air Scientific Advisory Committee (CASAC) later in 1999. The EPA will issue a subsequent **Federal Register** document to inform the public of the exact date and time of this meeting.

Dated: March 9, 1999.

William H. Farland,

Director, National Center for Environmental Assessment.

[FR Doc. 99–6508 Filed 3–16–99; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–6310–5]

ILCO Superfund Site; Notice of Proposed Settlement

AGENCY: Environmental Protection Agency.

ACTION: Notice of proposed settlement.

SUMMARY: The United States Environmental Protection Agency is proposing to enter into a settlement with Vinton Scrap & Metal, Inc., pursuant to section 122(h)(1) of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), 42 U.S.C. 9622(h)(1), with respect to costs incurred or to be incurred relative to the Interstate Lead Company (ILCO) Superfund Site in Leeds, Alabama on an ability-to-pay basis. EPA will consider public comments on the proposed settlement for thirty (30) days. EPA may withdraw from or modify the proposed settlement should such comments disclose facts or considerations which indicate the proposed settlement is inappropriate, improper or inadequate. Copies of the proposed settlement are available from:

Ms. Paula V. Batchelor, U.S. EPA, Region 4 (WMD–PSB), 61 Forsyth Street SW, Atlanta, Georgia 30303, (404) 562–8887.

Written comments may be submitted to Ms. Batchelor within 30 calendar days of the date of this publication.

Dated: March 3, 1999.

Franklin E. Hill,

Chief, Program Services Branch, Waste Management Division.

[FR Doc. 99–6510 Filed 3–16–99; 8:45 am]

BILLING CODE 6560–50–M

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

Agency Information Collection Activities: Submission for OMB Review; Final Comment Request

AGENCY: Equal Employment Opportunity Commission.

ACTION: Final notice of submission for OMB review.

SUMMARY: In accordance with the Paperwork Reduction Act, the Equal Employment Opportunity Commission (EEOC) has submitted a request for clearance of the information collection described below to the Office of Management and Budget (OMB). A notice that EEOC would be submitting this request was published in the **Federal Register** on December 24, 1998, allowing for a 60-day public comment period. No comments were received.

DATES: Written comments on this final notice must be submitted on or before April 16, 1999.

ADDRESSES: Comments on this final notice should be submitted to the Office of Information and Regulatory Affairs, Attention: Danny Werfel, Desk Officer for the U.S. Equal Employment Opportunity Commission, Office of Management and Budget, 725 17th Street, N.W., Room 10235, New Executive Office Building, Washington, D.C. 20503 or electronically mailed to DWERFEL@OMB.EOP.GOV. Requests for copies of the proposed information

collection request should be addressed to Mr. Neckere at the address below.

FOR FURTHER INFORMATION CONTACT: Joachim Neckere, Director, Program Research and Surveys Division, 1801 L street, NW, Room 9222, Washington, DC 20507, (202) 663–4958 (voice) or (202) 663–7063 (TDD).

SUPPLEMENTARY INFORMATION:

Collection Title: Elementary-Secondary Staff Information Report EEO–5.

OMB Number: 0346–0003.

Frequency of Report: Biennial.

Type of Respondent: Public elementary and secondary school districts with 100 or more employees.

Description of Affected Public: State and Local government.

Number of Responses: 5,000.

Reporting Hours: 12,000.

Federal Cost: $80,000.

Number of Forms: 1.

Abstract: Section 709(c) of Title VII of the Civil Rights Act of 1964 requires employers to make and keep records relevant to a determination of whether unlawful employment practices have been or are being committed and to make reports therefrom as required by the EEOC. Pursuant to that section, the EEOC has issued regulations which set forth the reporting requirement for various kinds of employers. Public elementary and secondary schools systems and districts have been required to submit EEO–5 reports to EEOC since 1974 (biennially in even numbered years since 1982). Since 1996 each school district or system has submitted all of the district data on a single form, EEOC Form 168A. The individual school form, EEOC Form 168B, was discontinued in 1996, greatly reducing the respondent burden and cost.

EEO–5 data are used by the EEOC to investigate charges of employment discrimination against public elementary and secondary school districts. The data are used to support EEOC decisions and conciliations, and for research. The data are shared with the Department of Education (Office for Civil Rights and the National Center for Education Statistics) and the Department of Justice. Pursuant to Section 709(d) of Title VII of the Civil Rights Act of 1964, EEO–5 data are also shared with State and local Fair Employment Practices Agencies.

Burden Statement: The estimated number of respondents included in the EEO–5 collection is 5,000 public elementary and secondary school districts. The number of responses per respondent is one (1) report. The annual number of responses is approximately 5,000 and the total hours per response is between one (1) and five (5) hours. Based upon the large number of school districts responding via diskette, the total number of response hours is estimated to equal 12,000 each time the survey is conducted (i.e. biennially). Respondents are encouraged to report data on electronic media such as magnetic tapes and diskettes.

Dated: March 9, 1999.

For the Commission.

Ida L. Castro,

Chairwoman.

[FR Doc. 99–6397 Filed 3–16–99; 8:45 am]

BILLING CODE 6570–01–M

FEDERAL DEPOSIT INSURANCE CORPORATION

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Notice of information collection to be submitted to OMB for review and approval under the Paperwork Reduction Act of 1995.

SUMMARY: In accordance with requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the FDIC hereby gives notice that it plans to submit to the Office of Management and Budget (OMB) a request for OMB review and approval of the information collection system described below.

Type of Review: Revision of a currently approved collection.

Title: Acquisition Services Information Requirements.

Form Number: 1600/07.

OMB Number: 3064–0072.

Annual Burden:

Estimated annual number of respondents: 31,528

Estimated time per response: varies from 0.25 hours to one hour

Average annual burden hours: 13,233 hours

Expiration Date of OMB Clearance: August 31, 2001.

OMB Reviewer: Alexander T. Hunt, (202) 395–7860, Office of Management and Budget, Office of Information and Regulatory Affairs, Washington, D.C. 20503.

FDIC Contact: Tamara R. Manly, (202) 898–7453, Office of the Executive Secretary, Room F–4058, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC 20429.

Comments: Comments on this collection of information are welcome and should be submitted on or before April 16, 1999 to both the OMB reviewer and the FDIC contact listed above.

ADDRESSES: Information about this submission, including copies of the proposed collection of information, may be obtained by calling or writing the FDIC contact listed above.

SUPPLEMENTARY INFORMATION: The collection involves the submission of information on Form 1600/07 by contractors who wish to do business, have done business, or are currently under contract with the FDIC. The information is used to enter contractors on the FDIC's nationwide contractor database (the National Contractor System); ensure compliance with established contractors ethics regulations (12 CFR 366); obtain information on a contractor's past performance for proposal evaluation purposes; and review a potential lessor's fitness and integrity prior to entering into a lease transaction.

Dated: March 10, 1999.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 99–6410 Filed 3–16–99; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL RESERVE SYSTEM

Agency Information Collection Activities: Announcement of Board Approval Under Delegated Authority and Submission to OMB

AGENCY: Board of Governors of the Federal Reserve System

BACKGROUND: Notice is hereby given of the final approval of proposed information collection by the Board of Governors of the Federal Reserve System (Board) under OMB delegated authority, as per 5 CFR 1320.16 (OMB Regulations on Controlling Paperwork Burdens on the Public). Board-approved collections of information are incorporated into the official OMB inventory of currently approved collections of information. Copies of the OMB 83-Is and supporting statements and approved collection of information instruments are placed into OMB's public docket files. The Federal Reserve may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

FOR FURTHER INFORMATION CONTACT: Chief, Financial Reports Section—Mary M. West—Division of Research and

Statistics, Board of Governors of the Federal Reserve System, Washington, DC 20551 (202-452-3829).

OMB Desk Officer—Alexander T. Hunt—Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 3208, Washington, DC 20503 (202-395-7860).

SUPPLEMENTARY INFORMATION:

General Information: On December 28, 1998, the Board issued for public comment proposed revisions to certain bank holding company reports (63 FR 71470). The comment period expired on February 26, 1999. The Board did not receive any letters of comment.

Final approval under OMB delegated authority of the extension for three years, with revision, of the following reports:

1. Report title: Consolidated Financial Statements for Bank Holding Companies

Agency form number: FR Y-9C

OMB control number: 7100-0128

Frequency: Quarterly

Reporters: Bank holding companies

Annual reporting hours: 211,995

Estimated average hours per response: 33.93

Number of respondents: 1,562

Small businesses are affected.

General description of report: This information collection is mandatory (12 U.S.C. 1844(b) and (c) and 12 CFR 225.5(b)). Confidential treatment is not routinely given to the data in these reports. However, confidential treatment for the reporting information, in whole or in part, can be requested in accordance with the instructions to the form. Data reported on the FR Y-9C, Schedule HC-H, Column A, requiring information of assets past due 30 through 89 days and still accruing and memorandum item 2 are confidential pursuant to Section (b)(8) of the Freedom of Information Act 5 U.S.C. 552(b)(8).

Abstract: The FR Y-9C consists of standardized consolidated financial statements similar to commercial bank Report of Condition and Income (Call Report) (FFIEC 031-034; OMB No. 7100-0036). The FR Y-9C is filed quarterly by top-tier bank holding companies that have total assets of $150 million or more and by lower-tier bank holding companies that have total consolidated assets of $1 billion or more. In addition, multibank holding companies with total consolidated assets of less than $150 million with debt outstanding to the general public or engaged in certain nonbank activities must file the FR Y-9C.

Current actions: The Board approved the following changes to the FR Y-9C effective with the March 31, 1999, reporting date.

CHANGES RELATED TO CURRENT REVISIONS TO THE CALL REPORT

Schedule HC — Consolidated Balance Sheet

(1) Add an item on the balance sheet for net gains (losses) on cash flow hedges due to Financial Accounting Standards Board (FASB) Statement No. 133, *Accounting for Derivative Instruments and Hedging Activities* (FAS 133). This statement takes effect for fiscal years beginning after June 15, 1999, with earlier application encouraged.

Under FAS 133, all derivatives must be reported as either assets or liabilities on the balance sheet and must be carried at fair value. If certain conditions are met, a derivative may be specifically designated as a cash flow hedge. In a cash flow hedge, to the extent the hedge is effective, the gain or loss on the derivative is initially reported outside of earnings in a component of equity capital. The gain or loss will subsequently go through earnings in the period or periods when the transaction being hedged affects earnings. The ineffective portion of the hedge is reported in earnings immediately.

As part of the disclosure requirements of FAS 133, an entity must disclose the accumulated net gains (losses) on cash flow hedges that are included in equity capital as of the balance sheet date. The Board approved adding the item Accumulated net gains (losses) on cash flow hedges, as of the report date, as new item 27.f in the equity capital section of the balance sheet. Current items 27.f through 27.h will be renumbered as items 27.g through 27.i.

(2) Revise balance sheet item 10.b(1), Purchased credit card relationships, to include nonmortgage servicing assets (NMSAs). The caption for this item will be Purchased credit card relationships and nonmortgage servicing assets. On August 10, 1998, the Federal Reserve published a final rule amending the regulatory capital treatment of servicing assets (63 FR 42668). Under this amendment, NMSAs will now be recognized (rather than deducted) for regulatory capital purposes. However, these servicing assets are subject to a sublimit of 25 percent of Tier 1 capital that previously applied only to purchased credit card relationships (PCCRs). To date, bank holding companies have reported their NMSAs as part of All other identifiable intangible assets, item 10.b.(2). This is because these intangibles generally have been deducted in full from Tier 1 capital and from assets in regulatory capital calculations. As a result of the revised regulatory capital treatment of NMSAs, these assets need to be distinguished from All other identifiable intangible assets. This change is needed to enable the Federal Reserve to verify the regulatory capital amounts that bank holding companies report in the FR Y-9C and to calculate regulatory capital ratios.

Schedule HC-A — Securities

Eliminate memorandum item 5, High-risk mortgage securities. The definition of high-risk mortgage securities was taken from the Supervisory Policy Statement on Securities Activities, which the FFIEC approved and the Federal Reserve adopted in December 1991, effective February 10, 1992 (57 FR 4029, February 3, 1992). In April 1998, the FFIEC and the Federal Reserve rescinded this policy statement and approved in its place a Supervisory Policy Statement on Investment Securities and End-User Derivatives Activities, effective May 26, 1998 (63 FR 20191, April 23, 1998). In adopting the new policy statement, the Federal Reserve removed the previous policy statements specific constraints concerning investments in high-risk mortgage securities, including its high risk tests, and substituted broader guidance covering all investment securities.

Schedule HC-I — Risk-Based Capital

Revise memorandum item 7.b, Fair market value of purchased credit card relationships to include the fair market value of nonmortgage servicing assets. This item would be renumbered memorandum item 7 since the current memorandum item 7.a will be eliminated (see Other Revisions Not Related to Call Report Changes section below). The caption for this item will be Fair value of purchased credit card relationships and nonmortgage servicing assets. The Federal Reserve has determined that this information is needed to accurately measure the risk-based capital treatment of servicing assets under the Federal Reserves amended capital adequacy guidelines.

Schedule HI-A — Changes in Equity Capital

Add an item for the change in accumulated net gains (losses) on cash flow hedges. As part of the disclosure requirements of FAS 133, bank holding companies will also disclose the year-to-date change in accumulated net gains (losses) on cash flow hedges that are included in equity capital. Bank holding companies will report the year-to-date change in these accumulated gains (losses), net of any reclassification adjustment, in the changes in equity capital schedule as new item 13.b.

Existing item 13 on Schedule HI-A will be renumbered as item 13.a.

Other Revisions Not Related to Call Report Changes

Schedule HC-A — Securities

Add an item for net unrealized holding gains on available-for-sale equity securities included in supplemental (Tier 2) capital. On August 26, 1998, the Federal Reserve along with the other banking agencies announced a final rule amending the capital treatment of unrealized holding gains on certain equity securities. The final rule permits bank holding companies to include in supplementary (Tier 2) capital up to 45 percent of the pretax net unrealized holding gains (that is, of the fair value over historical cost) on available-for-sale equity securities with readily determinable fair values. This is an optional designation for bank holding companies. However, if an institution opts to include an amount of unrealized holding gains in its Tier 2 capital, it must also include that same amount in its risk-weighted assets for all of its risk-based capital ratios (including the Tier 1 risk-based capital ratio). Bank holding companies that take this option will report net unrealized holding gains on available-for-sale equity securities included in Tier 2 and total capital ratios on Schedule HC-A, in new memorandum item 4.c.

Schedule HC-I — Risk-Based Capital

Eliminate the reporting requirements of memorandum item 7.a, Purchased credit card relationships: Discounted value. The Federal Reserve has determined that this item is of limited use.

Notes to the Balance Sheet/Income Statement

Expand the Notes to the Balance Sheet and Notes to the Income Statement sections to allow space for up to twenty optional comments.

Instructions

Instructional revisions and clarifications will be done in accordance with changes made to the Call Report instructions and revisions to the Capital Guidelines.

2. Report title: Parent Company Only Financial Statements for Large Bank Holding Companies

Agency form number: FR Y-9LP
OMB control number: 7100-0128
Frequency: Quarterly
Reporters: Bank holding companies
Annual reporting hours: 34,925
Estimated average hours per response: 4.61
Number of respondents: 1,894
Small businesses are affected.

General description of report: This information collection is mandatory (12 U.S.C. 1844(b) and (c) and 12 CFR 225.5(b)). Confidential treatment is not routinely given to the data in this report. However, confidential treatment for the reporting information, in whole or in part, can be requested in accordance with the instructions to the form.

Abstract: The FR Y-9LP includes standardized financial statements filed quarterly on a parent company only basis from each bank holding company that files the FR Y-9C. In addition, for tiered bank holding companies, a separate FR Y-9LP must be filed for each lower tier bank holding company.

Current actions: The Board approved the following revisions to the FR Y-9LP effective with the March 31, 1999, reporting date.

Schedule PC — Parent Company Only Balance Sheet

Add an item on the balance sheet for accumulated net gains (losses) on cash flow hedges. As part of the disclosure requirements for FAS 133, the Federal Reserve will add the item Accumulated net gains (losses) on cash flow hedges, as of the report date, as new item 20.f in the equity capital section of the balance sheet. Current items 20.f and 20.g would be renumbered as items 20.g and 20.h.

Instructions

Instructional revisions and clarifications will be made as necessary, to conform with changes made to the FR Y-9C.

3. Report title: Parent Company Only Financial Statements for Small Bank Holding Companies

Agency form number: FR Y-9SP
OMB control number: 7100-0128
Frequency: Semiannual
Reporters: Bank holding companies
Annual reporting hours: 31,324
Estimated average hours per response: 3.87
Number of respondents: 4,047
Small businesses are affected.

General description of report: This information collection is mandatory (12 U.S.C. 1844(b) and (c) and 12 CFR 225.5(b)). Confidential treatment is not routinely given to the data in this report. However, confidential treatment for the reporting information, in whole or in part, can be requested in accordance with the instructions to the form.

Abstract: The FR Y-9SP is a parent company only financial statement filed on a semiannual basis by one-bank holding companies with total consolidated assets of less than $150 million, and multibank holding companies with total consolidated assets of less than $150 million that meet certain other criteria. This report, an abbreviated version of the more extensive FR Y-9LP, is designed to obtain basic balance sheet and income statement information for the parent company, information on intangible assets, and information on intercompany transactions.

Current actions: The Board approved the following revisions to the FR Y-9SP effective with the June 30, 1999, reporting date.

Balance Sheet

Add an item on the balance sheet for accumulated net gains (losses) on cash flow hedges. As part of the disclosure requirements for FAS 133, the Federal Reserve will add the item Accumulated net gains (losses) on cash flow hedges, as of the report date, as new item 16.e in the equity capital section of the balance sheet. Current item 16.e will be renumbered as item 16.f.

Instructions

Instructional revisions and clarifications will be made as necessary, to conform with changes made to the FR Y-9C.

Final approval under OMB delegated authority of the extension for three years, without revision, of the following report:

1. Report title: Supplement to the Consolidated Financial Statements for Bank Holding Companies

Agency form number: FR Y-9CS
OMB control number: 7100-0128
Frequency: up to 4 times per year
Reporters: Bank holding companies
Annual reporting hours: 1,200
Estimated average hours per response: 0.50
Number of respondents: 600
Small businesses are affected.

General description of report: This information collection is mandatory (12 U.S.C. 1844(b) and (c)) and 12 CFR 225.5(b). Confidential treatment is not routinely given to the data in this report. However, confidential treatment for the reporting information, in whole or in part, can be requested in accordance with the instructions to the form.

Abstract: The FR Y-9CS is a free form supplement to the Consolidated Financial Statements for Bank Holding Companies (FR Y-9C; OMB No. 7100-0128) used to collect any additional information deemed critical and needed in an expedited manner. The FR Y-9C consists of standardized consolidated financial statements filed quarterly by bank holding companies.

Final approval under OMB delegated authority of the revision, without extension, of the following reports:

1. Report title: Quarterly Financial Statements of Nonbank Subsidiaries of Bank Holding Companies

Agency form number: FR Y-11Q
OMB control number: 7100-0244
Frequency: Quarterly
Reporters: Bank holding companies

Annual reporting hours: 10,683
Estimated average hours per response: 6.24
Number of respondents: 428
Small businesses are affected.
General description of report: This information collection is mandatory (12 U.S.C. 1844(b) and (c) and 12 CFR 225.5(b)). Confidential treatment is not routinely given to most of the data in this report. However, confidential treatment for the reporting information, in whole or in part, can be requested in accordance with the instructions to the form. FR Y-11Q, memorandum item 7.a, loans and leases past due 30 through 89 days and FR Y-11Q, memorandum item 7.d, loans and leases restructured and included in past due and nonaccrual loans are confidential pursuant to Section (b)(8) of the Freedom of Information Act 5 U.S.C. 552(b)(8).
Abstract: The FR Y-11Q is filed quarterly by the top tier bank holding companies for each nonbank subsidiary of a bank holding company with total consolidated assets of $150 million or more in which the nonbank subsidiary has total assets of 5 percent or more of the top-tier bank holding companys consolidated Tier 1 capital, or where the nonbank subsidiaries total operating revenue equals 5 percent or more of the top-tier bank holding companys consolidated total operating revenue. The report consists of a balance sheet, income statement, off-balance-sheet items, information on changes in equity capital, and a memoranda section.
Current actions: The Board approved minor revisions to the FR Y-11Q effective with the March 31, 1999, reporting date.
Balance Sheet
Add an item on the balance sheet for accumulated net gains (losses) on cash flow hedges. As part of the disclosure requirements for FAS 133, the Board approved adding the item Accumulated net gains (losses) on cash flow hedges, as of the report date, as new item 20.f in the equity capital section of the balance sheet. Current items 20.f through 20.h will be renumbered as items 20.g through 20.i.
Notes to the Financial Statements
Add a section for Notes to the Financial Statements. The Board approved adding this section to allow respondents the opportunity to provide, at their option, any material information included in specific line items on the financial statements that the bank holding company wishes to explain. The section will have space for up to ten comments.
Instructions
Instructional revisions and clarifications will be made as necessary, to conform with changes made to the FR Y-9C.

2. Report title: Annual Financial Statements of Nonbank Subsidiaries of Bank Holding Companies
Agency form number: FR Y-11I
OMB control number: 7100-0244
Frequency: Annual
Reporters: Bank holding companies
Annual reporting hours: 6,762
Estimated average hours per response: 3.24
Number of respondents: 2,087
Small businesses are affected.
General description of report: This information collection is mandatory (12 U.S.C. 1844(b) and (c) and 12 CFR 225.5(b)). Confidential treatment is not routinely given to the data in this report. However, confidential treatment for the reporting information, in whole or in part, can be requested in accordance with the instructions to the form. FR Y-11I, Schedule A, item 7.a, loans and leases past due 30 through 89 days and FR Y-11I, Schedule A, item 7.d, loans and leases restructured and included in past due and nonaccrual loans are confidential pursuant to Section (b)(8) of the Freedom of Information Act 5 U.S.C. 552(b)(8).
Abstract: The FR Y-11I is filed annually by the top tier bank holding companies for each of their nonbank subsidiaries that are not required to file a quarterly FR Y-11Q. The FR Y-11I report consists of similar balance sheet, income statement, off-balance-sheet, and change in equity capital information that is included on the FR Y-11Q. However, some of the items on the FR Y-11I are collected in a less detailed manner. In addition, the FR Y-11I also includes a loan schedule to be submitted only by respondents engaged in extending credit.
Current actions: The Board approved a minor revision to the FR Y-11I effective with the December 31, 1999, reporting date.
Notes to the Financial Statements
Add a section for Notes to the Financial Statements. The Board approved adding this section to allow respondents the opportunity to provide, at their option, any material information included in specific line items on the financial statements that the bank holding company wishes to explain. The section will have space for up to ten comments.
Instructions
Instructional revisions and clarifications will be made as necessary, to conform with changes made to the FR Y-9C.
Administrative Procedure Act
Because the data collections referred to herein are contained in a substantive rule, the Board has chosen to follow the more detailed notice and comment procedures of substantive rulemaking that are contained in the Administrative Procedure Act and the Paperwork Reduction Act. The Administrative Procedures Act (5 U.S.C. 553(d)) provides that the required publication or service of a substantive rule shall be made not less that 30 days before its effective date, except as otherwise provided by the agency for good cause found and published with the rule. The substantive changes to these reports are proposed to keep the reporting requirements consistent with those changes being incorporated in the Call Report to be filed by commercial banks as of March 31, 1999. In the past, bank holding companies have commented that the reporting burden is minimized by keeping the Call Report and the bank holding company reports consistent and by implementing the changes on the same date. Furthermore, the effective date of the revisions was published in the initial notice and no comments were received addressing the effective date. For these reasons, in accordance with 5 U.S.C. 553(d)(3), the Board finds there is good cause not to follow the 30-day notice requirements of 5 U.S.C. 553(d) and to make the implementation date for the revised FR Y-9C, FR Y-9LP, and FR Y-11Q reports effective for March 31, 1999.
Regulatory Flexibility Act Analysis
The Board certifies that the above bank holding company reporting requirements are not expected to have a significant economic impact on small entities within the meaning of the Regulatory Flexibility Act (5 U.S.C. 601 et seq.). The reporting requirements for the small companies require significantly fewer items of data to be submitted than the amount of information required of large bank holding companies.
The information that is collected on the reports is essential for the detection of emerging financial problems, the assessment of a holding company's financial condition and capital adequacy, the performance of pre-inspection reviews, and the evaluation of expansion activities through mergers and acquisitions. The imposition of the reporting requirements is essential for the Board's supervision of bank holding companies under the Bank Holding Company Act.

Board of Governors of the Federal Reserve System, March 11, 1999.

Robert deV. Frierson,

Associate Secretary of the Board.

[FR Doc. 99–6457 Filed 3–16–99; 8:45AM]
Billing Code 6210–01–F

FEDERAL RESERVE SYSTEM

Agency Information Collection Activities: Announcement of Board Approval Under Delegated Authority and Submission to OMB

AGENCY: Board of Governors of the Federal Reserve System

SUMMARY

Background. Notice is hereby given of the final approval of proposed information collections by the Board of Governors of the Federal Reserve System (Board) under OMB delegated authority, as per 5 CFR 1320.16 (OMB Regulations on Controlling Paperwork Burdens on the Public). Board-approved collections of information incorporated into the official OMB inventory of currently approved collections of information. Copies of the OMB 83-Is and supporting statements and approved collection of information instruments are placed into OMB's public docket files. The Federal Reserve may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

FOR FURTHER INFORMATION CONTACT:

Chief, Financial Reports Section—Mary M. West—Division of Research and Statistics, Board of Governors of the Federal Reserve System, Washington, DC 20551. (202-452-3829)Telecommunications Device for the Deaf (TDD) users may contact Diane Jenkins (202-452-3544), Board of Governors of the Federal Reserve System, Washington, DC 20551.

OMB Desk Officer—Alexander T. Hunt—Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 3208, Washington, DC 20503 (202-395-7860)

Final approval under OMB delegated authority of the extension for three years, without revision, of the following report:

1. Report title: Report of Net Debit Cap
Agency form number: FR 2226
OMB control number: 7100-0217
Frequency: annual
Reporters: depository institutions, Edge and agreement corporations, U.S. branches and agencies of foreign banks
Annual reporting hours: 2,160
Estimated average hours per response: 1.0
Number of respondents: 2,160
Small businesses are not affected.
General description of report: This information collection is mandatory (12 U.S.C. 248(i), 248-l, and 464) and is given confidential treatment (5 U.S.C. 552 (b)(4)).
Abstract: The Federal Reserve's payment system risk reduction policy relies in part on the efforts of individual institutions to identify, control, and reduce their exposure. Institutions that incur daylight overdrafts in their Federal Reserve accounts and wish to establish a capacity for overdrafts greater than that afforded by an exempt cap, or that use interaffiliate transfer arrangements, submit the FR 2226 resolutions.

Final approval under OMB delegated authority of the extension for three years, with minor revision, of the following reports:

1. Report title: Annual Daylight Overdraft Capital Report for U.S. Branches and Agencies of Foreign Banks
Agency form number: FR 2225
OMB control number: 7100-0216
Frequency: annual
Reporters: foreign banks with U.S. branches or agencies
Annual reporting hours: 50
Estimated average hours per response: 1.0
Number of respondents: 50
Small businesses are not affected.
General description of report: This information collection is voluntary (12 U.S.C. 248(i), 248-l, and 464) and is not given confidential treatment.
Abstract: This report was implemented in March 1986 as part of the procedures used to administer the Federal Reserve's Payments System Risk Policy. Foreign banks with U.S. branches or agencies have the option of filing the FR 2225 to provide the Federal Reserve with their parent bank's worldwide capital figure. A percentage of this figure is used in place of publicly available data to calculate the bank's daylight overdraft limit. Because the FR 2225 data are based on the capital of the worldwide bank, not just its United States offices, foreign banks seeking to maximize their daylight overdraft limit may find it advantageous to file the FR 2225.

Currently the FR 2225 data are treated as confidential. Because much of the data reported by respondents is publicly available, however, the Federal Reserve has determined upon review that it does not have the authority to treat all reports filed as confidential. The Federal Reserve changed the confidentiality statement on the form to a question to provide respondents an opportunity to request confidentiality treatment for any portion of the report.

2. Report titles:

Registration Statement for Persons Who Extend Credit Secured by Margin Stock (Other than Banks, Brokers, or Dealers);

Deregistration Statement for Persons Registered Pursuant to Regulation U;

Statement of Purpose for an Extension of Credit Secured by Margin Stock by a Person Subject to Registration Under Regulation U;

Annual Report;

Statement of Purpose for an Extension of Credit by a Creditor;

Statement of Purpose for an Extension of Credit Secured by Margin Stock

Agency form numbers: FR G-1, FR G-2, FR G-3, FR G-4, FR T-4, FR U-1
OMB control numbers:
7100-0011: FR G-1, FR G-2, FR G-4
7100-0018: FR G-3
7100-0019: FR T-4
7100-0115: FR U-1
Frequency:
FR G-1, FR G-2, FR G-3, FR T-4, FR U-1: on occasion
FR G-4: annual
Reporters: individuals and businesses
Annual reporting hours: 1,688 reporting; 254,032 recordkeeping
Estimated average hours per response:
FR G-1: 2.5
FR G-2: 15 minutes
FR G-3: 10 minutes
FR G-4: 2.0
FR T-4: 10 minutes
FR U-1: 10 minutes
Number of respondents:
FR G-1: 96
FR G-2: 71
FR G-3: 810
FR G-4: 715
FR T-4: 125
FR U-1: 6,971
Small businesses are affected.
General description of reports: This information collection is mandatory (FR G-1, FR G-3, FR G-4, FR T-4, FR U-1) or required to obtain a benefit (FR G-2) (15 U.S.C. 78g and 78w). The information in the FR G-1 and FR G-4 is given confidential treatment (5 U.S.C. 552 (b)(4)). The FR G-2 does not contain confidential information. The FR G-3, FR T-4, and FR U-1 are not submitted to the Federal Reserve and, as such, no issue of confidentiality arises.
Abstract: The Securities Exchange Act of 1934 authorizes the Federal Reserve to regulate securities credit issued by banks, brokers and dealers, and other lenders. The purpose statements, FR U-1, FR T-4, and FR G-3, are recordkeeping requirements for banks, brokers and dealers, and other lenders, respectively, to document the purpose of their loans secured by margin stock. Other lenders also must register and deregister with the Federal Reserve using the FR G-1 and FR G-2, respectively, and must file an annual report (FR G-4). The Federal Reserve

uses the data to identify lenders subject to Regulation U (which now incorporates Regulation G), to verify compliance with Regulations T, U, and X, and to monitor margin credit.

The revisions update the reports for recent modifications in the applicable regulations. The Federal Reserve amended Regulations G, T, U, and X effective April 1, 1998, to reflect changes in the Federal Reserve's statutory authority made by the National Securities Markets Improvement Act of 1996. None of the modifications result in substantive changes in the information collections.

Board of Governors of the Federal Reserve System, March 11, 1999.

Robert deV. Frierson,

Associate Secretary of the Board.

[FR Doc. 99–6427 Filed 3–16–99; 8:45AM]

Billing Code 6210–01–F

FEDERAL TRADE COMMISSION

[File No. 992–3025]

R.J. Reynolds Tobacco Company; Analysis to Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed Consent Agreement.

SUMMARY: the consent agreement in this matter settles alleged violations of federal law prohibiting unfair or deceptive acts or practices or unfair methods of competition. The attached Analysis to Aid Public Comment describes both the allegations in the draft compliant that accompanies the consent agreement and the terms of the consent order—embodied in the consent agreement—that would settle these allegations.

DATES: Comments must be received on or before May 17, 1999.

ADDRESSES: Comments should be directed to: FTC/Office of the Secretary, Room 159, 6th St. and Pa. Ave., NW., Washington, DC 20580.

FOR FURTHER INFORMATION CONTACT: Joel Winston or Beth Grossman, FTC/S–4002, Washington, DC 20580. (202) 326–3153 or 326–3019.

SUPPLEMENTARY INFORMATION: Pursuant to Section 6(f) of the Federal Trade Commission Act, 38 Stat. 721, 15 U.S.C. 46 and Section 2.34 of the Commission's Rules of Practice (16 CFR 2.34), notice is hereby given that the above-captioned consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of sixty (60) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement, and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC Home Page (for March 3,1999), on the World Wide Web, at ''http://www.ftc.gov/os/actions97.htm.'' A paper copy can be obtained from the FTC Public Reference Room, Room H–130, Sixth Street and Pennsylvania Avenue, NW, Washington, DC 20580, either in person or by calling (202) 326–3627. Public comment is invited. Such comments or views will be considered by the Commission and will be available for inspection and copying at its principal office in accordance with Section 4.9(b)(6)(ii) of the Commission's Rules of Practice (16 CFR 4.9(b)(6)(ii)).

Analysis of Proposed Consent Order to Aid Public Comment

The Federal Trade Commission has accepted an agreement to a proposed consent order from R.J. Reynolds Tobacco Company (''Reynolds'').

The proposed consent order has been placed on the public record for sixty (60 days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After sixty (60) days, the Commission will again review the agreement and the comments received, and will decide whether it should withdraw from the agreement or make final the agreements' proposed order.

This matter involves an alleged deceptive representation for Winston cigarettes, that Reynolds has advertised do not contain additives. According to the FTC complaint, through these advertisements, Reynolds represented that smoking Winston cigarettes, because they contain no additives, is less hazardous to a smoker's health than smoking otherwise comparable cigarettes that contain additives. The complaint alleges that Reynolds did not have a reasonable basis for the representation at the time it was made. Among other reasons, according to the complaint, the smoke from Winston cigarettes, like the smoke from all cigarettes, contains numerous carcinogens and toxins.

The proposed consent order contains provisions designed to prevent Reynolds from engaging in similar acts and practices in the future.

Part I of the order requires Reynolds to include the following clear and prominent disclosure in certain advertising for its Winston cigarettes: No additives in our tobacco does NOT mean a safer cigarette. (The order requires a similar disclosure in advertising for other tobacco products Reynolds advertises as having no additives.) The disclosure must be included in all advertising for Winston no-additive cigarettes, regardless of whether that advertising contains a ''no additives'' claim, for a period of one year beginning no later than July 15, 1999. The disclosure must be included in all Winston advertising that represents (through such phrases as ''no additives'' or ''100% tobacco'') that the product has no additives, for the duration of the order. This Part also contains certain exemptions from the disclosure requirement:

- Advertisements not required to bear the Surgeon General's health warning;
- Certain ads for bona fide events or teams sponsored by Winston which contain neither a ''No additives'' claim nor any other selling message or product description; and
- If Reynolds possesses scientific evidence demonstrating that its ''no additives'' cigarette poses materially lower health risks than other cigarettes of the same type.

Part I also specifies the manner in which the disclosure must be made, which is exemplified by two model advertisements attached to the order. In general, the disclosure must be within a rectangular box that is no less than 40% of the size of the box containing the Surgeon General's warning.

Part II of the order requires Reynolds to instruct each of its sales representatives to remove or sticker, with the applicable disclosure, any advertisement displayed in a retail establishment representing that Winston cigarettes have no additives. All such actions must be completed by July 15, 1999.

Part III–VII of the order require Reynolds to keep copies of relevant advertisements and materials substantiating claims made in the advertisements; to provide copies of the order to certain of its personnel; to notify the Commission of changes in the composition or formula of Winston cigarettes that may affect the order; to notify the Commission of changes in corporate structure; and to file compliance reports with the Commission. Part VIII provides that the order will terminate after twenty (20 years under certain circumstances.

The purpose of this analysis is to facilitate public comment on the proposed order, and it is not intended to constitute an official interpretation of the agreement and proposed order to modify in any way their terms.

By direction of the Commission.

Donald S. Clark,

Secretary.

Concurring Statement of Commissioner Orson Swindle

R.J. Reynolds Tobacco Co., File No. 992–3025

I have voted to accept this consent agreement for public comment because the remedies, including corrective statement in Winston Advertisements for one year, are warranted by the facts of this case. The nationwide advertising campaign for ''no additives'' Winston cigarettes, launched in August 1997, is unusually extensive. Based on my reading of the record, I am convinced that many consumers interpret ads containing express ''no additives'' claims to mean that Winstons are not as harmful as other cigarettes, and such health claim is presumably important to consumers in their purchasing decisions. Based on the extent and magnitude of the ongoing ad campaign and the demonstrated strength of the implied health claim, I am willing to infer that the claim will linger in the minds of consumers for one year absent a corrective statement. I am particularly concerned about a lingering effect of the ads because of the well-recognized health risks of smoking. Under these circumstances, I support the corrective advertising remedy contained in the proposed consent order.

[FR Doc. 99–6486 Filed 3–16–99; 8:45 am]

BILLING CODE 6750–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Notice of Meeting of the Advisory Committee on Blood Safety and Availability

AGENCY: Office of the Secretary.

ACTION: Notice of meeting.

The Advisory Committee on Blood Safety and Availability will meet on Thursday, April 29, 1999 from 8:00 a.m. to 5:00 p.m. and Friday, April 30, 1999, from 8:00 a.m. to 5:00 p.m. The meeting will take place in the Holiday Inn Bethesda, 8120 Wisconsin Avenue, Bethesda, Maryland 20814. The meeting will be entirely open to the public.

At its meeting the Committee will examine the extend of the nation's reserves of blood and blood products. The committee will review information presented to it by representatives of consumers, industry and government agencies. At the conclusion of these presentations, the public will be invited to comment. The committee will then discuss what, if any, recommendations to make to the Department on this matter. It will then consider old and new business as time permits.

Prospective speakers should notify the Executive Secretary of their desire to address the Committee and should plan for no more than 5 minutes of comment.

FOR FURTHER INFORMATION CONTACT: Stephen D. Nightingale, M.D., Executive Secretary, Advisory Committee on Blood Safety and Availability, Office of Public Health and Science, Department of Health and Human Services, Room 736E, 200 Independence Avenue SW., Washington, DC 20201. Phone (202) 690–5560, FAX (202) 690–6584 e-mail SNIGHTIN@osophs.dhh.gov.

Dated: March 8, 1999.

Stephen D. Nightingale,

Executive Secretary, Advisory Committee on Blood Safety and Availability.

[FR Doc. 99–6414 Filed 3–16–99; 8:45 am]

BILLING CODE 4160–17–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Assistant Secretary for Planning and Education

Privacy Act of 1974; Deletion of a System of Records

AGENCY: Office of the Assistant Secretary for Planning and Evaluation (ASPE), Office of the Secretary (OS).

ACTION: Notification of Deletion of Department of Health and Human Services Privacy Act System of Records.

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, as amended, 5 U.S.C. 552a, the Office of the Assistant Secretary for Planning and Evaluation, Department of Health and Human Services, is deleting form the agency's inventory the system of records entitled ''National Long-Term Care Channeling Demonstration, HHS/OS/ASPE, 09–90–0088.'' This system or records is obsolete and the information is no longer collected or maintained.

EFFECTIVE DATE: March 17, 1999.

FOR FURTHER INFORMATION CONTACT: Joan Turek, ASPE Privacy Act officer, Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation, H.H.H. Building—Room 447D, 200 Independence Ave, SW, Washington, DC 20201, Telephone: (202) 690–5965.

Dated: March 8, 1999.

Margaret A. Hamburg,

Assistant Secretary for Planning and Evaluation.

[FR Doc. 99–6415 Filed 3–16–99; 8:45 am]

BILLING CODE 4150–05–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control And Prevention

[INFO–99–12]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 the Center for Disease Control and Prevention is providing opportunity for public comment on proposed data collection projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call the CDC Reports Clearance Officer on (404) 639–7090.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques for other forms of information technology. Send comments to Seleda Perryman, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS–D24, Atlanta, GA 30333. Written comments should be received within 60 days of this notice.

Proposed Project

1. Management of Occupational Blood Exposures and Antibiotic Prescription Practices Among United States Dentists—NEW—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP). In U.S. health care facilities, both occupational transmission of bloodborne pathogens and antimicrobial resistance are important problems with significant morbidity and costs. Several public health initiatives have been undertaken or are being developed to increase compliance with recently published recommendations to reduce

occupational transmission of bloodborne pathogens and to assess current antibiotic use by physicians, hospital and other medical health-care workers. However, to date, there are limited data on dentists' implementation and knowledge of postexposure recommendations or on their antibiotic use. Therefore, the Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Division of Oral Health, intends to conduct a survey of the management of occupational blood exposures and antibiotic prescription practices among United States dentists. Information provided by these data are critical to the Division of Oral Health's ongoing efforts to protect dental workers from infection with bloodborne diseases and to target educational efforts aimed at increasing awareness of and compliance with current CDC recommendations. Information on antibiotic prescribing practices will help identify the most effective strategies for promoting appropriate use of antibiotics among dentists, provide an epidemiologic baseline on which to measure future behaviors, and assess the need for comprehensive guidelines.

A random sample of currently practicing U.S. dentists will be mailed questionnaires with two follow-up mailings to non-respondents. The information collected will include demographic information, office policies for management of occupational blood exposures and training of dental staff, the weekly number of antibiotic prescriptions, the most commonly prescribed antibiotics, and the most common oral conditions for which antibiotics are prescribed. The total cost to respondents is $24,000.00.

Respondents	Number of respondents	Number of responses/ respondent	Average burden/ response (in hours)	Total burden (in hours)
Practicing U.S. Dentists	3,600	1	0.25	900

2. An Evaluation of Targeted Health Communication Messages: Folic Acid and Neural Tube Defects—NEW–National Center for Environmental Health (NCEH). The Division of Birth Defects and Pediatric Genetics, National Center for Environmental Health, CDC, launched a national education campaign in January 1999 to increase women's knowledge about neural tube birth defects (NTDs) and the beneficial role folic acid, a B vitamin, plays in the prevention of NTDs. Studies show that a 50 to 70 percent reduction in the risk of neural tube birth defects is possible if all women capable of becoming pregnant consume 400 micrograms of folic acid daily both prior to and during early pregnancy.

CDC and the March of Dimes Birth Defects Foundation developed health communication media messages and educational materials targeted to health care providers, as well as to English and Spanish-speaking women. These media messages and educational materials consist of television and radio public service announcements (PSA), brochures and resource manuals.

Information about women's exposure to media messages and educational materials on folic acid information will be collected and measured to determine whether these exposures influenced the women's knowledge and usage of folic acid. Data will be collected via telephone interviews. The number and frequency of women's exposures to the media messages such as television and radio PSAs will be collected from media channels and compared to information collected from survey data, National Council on Folic Acid organizations and the National Clearinghouse on Folic Acid activities. The total cost to respondents is $0.

Respondents	Number of respondents	Number of responses/ respondent	Average burden/ response (in hours)	Total burden (in hours)
Targeted Market for the Folic Acid Messages	2,000	1	.33	666

3. Health Assessment of Persian Gulf War Veterans From Iowa: Follow-up on Asthma (0920–0425)—EXTENSION—National Center for Environmental Health (NCEH). The purpose of this proposed study is to collect additional data to validate health outcomes reported by participants in the Health Assessment of Persian Gulf War Veterans From Iowa. The original data collection consisted of a telephone survey of 3,695 military personnel who served during the time of the Persian Gulf War and listed Iowa as their home of residence. Data will be collected from subjects who participated in the telephone survey to validate the self-report of asthma. Lung function assessment, tests of airways hyperactivity, and standard respiratory health questionnaires will be administered. Review of medical records, standard physical examination, and laboratory evaluation will be conducted to validate multi systemic conditions, including chronic fatigue syndrome and fibromyalgia. The total cost to respondents is $0.00.

Respondents	Number of respondents	Number of responses/ respondent	Average burden/ response (in hrs)	Total burden (in hours)
PGW Exposed and Non-PGW Veterans self-reporting asthma. Questionnaire (ATS and Adult Respiratory Health); Pulmonary Function Tests (spirometry, DLCO, lung volumes); Histamine Challenge	100	1	2.25	225

Respondents	Number of respondents	Number of responses/ respondent	Average burden/ response (in hrs)	Total burden (in hours)
Normal Controls. (PGW/Non-PGW Vets denying symptoms of asthma). Questionnaire (ATS and Adult Respiratory Health); Pulmonary Function Tests (spirometry, DLCO, lung volumes); Histamine Challenge	50	1	2.25	112.5
TOTAL				337.5

Dated: March 11, 1999.

Nancy Cheal,

Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention (CDC).

[FR Doc. 99–6435 Filed 3–16–99; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control And Prevention

[INFO–99–13]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 the Centers for Disease Control and Prevention is providing opportunity for public comment on proposed data collection projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call the CDC Reports Clearance Officer on (404) 639–7090.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques for other forms of information technology. Send comments to Seleda Perryman, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS-D24, Atlanta, GA 30333. Written comments should be received with 10 days of this notice.

Proposed Project

1. PHS Supplements to the Application for Federal Assistance SF 424 (0920–0428)—Reinstatement—The Centers for Disease Control and Prevention (CDC) is requesting an emergency clearance for the three-year extension and revision of OMB approval for continued use of the Supplements to the Request for Federal Assistance Application (SF–424). We also plan on modifying the SF 424 form. The Checklist, Program Narrative, and the Public Health System Impact Statement (third party notification) (PHSIS) are a part of the standard application for State and local governments and for private non-profit and for-profit organizations when applying for financial assistance from PHS grant programs. The Checklist assists applicants to ensure that they have included all required information necessary to process the application. The Checklist data helps to reduce the time required to process and review grant applications, expediting the issuance of grant awards. The PHSIS Third Party Notification Form is used to inform State and local health agencies of community-based proposals submitted by non-governmental applicants for Federal funding. In addition, we are adding two new supplements to the information collection request. One form will be used by CDC and the other by SAMHSA.

The current OMB approval for the supplements was previously submitted by the Department of Health and Human Services (DHHS), Office of the Assistant Secretary of Health (OASH) under OMB number 0937–0189. This submission is time-sensitive and requests emergency approval because these supplements will be utilized by several agencies within DHHS immediately after clearance is granted. The total annual cost to the respondents is estimated to be $1,184,452.

Respondents	Number of respondents	Number of responses/ respondent	Average burden/ response (in hrs.)	Total burden (in hrs.)
State and local health departments; non-profit and for-profit organizations	7,643	1	4.215	32,215
Total				32,215

Dated: March 11, 1999.

Nancy Cheal,

Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention (CDC).

[FR Doc. 99–6434 Filed 3–16–99; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30DAY–09–99]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639–7090. Send written comments to CDC, Desk Officer; Human Resources and Housing Branch, New Executive Office Building, Room 10235; Washington, DC 20503. Written comments should be received within 30 days of this notice.

Proposed Project

1. Validity of Recall of Prostate and Colorectal Cancer Screening Tests—New—The National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Division of Cancer Prevention and Control. Prostate and colorectal cancer are among the leading causes of cancer deaths in the U.S. Prostate cancer screening has increased rapidly during the past few years although it is unknown whether screening decreases prostate cancer mortality and conflicting screening guidelines exist. Evidence suggests that colorectal cancer screening can save lives and efforts are under way to increase participation in screening. An increasing number of people are served by managed care organizations where they may receive cancer screening tests. However, for both types of cancer little screening information is available on screening guidelines for practitioners of managed care organizations (HMOs). Therefore, the Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Division of Cancer Prevention and Control, intends to conduct a pilot survey of HMOs to obtain information on the validity of recall on prostate and colorectal cancer screening tests. Members of three prepaid health plans (HMO's) will be interviewed by telephone, and medical records will be abstracted. Information from this pilot study will allow the Program to explore whether screening rates can be determined from self-reports and whether future studies are warranted. The total annual burden hours are 573.

Respondents	Number of respondents	Number of responses/ respondent	Average burden/ respondent (in hrs.)
HMOs	2,293	1	0.25

2. Evaluation of the Use of Data Transmitted Through the National Electronic Telecommunications System for Surveillance (NETSS)—New—Epidemiology Program Office (EPO). A questionnaire has been designed to collect information for the project entitled: ''Evaluation of the Use of Data Transmitted Through the National Electronic Telecommunications System for Surveillance (NETSS)''. The purpose of the project is to develop and implement a comprehensive evaluation strategy which will provide EPO, and the National Center for Infectious Diseases (NCID), Centers for Disease Control and Prevention (CDC) with the capacity to assess the degree to which data processed locally and at CDC after transmission through NETSS is used by State and Local Health Departments. This evaluation will encompass: (1) Dissemination of processed data, (2) Access to disseminated data, and (3) Use of accessed data for analysis by State and Local health authorities. The information gathered will be analyzed, in conjunction with data collected from other sources, to address these issues. The results of the project will assist the EPO, and NCID in carrying out CDC's mission of protecting the health of the United States public, through improved use of surveillance data by public health officials at local, state, and national levels. In order to focus efforts and resource allocation, a clear understanding of the barriers to access and use of NETSS data is needed. The total annual burden hours are 129.

Respondents	Number of respondents	Number of responses/ respondent	Average burden/ respondent (in hrs.)
State and Territorial Epidemiologists	56	1	0.25
CDC Program Staff who work with NETSS	40	.....	0.25
State Infectious Disease Control Staff who work with NETSS	42	1	1.5
State and Local Health Departments who work with VPD* from NETSS	28	1	1.5

*vaccine-preventable diseases

Dated: March 11, 1999.

Nancy Cheal,

Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention (CDC).

[FR Doc. 99–6436 Filed 3–16–99; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 99018]

Water Intervention Studies To Determine the Fraction of Gastrointestinal Illness Attributable to Drinking Water; Notice of Availability of Funds; Amendment

A notice announcing the availability of Fiscal Year 1999 funds for the Water Intervention Studies to Determine the Fraction of Gastrointestinal Illness Attributable to Drinking Water was published in the **Federal Register** on March 8, 1999, [Vol. 64 FR No. 44]. The notice is amended as follows:

On page 11025, second column, under ''C. Availability of Funds'', the first paragraph should read:

Approximately $1,800,000 is available in FY 1999 to fund approximately two awards. It is expected that the average award will be $900,000 ranging from $900,000 to $1,800,000. It is expected that the awards will begin on or about August 15, 1999, and will be made for a 12-month budget period within a project period of up to two years. The funding estimate may change.

Dated: March 10, 1999.

John L. Williams,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 99–6433 Filed 3–16–99; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention (CDC)

Office of the Director, National Center for HIV, STD and TB Prevention of the Center for Disease Control and Prevention (CDC), Announces the Following Meeting

Name: Consultation Meeting to discuss the revision of the U.S. Public Health Service recommendations for human immunodeficiency virus counseling and voluntary testing for pregnant women [MMWR 1995; 44 (No. RR–7)].

Times and Dates: 10 a.m.–5 p.m., April 26,1999; 8 a.m.–3 p.m., April 27, 1999.

Place: Atlanta Marriot Marquis Hotel, 265 Peachtree Center Ave., Atlanta, GA 30303, telephone 404/521–0000.

Status: Attendees will include invited experts in the area of perinatal transmission of HIV; legal issues; behavioral science; and ethicists from both public and private organizations; representing public health; medical professionals; advocacy groups; patient populations; persons with HIV/AIDS; and maternal and child health groups. The meeting is open to the public, limited only by space available. The meeting room will accommodate approximately 70 people.

Purpose: Attendees will discuss the potential revisions to the U.S. Public Health Service recommendations for human immunodeficiency virus counseling and voluntary testing for pregnant women. [MMWR 1995; 44 (No. RR–7)].

Matters to be Discussed: Agenda items include discussion of the recent report issued by the National Research Council, Institute of Medicine, ''Reducing the Odds, Preventing Perinatal Transmission of HIV in the United States''.

CONTACT PERSON FOR MORE INFORMATION: Mary Helen Witten, Office of the Director, National Center for HIV, STD and TB Prevention, Division of HIV and AIDS Prevention 1600 Clifton Rd., NE, M/S D–21, Atlanta, GA, 30333, 404/639–4592. E-mail: muw4@cdc.gov.

The Director, Management Analysis and Services office has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 99–6432 Filed 3–16–99; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel, ZRG1–SSS–2 (5).

Date: March 16–17, 1999.

Time: 8:00 AM to 4:00 PM.

Agenda: To review and evaluate grant applications.

Place: St. James Hotel, 950 24th Street, N.W., Washington, DC 20037.

Contact Person: Jean D. Sipe, PHD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5152, MSC 7842, Bethesda, MD 20892, (301) 435–1743.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel, ZRG1–(06)–(01).

Date: March 18–19, 1999.

Time: 8:00 AM to 5:30 PM.

Agenda: To review and evaluate grant applications.

Place: Bethesda Holiday Inn, Versailles III, 8120 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Sami A. Mayyasi, PHD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5112, MSC 7852, Bethesda, MD 20892, (301) 435–1169.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel.

Date: March 18, 1999.

Time: 10:00 AM to 4:00 PM.

Agenda: To review and evaluate grant applications.

Place: Washington, National Airport Hilton, 2399 Jefferson Davis Highway, Arlington, VA 22202.

Contact Person: Everett E. Sinnett, PHD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4120, MSC 7818, Bethesda, MD 20892, (301) 435–1016, ev.__sinnett@nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel.

Date: March 18, 1999.

Time: 2:00 PM to 5:00 PM.

Agenda: To review and evaluate grant applications.

Place: Hotel Sofitel, 1914 Connecticut Ave, NW, Washington, DC 20009.

Contact Person: Zakir Bengali, PHD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5150, MSC 7842, Bethesda, MD 20892, (301) 435–1742.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel.

Date: March 19, 1999.

Time: 8:00 AM to 5:00 PM.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn, 5520 Wisconsin Avenue, Chevy Chase, MD 20815.

Contact Person: Mohindar Poonian PHD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5110, MSC 7852, Bethesda, MD 20892, 301–435–1168, poonianm@drg.nih.gov.

This notice is being published less than 15 day prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel, ZRG–1 VACC (02).

Date: March 19, 1999.

Time: 8:30 AM to 5:00 PM.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Chevy Chase, 5520 Wisconsin Avenue, Chevy Chase, MD 20815.

Contact Person: Mary Clare Walker, PHD, Scientific Review Administrator, Center for Scientific Review, National Institutes of

Health, 6701 Rockledge Drive, Room 5104, MSC 7852, Bethesda, MD 20892, (301) 435–1165.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel BBCB ZRG1 (3).

Date: March 19, 1999.

Time: 2:00 PM to 3:00 PM.

Agenda: To review and evaluate grant applications.

Place: NIH Rockledge 2, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Donald Schneider PHD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4172, MSC 7806, Bethesda, MD 20892, (301) 435–1727.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel, ZRG1–SSS–8 (53).

Date: March 21–23, 1999.

Time: 7:00 PM to 2:00 PM.

Agenda: To review and evaluate grant applications.

Place: St. Louis Marriott Pavilion, One Broadway, St. Louis, MO 63102.

Contact Person: Nadarajen Vydelingum, PHD, Scientific Review Administrator, Special Study Section—8, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, MSC 7854, Rm 5122, Bethesda, MD 20892, (301) 435–1176, vydelinn@csr.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel.

Date: March 23, 1999.

Time: 1:00 PM to 2:00 PM.

Agenda: To review and evaluate grant applications.

Place: NIH, Rockledge 2, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Priscilla B. Chen, PHD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4104, MSC 7814, Bethesda, MD 20892, (301) 435–1787.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel.

Date: March 23, 1999.

Time: 1:00 PM to 3:00 PM.

Agenda: To review and evaluate grant applications.

Place: NIH, Rockledge 2, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Eugene Zimmerman, PHD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4202, MSC 7812, Bethesda, MD 20892, (301) 435–1220.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel.

Date: March 23, 1999.

Time: 1:00 PM to 4:00 PM.

Agenda: To review and evaluate grant applications.

Place: NIH, Rockledge 2, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Jo Pelham, BA, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4104, MSC 7814, Bethesda, MD 20892, (301) 435–1786.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel, ZRG1–AARR 6–03.

Date: March 23, 1999.

Time: 3:00 PM to 4:00 PM.

Agenda: To review and evaluate grant applications.

Place: NIH, Rockledge 2, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Sami A. Mayyasi, PHD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5112, MSC 7852, Bethesda, MD 20892, (301) 435–1169.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine, 93.306; 93.333, Clinical Research, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93–846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: March 9, 1999.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 99–6409 Filed 3–16–99; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Agency Recordkeeping/Reporting Requirements Under Emergency Review by the Office of Management and Budget (OMB)

Title: ACF–696 Child Care Development Fund Financial Reporting Form.

OMB No.: 0970–0163.

Description: The form provides specific data regarding claims and provides a mechanism for States to request grant awards and certify the availability of State matching funds. Failure to collect this data would seriously compromise ACF's ability to monitor expenditures. This information is also used to estimate outlays and may be used to prepare ACF budget submissions to Congress.

Respondents: State, Local or Tribal Govt.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ACF–696	54	4	8	1,728

Estimated Total Annual Burden Hours: 1,728.

Additional Information: ACF is requesting that OMB grant a 180 day approval for this information collection under procedures for emergency processing by May 31, 1999. A copy of this information collection, with applicable supporting documentation, may be obtained by calling the Administration for Children and Families, Reports Clearance Officer, Bob Sargis at (202) 690–7275.

Comments and questions about the information collection described above should be directed to the following address by May 31, 1999: Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for ACF, Office of Management and Budget, Paper Reduction Project, 725 17th Street, NW., Washington, DC 20503 (202) 395–7316.

Dated: March 10, 1999.

Bob Sargis,

Reports Clearance Officer.

[FR Doc. 99–6396 Filed 3–16–99; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[Program Announcement No. 93631–99–01]

Developmental Disabilities: Final Notice of Availability of Financial Assistance and Request for Applications To Support Family Support Model Demonstration Projects Under the Projects of National Significance Program

AGENCY: Administration on Developmental Disabilities (ADD), ACF, DHHS.

ACTION: Invitation to apply for financial assistance.

SUMMARY: The Administration on Developmental Disabilities, Administration for Children and Families (ACF), announces that applications are being accepted for funding of Fiscal Year 1999 under family support.

This program announcement consists of five parts. Part I, the Introduction, discusses the goals and objectives of ACF and ADD. Part II provides the necessary background information on ADD for applicants. Part III describes the review process. Part IV describes the priority under which ADD requests applications for Fiscal Year 1999 funding of projects. Part V describes in detail how to prepare and submit an application.

Grants will be awarded under this program announcement subject to the availability of funds for support of these activities.

DATES: The closing date for submittal of applications under this announcement May 17, 1999. Mailed or handcarried applications received after 4:30 p.m. on the closing date will be classified as late.

DEADLINE: Mailed applications shall be considered as meeting an announced deadline if they are received on or before the deadline time and date at the U.S. Department of Health and Human Services, ACF/Administration on Developmental Disabilities, 370 L'Enfant Promenade SW, Mail Stop 6C–462, Washington, DC 20447, Attention: Lois Hodge.''?

Applicants must ensure that a legibly dated U.S. Postal Service postmark or a legibly dated, machine produced postmark of a commercial mail service is affixed to the envelope/package containing the application(s). To be acceptable as proof of timely mailing, a postmark from a commercial mail service must include the logo/emblem of the commercial mail service company and must reflect the date the package was received by the commercial mail service company from the applicant. Private Metered postmarks shall not be acceptable as proof of timely mailing.

Applications handcarried by applicants, applicant couriers, other representatives of the applicant, or by overnight/express mail couriers shall be considered as meeting an announced deadline if they are received on or before the deadline date, between the hours of 8:00 a.m. and 4:30 p.m., EST, at the U.S. Department of Health and Human Services, ACF/Administration on Developmental Disabilities, 370 L'Enfant Promenade SW, ACF Mail Center, 2nd Floor (near loading dock), Aerospace Center, 901 D Street, SW, Washington, DC 20024, between Monday and Friday (excluding Federal holidays). This address must appear on the envelope/package containing the application with the note ''Attention: Lois Hodge. Applicants using express/overnight services should allow two working days prior to the deadline date for receipt of applications. (Applicants are cautioned that express/overnight mail services do not always deliver as agreed.) Any applications received after 4:30 p.m. on the deadline date will not be considered for competition.

ADD cannot accommodate transmission of applications by fax or through other electronic media. Therefore, applications transmitted to ADD electronically will not be accepted regardless of date or time of submission and time of receipt.

LATE APPLICATIONS: Applications that do not meet the criteria above are considered late applications. ADD shall notify each late applicant that its application will not be considered in the current competition.

EXTENSION OF DEADLINES: ADD may extend the deadline for all applicants because of acts of God such as floods and hurricanes, or when there is widespread disruption of the mails. However, if ADD does not extend the deadline for all applicants, it may not waive or extend the deadline for any applicants.

ADDRESSES: Application materials are available from Pat Laird, 370 L'Enfant Promenade, S.W., Washington, D.C. 20447, 202/690–7447; http://www.acf.dhhs.gov/programs/add; or add@acf.dhhs.gov.

FOR FURTHER INFORMATION CONTACT: Administration for Children and Families (ACF), Pat Laird, 370 L'Enfant Promenade, S.W., Washington, D.C., 20447, 202/690–7447; or add@acf.dhhs.gov.

NOTICE OF INTENT TO SUBMIT APPLICATION: If you intend to submit an application, please send a post card with the number and title of this announcement, your organization's name and address, and your contact person's name, phone and fax numbers, and e-mail address to: Administration on Developmental Disabilities, 370 L'Enfant Promenade SW, Washington, DC, 20447, Attn: Family Support.

This information will be used to determine the number of expert reviewers needed and to update the mailing list to whom program announcements are sent.

SUPPLEMENTARY INFORMATION:

Part I. General Information

A. Goals of the Administration on Developmental Disabilities

The Administration on Developmental Disabilities (ADD) is located within the Administration for Children and Families (ACF), Department of Health and Human Services (DHHS). Although different from the other ACF program administrations in the specific populations it serves, ADD shares a common set of goals that promote the economic and social well being of families, children, individuals and communities. Through national leadership, ACF and ADD envision:

- Families and individuals empowered to increase their own economic independence and productivity;
- Strong, healthy, supportive communities having a positive impact on the quality of life and the development of children;
- Partnerships with individuals, front-line service providers, communities, States and Congress that enable solutions which transcend traditional agency boundaries;
- Services planned and integrated to improve client access;
- A strong commitment to working with Native Americans, persons with developmental disabilities, refugees and migrants to address their needs, strengths and abilities; and
- A community-based approach that recognizes and expands on the resources and benefits of diversity.

Emphasis on these goals and progress toward them will help more

individuals, including people with developmental disabilities, to live productive and independent lives integrated into their communities.

B. Purpose of the Administration on Developmental Disabilities

The Administration on Developmental Disabilities (ADD) is the lead agency within ACF and DHHS responsible for planning and administering programs that promote the self-sufficiency and protect the rights of persons with developmental disabilities.

The Developmental Disabilities Assistance and Bill of Rights Act (42 U.S.C. 6000, *et seq.*) (the Act) supports and provides assistance to States and public and private nonprofit agencies and organizations to assure that individuals with developmental disabilities and their families participate in the design of and have access to culturally competent services, supports, and other assistance and opportunities that promote independence, productivity, integration and inclusion into the community.

In the Act, Congress expressly found that:

- Disability is a natural part of the human experience that does not diminish the right of individuals with developmental disabilities to enjoy the opportunity for independence, productivity, integration and inclusion into the community;
- Individuals whose disabilities occur during their developmental period frequently have severe disabilities that are likely to continue indefinitely;
- Individuals with developmental disabilities often require lifelong specialized services and assistance, provided in a coordinated and culturally competent manner by many agencies, professionals, advocates, community representatives, and others to eliminate barriers and to meet the needs of such individuals and their families;

The Act further established as the policy of the United States:

- Individuals with developmental disabilities, including those with the most severe developmental disabilities, are capable of achieving independence, productivity, integration and inclusion into the community, and often require the provision of services, supports and other assistance to achieve such;
- Individuals with developmental disabilities have competencies, capabilities and personal goals that should be recognized, supported, and encouraged, and any assistance to such individuals should be provided in an individualized manner, consistent with the unique strengths, resources, priorities, concerns, abilities, and capabilities of the individual;
- Individuals with developmental disabilities and their families are the primary decision makers regarding the services and supports such individuals and their families receive; and play decision making roles in policies and programs that affect the lives of such individuals and their families; and
- It is in the nation's interest for people with developmental disabilities to be employed, and to live conventional and independent lives as a part of families and communities.

Toward these ends, ADD seeks: to enhance the capabilities of families in assisting people with developmental disabilities to achieve their maximum potential; to support the increasing ability of people with developmental disabilities to exercise greater choice and self-determination; to engage in leadership activities in their communities; as well as to ensure the protection of their legal and human rights.

The four programs funded under the Act are:

- Federal assistance to State developmental disabilities councils;
- State system for the protection and advocacy of individuals rights;
- Grants to University Affiliated Programs for interdisciplinary training, exemplary services, technical assistance, and information dissemination; and
- Grants for Projects of National Significance.

C. Statutory Authorities Covered Under This Announcement

The Developmental Disabilities Assistance and Bill of Rights Act of 1996, 42 U.S.C. 6000, *et.seq.* The Projects of National Significance is Part E of the Developmental Disabilities Assistance and Bill of Rights Act of 1996, 42 U.S.C. 6081, *et.seq.* The Omnibus Appropriations Bill, FY '99, P.L. 105–277, 31 U.S.C. 1553(b).

Part II. Background Information For Applicants

A. Description of Family Support Program

The Individuals with Disabilities Education Act (20 U.S.C. 1400 et. seq.) was amended in 1994 by adding at the end the ''Families of Children With Disabilities Support Act of 1994''. The purpose of this new family support program was for states to create or expand statewide systems change. Although authorization levels were provided, funds were never appropriated. The administrative authority for implementing the family support program was given to the U.S. Department of Health and Human Services and within that Department it was delegated to the Administration on Developmental Disabilities. The authority for this program was to expire at the end of fiscal year 1998 or September 30, 1998.

In the fiscal year 1999 appropriations bill funds were provided for this program for one year. It allows for the award of competitive, statewide systems change grants to conduct training and technical assistance and other national activities designed to address the problems which impede the self-sufficiency of families of children with disabilities.

Part III. The Review Process

A. Eligible Applicants

Before applications under this Announcement are reviewed, each will be screened to determine that the applicant is eligible for funding as specified under the selected priority area. Applications from organizations that do not meet the eligibility requirements for the priority area will not be considered or reviewed in the competition, and the applicant will be so informed.

Only public or non-profit private entities, not individuals, are eligible to apply under any of the priority areas. All applications developed jointly by more than one agency or organization must identify only one organization as the lead organization and official applicant. The other participating agencies and organizations can be included as co-participants, subgrantees or subcontractors.

Nonprofit organizations must submit proof of nonprofit status in their applications at the time of submission. One means of accomplishing this is by providing a copy of the applicant's listing in the Internal Revenue Service's most recent list of tax-exempt organizations described in section 501 (c) (3) of the IRS code or by providing a copy of the currently valid IRS tax exemption certificate, *or* by providing a copy of the articles of incorporation bearing the seal of the State in which the corporation or association is domiciled.

ADD cannot fund a nonprofit applicant without acceptable proof of its nonprofit status.

Under this priority area proof of designation as lead agency by the governor/CEO must be provided.

B. Review Process and Funding Decisions

Timely applications under this Announcement from eligible applicants received by the deadline date will be reviewed and scored competitively. Experts in the field, generally persons from outside of the Federal government, will use the appropriate evaluation criteria listed later in this Part to review and score the applications. The results of this review are a primary factor in making funding decisions.

ADD reserves the option of discussing applications with, or referring them to, other Federal or non-Federal funding sources when this is determined to be in the best interest of the Federal government or the applicant. It may also solicit comments from ADD Regional Office staff, other Federal agencies, interested foundations, national organizations, specialists, experts, States and the general public. ADD will consider these comments, along with those of the expert reviewers, in making funding decisions.

In making decisions on awards, ADD will consider whether applications focus on or feature: services to culturally diverse or ethnic populations among others; a substantially innovative strategy with the potential to improve theory or practice in the field of human services; a model practice or set of procedures that holds the potential for replication by organizations administering or delivering of human services; substantial involvement of volunteers; substantial involvement (either financial or programmatic) of the private sector; a favorable balance between Federal and non-Federal funds available for the proposed project; the potential for high benefit for low Federal investment; a programmatic focus on those most in need; and/or substantial involvement in the proposed project by national or community foundations.

This year, 5 points will be awarded in scoring for any project that includes partnership and collaboration with the 112 Empowerment Zones/Enterprise Communities.

To the greatest extent possible, efforts will be made to ensure that funding decisions reflect an equitable distribution of assistance among the States and geographical regions of the country, rural and urban areas, and ethnic populations. In making these decisions, ADD may also take into account the need to avoid unnecessary duplication of effort.

C. Evaluation Process

Using the evaluation criteria below, a panel of at least three reviewers (primarily experts from outside the Federal government) will review the applications. To facilitate this review, applicants should ensure that they address each minimum requirement in the priority area description under the appropriate section of the Program Narrative Statement.

Reviewers will determine the strengths and weaknesses of each application in terms of the evaluation criteria listed below, provide comments, and assign numerical scores. The point value following each criterion heading indicates the maximum numerical weight that each section may be given in the review process.

D. Structure of Priority Area Descriptions

The priority area description is composed of the following sections:

- Eligible Applicants: This section specifies the type of organization that is eligible to apply under the particular priority area. Specific restrictions are also noted, where applicable.
- Purpose: This section presents the basic focus and/or broad goal(s) of the priority area.
- Background Information: This section briefly discusses the legislative background as well as the current state-of-the-art and/or current state-of-practice that supports the need for the particular priority area activity. Relevant information on projects previously funded by ACF and/or other State models are noted, where applicable.
- Evaluation Criteria: This section presents the basic set of issues that must be addressed in the application. Typically, they relate to need for assistance, results expected, project design, and organizational and staff capabilities. Inclusion and discussion of these items is important since the information provided will be used by the reviewers in evaluating the application against the evaluation criteria.
- Minimum Requirements for Project Design: This section presents the basic set of issues that must be addressed in the application. Typically, they relate to project design, evaluation, and community involvement. This section also asks for specific information on the proposed project. Inclusion and discussion of these items is important since they will be used by the reviewers to evaluate the applications against the evaluation criteria. Project products, continuation of the project after Federal support ceases, and dissemination/utilization activities, if appropriate, are also addressed.
- Project Duration: This section specifies the maximum allowable length of the project period; it refers to the amount of time for which Federal funding is available.
- Federal Share of Project Costs: This section specifies the maximum amount of Federal support for the project.
- Matching Requirement: This section specifies the minimum non-Federal contribution, either cash or in-kind match, required.
- Anticipated Number of Projects To Be Funded: This section specifies the number of projects ADD anticipates funding under the priority area.
- CFDA: This section identifies the Catalog of Federal Domestic Assistance (CFDA) number and title of the program under which applications in this priority area will be funded. This information is needed to complete item 10 on the SF 424.

Please note that applications under this Announcement that do not comply with the specific priority area requirements in the section on ''Eligible Applicants'' will not be reviewed. Applicants under this Announcement must clearly identify the specific priority area under which they wish to have their applications considered, and tailor their applications accordingly. Experience has shown that an application which is broader and more general in concept than outlined in the priority area description is less likely to score as well as an application more clearly focused on, and directly responsive to, the concerns of that specific priority area.

E. Available Funds

ADD intends to award new grants resulting from this announcement during the fourth quarter of fiscal year 1999, subject to the availability of funding. The size of the awards will vary. Each priority area description includes information on the maximum Federal share of the project costs and the anticipated number of projects to be funded.

The term ''budget period'' refers to the interval of time (usually 12 months) into which a multi-year period of assistance (project period) is divided for budgetary and funding purposes. The term ''project period'' refers to the total time a project is approved for support, including any extensions.

Where appropriate, applicants may propose shorter project periods than the maximums specified in the various priority areas. Non-Federal share contributions may exceed the minimums specified in the various priority areas.

For multi-year projects, continued Federal funding beyond the first budget period, but within the approved project period, is subject to the availability of funds, satisfactory progress of the grantee and a determination that continued funding would be in the best interest of the Government.

F. Grantee Share of Project Costs

Grantees must match $1 for every $3 requested in Federal funding to reach 25% of the total approved cost of the project. The total approved cost of the project is the sum of the ACF share and the non-Federal share. Cash or in-kind contributions may meet the non-Federal share, although applicants are encouraged to meet their match requirements through cash contributions. Therefore, a project requesting $100,000 in Federal funds (based on an award of $100,000 per budget period) must include a match of at least $33,333 (total project cost is $133,333, of which $33,333 is 25%).

An exception to the grantee cost-sharing requirement relates to applications originating from American Samoa, Guam, the Virgin Islands, and the Commonwealth of the Northern Mariana Islands. Applications from these areas are covered under Section 501(d) of P. L. 95–134, which requires that the Department waive ''any requirement for local matching funds for grants under $200,000.''

The applicant contribution must generally be secured from non-Federal sources. Except as provided by Federal statute, a cost sharing or matching requirement may not be met by costs borne by another Federal grant. However, funds from some Federal programs benefiting Tribes and Native American organizations have been used to provide valid sources of matching funds. If this is the case for a Tribe or Native American organization submitting an application to ADD, that organization should identify the programs which will be providing the funds for the match in its application. If the application successfully competes for PNS grant funds, ADD will determine whether there is statutory authority for this use of the funds. The Administration for Native Americans and the DHHS Office of General Counsel will assist ADD in making this determination.

G. General Instructions for the Uniform Project Description

The following ACF Uniform Project Description (UPD) has been approved under OMB Control Number 0970–0139.

1. Introduction: Applicants required to submit a full project description shall prepare the project description statement in accordance with the following instructions.

2. Project summary/abstract: Provide a summary of the project description (a page or less) with reference to the funding request.

3. Objectives and need for assistance: Clearly identify the physical, economic, social, financial, institutional, and/or other problem(s) requiring a solution. The need for assistance must be demonstrated and the principal and subordinate objectives of the project must be clearly stated; supporting documentation, such as letters of support and testimonials from concerned interests other than the applicant, may be included. Any relevant data based on planning studies should be included or referred to in the endnotes/footnotes. Incorporate demographic data and participant/beneficiary information, as needed. In developing the project description, the applicant may volunteer or be requested to provide information on the total range of projects currently being conducted and supported (or to be initiated), some of which may be outside the scope of the program announcement.

4. Results or benefits expected: Identify the results and benefits to be derived. For example, when applying for a grant to establish a neighborhood child care center, describe who will occupy the facility, who will use the facility, how the facility will be used, and how the facility will benefit the community which it will serve.

5. Approach: Outline a plan of action which describes the scope and detail of how the proposed work will be accomplished. Account for all functions or activities identified in the application. Cite factors which might accelerate or decelerate the work and state your reason for taking the proposed approach rather than others. Describe any unusual features of the project such as design or technological innovations, reductions in cost or time, or extraordinary social and community involvement.

Provide quantitative monthly or quarterly projections of the accomplishments to be achieved for each function or activity. When accomplishments cannot be quantified by activity or function, list them in chronological order to show the schedule of accomplishments and their target dates.

Identify the kinds of data to be collected, maintained, and/or disseminated. Note that clearance from the U.S. Office of Management and Budget might be needed prior to a ''collection of information'' that is ''conducted or sponsored'' by ACF. List organizations, cooperating entities, consultants, or other key individuals who will work on the project along with a short description of the nature of their effort or contribution.

6. Organization Profile: Provide information on the applicant organization(s) and cooperating partners such as organizational charts, financial statements, audit reports or statements from CPAs/Licensed Public Accountants, Employer Identification Numbers, names of bond carriers, contact persons and telephone numbers, child care licenses and other documentation of professional accreditation, information on compliance with Federal/State/local government standards, documentation of experience in the program area, and other pertinent information.

Any non-profit organization submitting an application must submit proof of its non-profit status in its application at the time of submission. The non-profit agency can accomplish this by providing a copy of the applicant's listing in the Internal Revenue Service's (IRS) most recent list of tax-exempt organizations described in Section 501(c)(3) of the IRS code, *or* by providing a copy of the currently valid IRS tax exemption certificate, *or* by providing a copy of the articles of incorporation bearing the seal of the State in which the corporation or association is domiciled.

H. Cooperation in Evaluation Efforts

Grantees funded by ADD may be requested to cooperate in evaluation efforts funded by ADD. The purpose of these evaluation activities is to learn from the combined experience of multiple projects funded under a particular priority area.

I. Closed Captioning for Audiovisual Efforts

Applicants should include ''closed captioning'' in the development of any audiovisual products.

Part IV. Fiscal Year 1999 Families of Children With Disabilities Support Projects—Description and Requirements

The following section presents the final announcement for the area of family support for Fiscal Year 1999 and solicits the appropriate applications.

- *Eligible Applicants:* A State entity or office designated by the chief executive officer of the state as the lead agency for this project.
- *Purpose:* Project funds are to be utilized to support systems change

activities designed to assist each State to develop and implement, or expand and enhance, a family-centered and family-directed, culturally competent, community-centered, comprehensive, statewide system of family support for families of children with disabilities designed to—

(1) Ensure the full participation, choice and control of families of children with disabilities in decisions related to the provision of such family support for their family;

(2) Ensure the active involvement of families of children with disabilities in the planning, development, implementation, and evaluation of such a statewide system;

(3) Increase the availability of, funding for, access to, and provision of family support for families of children with disabilities;

(4) Promote training activities that are family-centered and family-directed and that enhance the ability of family members of children with disabilities to increase participation, choice, and control in the provision of family support for families of children with disabilities;

(5) Increase and promote interagency coordination among State agencies, and between State agencies and private entities that are involved in these projects; and

(6) Increase the awareness of laws, regulations, policies, practices, procedures, and organizational structures, which facilitate or impede the availability or provision of family support for families of children with disabilities.

• Background Information: The concept of family support for families with a child with a disability is a relatively new phenomenon in disability policy. Historically, the only means of receiving publicly funded services for a child with a severe disability was by placing the child in a state institution. With a shift in thinking in the early 1980s to a more family-centered approach to service provision many states initiated family support legislation. This legislation was often the result of initiatives developed by the state developmental disabilities councils. Currently, all the states plus the District of Columbia offer some type of family support program; this has consisted of any community-based service administered or financed by the state MR/DD agency providing for vouchers, direct cash payments to families, reimbursement, or direct payments to service providers which the state agency itself identified as family support. A review of these programs reveals the range of services that fall within ''family support''—cash subsidy payments, respite care, family counseling, architectural adaptation of the home, in-home counseling, sibling support programs, education and behavior management services and the purchase of specialized equipment. Family support is a growing expenditure in state budgets; in 1996 it constituted 2.3% of total MR/DD resources, compared to 1.6% in 1992. The number of families supported is also growing, from 174,441 in 1992 to 280,535 in 1996.

The Federal government's involvement in family support began in 1982 with what is known as the ''Katie Beckett Waiver'', an option under Medicaid which allows a state to waive the deeming of parental income and resources for any child eighteen years of age and under who is eligible for placement in a Medicaid certified long term care institution or hospital, ICF/MR or nursing home. This waiver allows parents access to an array of family, home and community supports. A majority of states have not exercised this option.

Federal disability policy in the 1980s increasingly began to reflect the principles of family-centered, community-based, coordinated care as Federal programs were established or reauthorized. The Temporary Respite Care and Crisis Nurseries Act of 1986 funded a variety of in-home and out-of-home respite programs; a new Part H for infants, toddlers, and their families was added in 1986 to the then Education of the Handicapped Act; the reauthorization of the Maternal and Child Health Care Block grant in 1989 emphasized these principles in it's Children with Special Health Care Needs program; and in the Developmental Disabilities Assistance and Bill of Rights Act a definition of family support services was added in 1990.

• Minimum Requirements for Project Design: ADD is interested in awarding grant funds that will maximize opportunities for systems change through the collaboration with and strengthening of generic community action service organizations in order to ensure the provision of family support to families of children with disabilities. Activities should contain the following key components:

• Establish a state policy council of families of children with disabilities or utilize an existing council which will advise and assist the lead entity in the performance of activities of this application and be composed of a majority of members who are family members of children with disabilities and who are youth with disabilities (ages 18–21);

• Training and technical assistance for family members, service providers, community members, professionals, members of the Policy Council, state agency staff, students and others;

• Interagency coordination of Federal and State policies, resources, and services; interagency workgroups to enhance public funding options and coordination; and other interagency activities that promote coordination;

• Outreach to locate families who are eligible for family support and to identify groups who are underserved or unserved;

• Policy studies that relate to the development and implementation, or expansion and enhancement, of a statewide system of family support for families of children with disabilities;

• Hearings and forums to solicit input from families of children with disabilities regarding family support programs, policies, and plans for such families;

• Public awareness and education to families of children with disabilities, parent groups and organizations, public and private agencies, students, policymakers, and the general public;

• Needs assessment;

• Data collection and analysis related to the statewide system of family support for families of children with disabilities;

• Implementation plans to utilize generic community service organizations in innovative partnerships to include families of children with disabilities;

• Pilot demonstration projects to demonstrate new approaches to the provision of family support for families of children with disabilities;

• Evaluation system using measurable outcomes based on family satisfaction indicators such as the extent to which a service or support meets a need, solves a problem, or adds value for a family, as determined by the individual family.

ADD is particularly interested in applications that incorporate into these activities one or more of the following populations relevant to their state: (1) Unserved and underserved populations which includes populations such as individuals from racial and ethnic minority backgrounds, economically disadvantaged individuals, individuals with limited-English proficiency, and individuals from underserved geographic areas (rural or urban); (2) aging families of adult children with disabilities who are over age 21 with a focus on assisting those families and their adult child to be included as self-determining members of their

communities; (3) foster/adoptive families of children with disabilities; (4) families participating in the state's Temporary Assistance to Needy Families Program (TANF) , welfare-to-work, and/or SSI program; (5) veterans with families having a child with a disability; (6) parents with disabilities, especially with cognitive disabilities, having children with or without disabilities; and (7) families of children with behavioral/emotional issues

As a general guide, ADD will expect to fund only those proposals for projects that incorporate the following elements:

- Consumer/self-advocate orientation and participation.
- Key project personnel with direct life experience with living with a disability.
- Strong advisory components that consist of a majority of individuals with disabilities and a structure where individuals with disabilities make real decisions that determine the outcome of the grant.
- Research reflects the principles of participatory action.
- Cultural competency.
- A description of how individuals with disabilities and their families will be involved in all aspects of the design, implementation, and evaluation of the project.
- Attention to unserved and inadequately served individuals, having a range of disabilities from mild to severe, from multicultural backgrounds, rural and inner-city areas, migrant, homeless, and refugee families, with severe disabilities.
- Compliance with the Americans with Disabilities Act and Section 504 of the Rehabilitation Act of 1973 as amended by the Rehabilitation Act amendments of 1998 (P.L. 105–220).
- Collaboration through partnerships and coalitions.
- Development of the capacity to communicate and disseminate information and technical assistance through e-mail and other effective, affordable, and accessible forms of electronic communication.

Applications should also include provisions for the travel of a key staff person during the first and last years of the project to Washington, DC for a one-day meeting with ADD staff.

- Evaluation Criteria: The four criteria that follow will be used to review and evaluate each application under this announcement. Each of these criterion should be addressed in the project description section of the application. The point values indicate the maximum numerical weight each criterion will be accorded in the review process. The specific information to be included under each of these headings is described in Section G of Part III, General Instructions for the Uniform Project Description. Additional information that should be included is described below.

Criterion 1: Objectives and Need for Assistance (20 points)

The application must identify the precise location of the project and area to be served by the proposed project. Maps and other graphic aids should be attached

Criterion 2: Results or Benefits Expected (20 points) The extent to which they are consistent with the objectives of the application, and the extent to which the application indicates the anticipated contributions to policy, practice, theory and/or research. The extent to which the proposed project costs is reasonable in view of the expected results.

Criterion 3: Approach (35 points)

Discuss the criteria to be used to evaluate the results, and explain the methodology that will be used to determine if the needs identified and discussed are being met and if the results and benefits identified are being achieved.

Criterion 4: Organization Profile (25 points)

The application identifies the background of the project director/ principal investigator and key project staff (including name, address, training, educational background and other qualifying experience) and the experience of the organization to demonstrate the applicant's ability to effectively and efficiently administer this project. The application describes the relationship between this project and other work planned, anticipated or under way by the applicant which is being supported by Federal assistance.

This section should consist of a brief (two to three pages) background description of how the applicant organization (or the unit within the organization that will have responsibility for the project) is organized, the types and quantity of services it provides, and/or the research and management capabilities it possesses. It may include descriptions of any current or previous relevant experience, or describe the competence of the project team and its demonstrated ability to produce a final product that is readily comprehensible and usable. An organization chart showing the relationship of the project to the current organization should be included.

- Project Duration: This announcement is soliciting applications for a project period up to seventeen (17) months under this area with the possibility of additional project periods. Awards, on a competitive basis, can be up to a seventeen-month budget period although project periods may be for a longer period. Applications for continuation grants funded under this announcement beyond the budget period, but within a project period, will be entertained in subsequent years on a non-competitive basis, subject to the availability of funds, satisfactory progress of the grantee, and a determination that continued funding would be in the best interest of the Government.
- Federal Share of Project Costs: The maximum Federal share is not to exceed $200,000 for a state and not to exceed $100,000 for a territory for the first budget period or a minimum of $600,000 for a state and $300,000 for a territory for the entire project period. There is a possibility of increased funding in year two and three contingent on additional funds.
- Matching Requirement: Grantees must match $1 for every $3 requested in Federal funding to reach 25% of the total approved cost of the project. The total approved cost of the project is the sum of the ACF share and the non-Federal share. Cash or in-kind contributions may meet the non-Federal share, although applicants are encouraged to meet their match requirements through cash contributions. Therefore, a project requesting $200,000 in Federal funds (based on an award of $200,000 per budget period) must include a match of at least $66,666 (the total project cost is $266,666, of which $66,666 is 25%).
- Anticipated Number of Projects to be Funded: It is anticipated that up to seventeen (17) projects will be funded. Subject to availability of additional resources in FY 2000 and the number of acceptable applications received as a result of this program announcement, the ADD Commissioner may elect to select recipients for the FY 2000 cohort of programs out of the pool of applications submitted for FY 1999 funds.
- CFDA: ADD's CFDA (Code of Federal Domestic Assistance) number is 93.631—Developmental Disabilities—Projects of National Significance. This information is needed to complete item 10 on the SF 424.

Part V. Instructions for the Development and Submission of Applications

This Part contains information and instructions for submitting applications in response to this announcement. Application forms and package along with a checklist and other materials can

be obtained by any of the following methods: Pat Laird, ADD, 370 L'Enfant Promenade SW, Washington, DC, 20447, 202/690–7447; http:// www. acf. dhhs. gov/programs/add; oradd@acf.dhhs.gov. Please copy and use these forms in submitting an application.

Potential applicants should read this section carefully in conjunction with the information contained within the specific priority area under which the application is to be submitted. The priority area description is in Part IV.

A. Required Notification of the State Single Point of Contact (SPOC)

All applications under the ADD priority areas are required to follow the Executive Order (E.O.) 12372 process, ''Intergovernmental Review of Federal Programs,'' and 45 CFR Part 100, ''Intergovernmental Review of Department of Health and Human Services Program and Activities.'' Under the Order, States may design their own processes for reviewing and commenting on proposed Federal assistance under covered programs.

Note: State/territory participation in the intergovernmental review process does not signify applicant eligibility for financial assistance under a program. A potential applicant must meet the eligibility requirements of the program for which it is applying prior to submitting an application to its SPOC, if applicable, or to ACF.

As of November 20, 1998, all States and territories, except Alabama, Alaska, American Samoa, Colorado, Connecticut, Hawaii, Idaho, Kansas, Louisiana, Massachusetts, Minnesota, Montana, Nebraska, New Jersey, Ohio, Oklahoma, Oregon, Palau, Pennsylvania, South Dakota, Tennessee, Vermont, Virginia, and Washington, have elected to participate in the Executive Order process and have established a State Single Point of Contact (SPOC). Applicants from these jurisdictions or for projects administered by Federally recognized Indian Tribes need take no action regarding E.O. 12372. Otherwise, applicants should contact their SPOCs as soon as possible to alert them of the prospective applications and receive any necessary instructions.

Applicants must submit all required materials to the SPOC as soon as possible so that the program office can obtain and review SPOC comments as part of the award process. It is imperative that the applicant submit all required materials and indicate the date of this submittal (or date SPOC was contacted, if no submittal is required) on the SF 424, item 16a.

Under 45 CFR 100.8(a)(2), a SPOC has 60 days from the application due date to comment on proposed new or competing continuation awards. However, there is insufficient time to allow for a complete SPOC comment period. Therefore, we have reduced the comment period to 30 days from the closing date for applications. These comments are reviewed as part of the award process. Failure to notify the SPOC can result in delays in awarding grants.

SPOCs are encouraged to eliminate the submission of routine endorsements as official recommendations. Additionally, SPOCs are requested to clearly differentiate between mere advisory comments and those Official State process recommendations that may trigger the ''accommodate or explain'' rule.

When comments are submitted directly to ACF, they should be addressed to: Department of Health and Human Services, Administration for Children and Families, Division of Discretionary Grants and Audit Resolution, 370 L'Enfant Promenade, SW, Mail Stop 6C–462, Washington, DC 20447, Attn: 93.631 ADD—Projects of National Significance.

Contact information for each State's SPOC is found in the application package.

B. Notification of State Developmental Disabilities Planning Councils

A copy of the application must also be submitted for review and comment to the State Developmental Disabilities Council in each State in which the applicant's project will be conducted. A list of the State Developmental Disabilities Councils is included in the application package.

C. Deadline for Submittal of Applications

One signed original and two copies of the application must be submitted on or before May 17, 1999 to: U.S. Department of Health and Human Services, Administration for Children and Families, Administration on Developmental Disabilities, 370 L'Enfant Promenade, SW, Mail Stop 6C–462, Washington, DC 20447, Attn: Lois Hodge.

Applications may be mailed or hand-delivered. Hand-delivered applications are accepted during the normal working hours of 8:00 a.m. to 4:30 p.m., Monday through Friday. Applications shall be considered as meeting an announced deadline if received by the deadline date at the ACF Grants Office (Close of Business: 4:30 p.m., local prevailing time).

Late applications: Applications that do not meet the criterion stated above are considered late applications. ACF/ADD shall notify each late applicant that its application will not be considered in the current competition.

Extension of deadlines: ACF may extend the deadline for all applicants due to acts of God, such as floods, hurricanes, or earthquakes; or when there is a widespread disruption of the mails. However, if the granting agency does not extend the deadline for all applicants, it may not waive or extend the deadline for any applicants.

D. Instructions for Preparing the Application and Completing Application Forms

The SF 424, SF 424A, SF 424A-Page 2 and Certifications/ Assurances are contained in the application package that can be accessed as mentioned earlier in this announcement. Please prepare your application in accordance with the following instructions:

1. SF 424 Page 1, Application Cover Sheet

Please read the following instructions before completing the application cover sheet. An explanation of each item is included. Complete only the items specified.

Top of Page. Enter the single priority area number under which the application is being submitted. An application should be submitted under only one priority area.

Item 1. ''Type of Submission''—Preprinted on the form.

Item 2. ''Date Submitted'' and ''Applicant Identifier''—Date application is submitted to ACF and applicant's own internal control number, if applicable.

Item 3. ''Date Received By State''—State use only (if applicable).

Item 4. ''Date Received by Federal Agency''—Leave blank.

Item 5. ''Applicant Information''.

''Legal Name''—Enter the legal name of applicant organization. For applications developed jointly, enter the name of the lead organization only. There must be a single applicant for each application.

''Organizational Unit''—Enter the name of the primary unit within the applicant organization which will actually carry out the project activity. Do not use the name of an individual as the applicant. If this is the same as the applicant organization, leave the organizational unit blank.

''Address''—Enter the complete address that the organization actually uses to receive mail, since this is the address to which all correspondence will be sent. Do not include both street

address and P.O. box number unless both must be used in mailing.

''Name and telephone number of the person to be contacted on matters involving this application (give area code)''—Enter the full name (including academic degree, if applicable) and telephone number of a person who can respond to questions about the application. This person should be accessible at the address given here and will receive all correspondence regarding the application.

Item 6. ''Employer Identification Number (EIN)''—Enter the employer identification number of the applicant organization, as assigned by the Internal Revenue Service, including, if known, the Central Registry System suffix.

Item 7. ''Type of Applicant''—Self-explanatory.

Item 8. ''Type of Application''—Preprinted on the form.

Item 9. ''Name of Federal Agency''—Preprinted on the form.

Item 10. ''Catalog of Federal Domestic Assistance Number and Title''—Enter the Catalog of Federal Domestic Assistance (CFDA) number assigned to the program under which assistance is requested and its title. For all of ADD's priority areas, the following should be entered, ''93.631—Developmental Disabilities: Projects of National Significance.''

Item 11. ''Descriptive Title of Applicant's Project''—Enter the project title. The title is generally short and is descriptive of the project, not the priority area title.

Item 12. ''Areas Affected by Project''—Enter the governmental unit where significant and meaningful impact could be observed. List only the largest unit or units affected, such as State, county, or city. If an entire unit is affected, list it rather than subunits.

Item 13. ''Proposed Project''—Enter the desired start date for the project and projected completion date.

Item 14. ''Congressional District of Applicant/Project''—Enter the number of the Congressional district where the applicant's principal office is located and the number of the Congressional district(s) where the project will be located. If Statewide, a multi-State effort, or nationwide, enter ''00.''

Items 15. Estimated Funding Levels

In completing 15a through 15f, the dollar amounts entered should reflect, for a 17-month or less project period, the total amount requested. If the proposed project period exceeds 17 months, enter only those dollar amounts needed for the first 12 months of the proposed project.

Item 15a. Enter the amount of Federal funds requested in accordance with the preceding paragraph. This amount should be no greater than the maximum amount specified in the priority area description.

Items 15b-e. Enter the amount(s) of funds from non-Federal sources that will be contributed to the proposed project. Items b-e are considered cost sharing or ''matching funds.'' The value of third party in-kind contributions should be included on appropriate lines as applicable. For more information regarding funding as well as exceptions to these rules, see Part III, Sections E and F, and the specific priority area description.

Item 15f. Enter the estimated amount of program income, if any, expected to be generated from the proposed project. Do not add or subtract this amount from the total project amount entered under item 15g. Describe the nature, source and anticipated use of this program income in the Project Narrative Statement.

Item 15g. Enter the sum of items 15a–15e.

Item 16a. ''Is Application Subject to Review By State Executive Order 12372 Process? Yes.''—Enter the date the applicant contacted the SPOC regarding this application. Select the appropriate SPOC from the listing provided at the end of Part IV. The review of the application is at the discretion of the SPOC. The SPOC will verify the date noted on the application.

Item 16b. ''Is Application Subject to Review By State Executive Order 12372 Process? No.''—Check the appropriate box if the application is not covered by E.O. 12372 or if the program has not been selected by the State for review.

Item 17. ''Is the Applicant Delinquent on any Federal Debt?''—Check the appropriate box. This question applies to the applicant organization, not the person who signs as the authorized representative. Categories of debt include audit disallowances, loans and taxes.

Item 18. ''To the best of my knowledge and belief, all data in this application/preapplication are true and correct. The document has been duly authorized by the governing body of the applicant and the applicant will comply with the attached assurances if the assistance is awarded.''—To be signed by the authorized representative of the applicant. A copy of the governing body's authorization for signature of this application by this individual as the official representative must be on file in the applicant's office, and may be requested from the applicant.

Item 18a-c. ''Typed Name of Authorized Representative, Title, Telephone Number''—Enter the name, title and telephone number of the authorized representative of the applicant organization.

Item 18d. ''Signature of Authorized Representative'' —Signature of the authorized representative named in Item 18a. At least one copy of the application must have an original signature. Use colored ink (not black) so that the original signature is easily identified.

Item 18e. ''Date Signed''—Enter the date the application was signed by the authorized representative.

2. SF 424A—Budget Information—Non-Construction Programs

This is a form used by many Federal agencies. For this application, Sections A, B, C, E and F are to be completed. Section D does not need to be completed.

Sections A and B should include the Federal as well as the non-Federal funding for the proposed project covering (1) the total project period of 17 months or less or (2) the first year budget period, if the proposed project period exceeds 15 months.

Section A—Budget Summary. This section includes a summary of the budget. On line 5, enter total Federal costs in column (e) and total non-Federal costs, including third party in-kind contributions, but not program income, in column (f). Enter the total of (e) and (f) in column (g).

Section B—Budget Categories. This budget, which includes the Federal as well as non-Federal funding for the proposed project, covers (1) the total project period of 17 months or less or (2) the first-year budget period if the proposed project period exceeds 17 months. It should relate to item 15g, total funding, on the SF 424. Under column (5), enter the total requirements for funds (Federal and non-Federal) by object class category.

A separate budget justification should be included to explain fully and justify major items, as indicated below. The types of information to be included in the justification are indicated under each category. For multiple year projects, it is desirable to provide this information for each year of the project. The budget justification should immediately follow the second page of the SF 424A.

Personnel—Line 6a. Enter the total costs of salaries and wages of applicant/grantee staff. Do not include the costs of consultants, which should be included on line 6h, ''Other.''

Justification: Identify the principal investigator or project director, if

known. Specify by title or name the percentage of time allocated to the project, the individual annual salaries, and the cost to the project (both Federal and non-Federal) of the organization's staff who will be working on the project.

Fringe Benefits—Line 6b. Enter the total costs of fringe benefits, unless treated as part of an approved indirect cost rate.

Justification: Provide a break-down of amounts and percentages that comprise fringe benefit costs, such as health insurance, FICA, retirement insurance, etc.

Travel—6c. Enter total costs of out-of-town travel (travel requiring per diem) for staff of the project. Do not enter costs for consultant's travel or local transportation, which should be included on Line 6h, ''Other.''

Justification: Include the name(s) of traveler(s), total number of trips, destinations, length of stay, transportation costs and subsistence allowances.

Equipment—Line 6d. Enter the total costs of all equipment to be acquired by the project. For State and local governments, including Federally recognized Indian Tribes, ''equipment'' is tangible, non-expendable personal property having a useful life of more than one year and acquisition cost of $5,000 or more per unit.

Justification: Equipment to be purchased with Federal funds must be justified. The equipment must be required to conduct the project, and the applicant organization or its subgrantees must not have the equipment or a reasonable facsimile available to the project. The justification also must contain plans for future use or disposal of the equipment after the project ends.

Supplies—Line 6e. Enter the total costs of all tangible expendable personal property (supplies) other than those included on Line 6d.

Justification: Specify general categories of supplies and their costs.

Contractual—Line 6f. Enter the total costs of all contracts, including (1) procurement contracts (except those which belong on other lines such as equipment, supplies, etc.) and (2) contracts with secondary recipient organizations, including delegate agencies. Also include any contracts with organizations for the provision of technical assistance. Do not include payments to individuals on this line. If the name of the contractor, scope of work, and estimated total costs are not available or have not been negotiated, include on Line 6h, ''Other.''

Justification: Attach a list of contractors, indicating the names of the organizations, the purposes of the contracts, and the estimated dollar amounts of the awards as part of the budget justification. Whenever the applicant/grantee intends to delegate part or the entire program to another agency, the applicant/grantee must complete this section (Section B, Budget Categories) for each delegate agency by agency title, along with the supporting information. The total cost of all such agencies will be part of the amount shown on Line 6f. Provide backup documentation identifying the name of contractor, purpose of contract, and major cost elements.

Construction—Line 6g. Not applicable. New construction is not allowable.

Other—Line 6h. Enter the total of all other costs. Where applicable, such costs may include, but are not limited to: insurance; medical and dental costs; noncontractual fees and travel paid directly to individual consultants; local transportation (all travel which does not require per diem is considered local travel); space and equipment rentals; printing and publication; computer use; training costs, including tuition and stipends; training service costs, including wage payments to individuals and supportive service payments; and staff development costs. Note that costs identified as ''miscellaneous'' and ''honoraria'' are not allowable.

Justification: Specify the costs included.

Total Direct Charges—Line 6i. Enter the total of Lines 6a through 6h.

Indirect Charges—6j. Enter the total amount of indirect charges (costs). If no indirect costs are requested, enter ''none.'' Generally, this line should be used when the applicant (except local governments) has a current indirect cost rate agreement approved by the Department of Health and Human Services or another Federal agency.

Local and State governments should enter the amount of indirect costs determined in accordance with HHS requirements. When an indirect cost rate is requested, these costs are included in the indirect cost pool and should not be charged again as direct costs to the grant.

In the case of training grants to other than State or local governments (as defined in title 45, Code of Federal Regulations, part 74), the Federal reimbursement of indirect costs will be limited to the lesser of the negotiated (or actual) indirect cost rate or 8 percent of the amount allowed for direct costs, exclusive of any equipment charges, rental of space, tuition and fees, post-doctoral training allowances, contractual items, and alterations and renovations.

For training grant applications, the entry under line 6j should be the total indirect costs being charged to the project. The Federal share of indirect costs is calculated as shown above. The applicant's share is calculated as follows:

(a) Calculate total project indirect costs (a*) by applying the applicant's approved indirect cost rate to the total project (Federal and non-Federal) direct costs.

(b) Calculate the Federal share of indirect costs (b*) at 8 percent of the amount allowed for total project (Federal and non-Federal) direct costs exclusive of any equipment charges, rental of space, tuition and fees, post-doctoral training allowances, contractual items, and alterations and renovations.

(c) Subtract (b*) from (a*). The remainder is what the applicant can claim as part of its matching cost contribution.

Justification: Enclose a copy of the indirect cost rate agreement. Applicants subject to the limitation on the Federal reimbursement of indirect costs for training grants should specify this.

Total—Line 6k. Enter the total amounts of lines 6i and 6j.

Program Income—Line 7. Enter the estimated amount of income, if any, expected to be generated from this project. Do not add or subtract this amount from the total project amount.

Justification: Describe the nature, source, and anticipated use of program income in the Program Narrative Statement.

Section C—Non-Federal Resources. This section summarizes the amounts of non-Federal resources that will be applied to the grant. Enter this information on line 12 entitled ''Totals.'' In-kind contributions are defined in title 45 of the Code of Federal Regulations, Parts 74.51 and 92.24, as ''property or services which benefit a grant-supported project or program and which are contributed by non-Federal third parties without charge to the grantee, the subgrantee, or a cost-type contractor under the grant or subgrant.''

Justification: Describe third party in-kind contributions, if included.

Section D—Forecasted Cash Needs. Not applicable.

Section E—Budget Estimate of Federal Funds Needed For Balance of the Project. This section should only be completed if the total project period exceeds 17 months.

Totals—Line 20. For projects that will have more than one budget period, enter the estimated required Federal funds for the second budget period (months 13 through 24) under column ''(b) First.'' If

a third budget period will be necessary, enter the Federal funds needed for months 25 through 36 under ''(c) Second.'' Columns (d) and (e) are not applicable in most instances, since ACF funding is almost always limited to a three-year maximum project period. They should remain blank.

Section F—Other Budget Information.

Direct Charges—Line 21. Not applicable.

Indirect Charges—Line 22. Enter the type of indirect rate (provisional, predetermined, final or fixed) that will be in effect during the funding period, the estimated amount of the base to which the rate is applied, and the total indirect expense.

Remarks—Line 23. If the total project period exceeds 17 months, you must enter your proposed non-Federal share of the project budget for each of the remaining years of the project.

3. Project Summary/Abstract

Clearly mark this separate page with the applicant name as shown in item 5 of the SF 424, the priority area number as shown at the top of the SF 424, and the title of the project as shown in item 11 of the SF 424. The summary description should not exceed 300 words. These 300 words become part of the computer database on each project.

Care should be taken to produce a summary description that accurately and concisely reflects the proposal. It should describe the objectives of the project, the approaches to be used and the outcomes expected. The description should also include a list of major products that will result from the proposed project, such as software packages, materials, management procedures, data collection instruments, training packages, or videos (please note that audiovisuals should be closed captioned). The project summary description, together with the information on the SF 424, will constitute the project ''abstract.'' It is the major source of information about the proposed project and is usually the first part of the application that the reviewers read in evaluating the application.

4. Project Description

The Project Description is a very important part of an application. It should be clear, concise, and address the specific requirements mentioned under the priority area description in Part IV. The narrative should also provide information concerning how the application meets the evaluation criteria, using the following headings:

(a) Objectives and Need for Assistance;

(b) Results and Benefits Expected;

(c) Approach; and

(d) Organization Profile.

The specific information to be included under each of these headings is described in Section G of Part III, General Instructions for the Uniform Project Description.

The narrative should be typed double-spaced on a single-side of an 8 1/2″ x 11″ plain white paper, with 1″ margins on all sides, using black print no smaller than 12 pitch or 12 point size. All pages of the narrative (including charts, references/footnotes, tables, maps, exhibits, etc.) must be sequentially numbered, beginning with ''Objectives and Need for Assistance'' as page number one. Applicants should not submit reproductions of larger size paper, reduced to meet the size requirement.

The length of the application, including the application forms and all attachments, should not exceed 60 pages. This will be strictly enforced. A page is a single side of an 8 1/2 x 11″ sheet of paper. Applicants are requested not to send pamphlets, brochures or other printed material along with their application as these pose copying difficulties. These materials, if submitted, will not be included in the review process if they exceed the 60-page limit. Each page of the application will be counted to determine the total length.

5. Part V—Assurances/Certifications

Applicants are required to file a SF 424B, Assurances—Non-Construction Programs and the Certification Regarding Lobbying. Both must be signed and returned with the application. Applicants must also provide certifications regarding: (1) Drug-Free Workplace Requirements; and (2) Debarment and Other Responsibilities. These two certifications are self-explanatory. Copies of these assurances/certifications are reprinted at the end of this announcement and should be reproduced, as necessary. A duly authorized representative of the applicant organization must certify that the applicant is in compliance with these assurances/certifications. A signature on the SF 424 indicates compliance with the Drug Free Workplace Requirements, and Debarment and Other Responsibilities certifications, and need not be mailed back with the application.

In addition, applicants are required under Section 162(c)(3) of the Act to provide assurances that the human rights of all individuals with developmental disabilities (especially those individuals without familial protection) who will receive services under projects assisted under Part E will be protected consistent with section 110 (relating to the rights of individuals with developmental disabilities). Each application must include a statement providing this assurance.

For research projects in which human subjects may be at risk, a Protection of Human Subjects Assurance may be required. If there is a question regarding the applicability of this assurance, contact the Office for Research Risks of the National Institutes of Health at (301) 496–7041.

E. Checklist for a Complete Application

The checklist below is for your use to ensure that your application package has been properly prepared.

—One original, signed and dated application, plus two copies. Applications for different priority areas are packaged separately;

—Application is from an organization that is eligible under the eligibility requirements defined in the priority area description (screening requirement);

—Application length does not exceed 60 pages, unless otherwise specified in the priority area description.

A complete application consists of the following items in this order:

—Application for Federal Assistance (SF 424, REV 4–88);

—A completed SPOC certification with the date of SPOC contact entered in line 16, page 1 of the SF 424 if applicable.

—Budget Information—Non-Construction Programs (SF 424A, REV 4–88);

—Budget justification for Section B—Budget Categories;

—Table of Contents;

—Letter from the Internal Revenue Service, etc. to prove non-profit status, if necessary;

—Copy of the applicant's approved indirect cost rate agreement, if appropriate;

—Project Description (See Part III, Section C);

—Any appendices/attachments;

—Assurances—Non-Construction Programs (Standard Form 424B, REV 4–88);

—Certification Regarding Lobbying; and Certification of Protection of Human Subjects, if necessary.

—Certification of the Pro-Children Act of 1994; signature on the application represents certification.

F. The Application Package

Each application package must include an original and two copies of

the complete application. Each copy should be stapled securely (front and back if necessary) in the upper left-hand corner. All pages of the narrative (including charts, tables, maps, exhibits, etc.) must be sequentially numbered, beginning with page one. In order to facilitate handling, please do not use covers, binders or tabs. Do not include extraneous materials as attachments, such as agency promotion brochures, slides, tapes, film clips, minutes of meetings, survey instruments or articles of incorporation.

G. Paper Reduction Act of 1995 (P.L. 104–13)

The Uniform Project Description information collection within this announcement is approved under the Uniform Project Description (0970–0139), Expiration Date 10/31/2000.

Public reporting burden for this collection of information is estimated to average 10 hours per response, including the time for reviewing instructions, gathering and maintaining the data needed, and reviewing the collection of information.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

(Federal Catalog of Domestic Assistance Number 93.631 Developmental Disabilities—Projects of National Significance)

Dated: March 11, 1999.

Sue Swenson,

Commissioner, Administration on Developmental Disabilities.

[FR Doc. 99–6456 Filed 3–16–99; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Subcommittee of the Anti-Infective Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Subcommittee of the Anti-Infective Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on April 23, 1999, 8:30 a.m. to 5 p.m.

Location: Holiday Inn, Kennedy Grand Ballroom, 8777 Georgia Ave., Silver Spring, MD.

Contact Person: Rhonda W. Stover, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6767, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12530. Please call the Information Line for up-to-date information on this meeting.

Agenda: The subcommittee will discuss issues in the development and study of all therapies in children relative to the implementation of the agency's new legislative and regulatory efforts to ensure adequate labeling and proper pediatric use.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the subcommittee. Written submissions may be made to the contact person by April 16, 1999. Oral presentations from the public will be scheduled between approximately 11 a.m. and 12 m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before April 16, 1999, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: March 10, 1999.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 99–6459 Filed 3–16–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Human Tissue Seminar

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

The Food and Drug Administration (FDA), Los Angeles District Office, in cooperation with the American Society for Quality-Food, Drug, and Cosmetic Division (ASQ–FDC) is announcing the following seminar: Human Tissue Seminar. The topic to be discussed is public health regulations and guidance for recovery, screening, testing, processing, storage, or distribution of human tissue intended for transplantation. This seminar is being held for tissue firms in Southern California and Arizona.

Date and Time: The seminar will be held on Thursday, April 8, 1999, 8 a.m. to 5 p.m. Return the registration form by Thursday, April 1, 1999.

Location: The seminar will be held at the Food and Drug Administration, Los Angeles District Office, 19900 MacArthur Blvd., suite 300, Irvine, CA 92612.

Contact: Jonetta I. Collins, Supervisory Consumer Safety Officer, Food and Drug Administration, 19900 MacArthur Blvd., suite 300, Irvine, CA 92612, 949–798–7780, FAX 949–798–7771, e-mail ''jcollins@ora.fda.gov'', or Ofelia U. Barretto, West Coast Program Chair, ASQ–FDC, 714–870–4471, FAX 714–879–2737.

Registration: Space is limited; therefore, preregistration and confirmation is required. Obtain registration forms from Ofelia U. Barretto, ASQ–FDC (see above). There is a $95 registration fee payable to ASQ–FDC (address above) for the seminar. The fee will cover actual expenses including refreshments, a boxed lunch, materials, and some speaker expenses. In addition, building parking is $8 per car to attend the seminar. Return your completed registration form to Ofelia U. Barretto by Thursday, April 1, 1999.

If you need special accommodations due to a disability, please contact Jonetta I. Collins at least 7 days in advance.

Dated: March 9, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99–6395 Filed 3–16–99; 8:45 am]

BILLING CODE 4160–01–F'

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the

provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel, ''Innovative Approaches to Clinical Trials Information''.

Date: March 24, 1999.

Time: 1:00 pm to 3:00 pm.

Agenda: To review and evaluate contract proposals.

Place: 6130 Executive Blvd., 6th Floor, Rockville, MD 20852.

Contact Person: Wilna A. Woods, PhD, Deputy Chief, Special Review, Referral and Research Branch, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, Rockville, MD 20852, (301) 496–7903.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: March 9, 1999.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 99–6408 Filed 3–16–99; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Advisory Neurological Disorders and Stroke Special Emphasis Panel, February 26, 1999, 10:00 a.m., Hotel Washington, 15th St. & Pennsylvania Ave, NW, Washington, DC, 20005, which was published in the **Federal Register** on January 28, 1999, (64 FR 4456).

The meeting will now be held as a teleconference on March 11 from 11:00 a.m. to 12:00 p.m. at NIH/NINDS, Federal Building, Room 9C10, 7550 Wisconsin Ave., Bethesda, MD 20892. The meeting is closed to the public.

Dated: March 10, 1999.

Anna Snouffer,

Acting NIH Committee Management Officer.

[FR Doc. 99–6404 Filed 3–16–99; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institutes of Nursing Research; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Nursing Research Special emphasis Panel, Review Nursing Research Center Core Grant Applications (P30s).

Date: April 1–2, 1999.

Time: April 1, 1999, 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Ramada Inn, 8400 Wisconsin Ave., Bethesda, MD 20814.

Time: April 2, 1999, 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Ramada Inn, 8400 Wisconsin Ave., Bethesda, MD 20814.

Contact Person: Mary J. Stephens-Frazier, PhD, Scientific Review Administrator, National Institute of Nursing Research, National Institutes of Health, Natcher Building, Room 3AN32, Bethesda, MD 20892, (301) 594–5971.

(Catalogue of Federal Domestic Assistance Program Nos. 93.361, Nursing Research, National Institutes of Health, HHS)

Dated: March 9, 1999.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 99–6405 Filed 3–16–99; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Deafness and Other Communication Disorders; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Deafness and Other Communications Disorders Special Emphasis Panel.

Date: April 8, 1999.

Time: 8:00 am to 5:00 pm.

Agenda: To review and evaluate grant applications.

Place: Best Western Inn, 1251 W. Montgomery Avenue, Rockville, MD 20850.

Contact Person: Richard S. Fisher, PhD, Scientific Review Administrator, Scientific Review Branch, Division of Extramural Activities, NIDCD/NIH, 6120 Executive Blvd., Room 400C, MSC–7180, Bethesda, MD 20892, 301–496–8683.

(Catalogue of Federal Domestic Assistance Program Nos. 93.173, Biological Research Related to Deafness and Communicative Disorders, National Institutes of Health, HHS)

Dated: March 9, 1999.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 99–6406 Filed 3–16–99; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Deafness and Other Communication Disorders; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C.,

as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Deafness and Other Communications Disorders Special Emphasis Panel.

Date: April 5, 1999.

Time: 1:00 pm to 3:30 pm.

Agenda: To review and evaluate grant applications.

Place: Executive Plaza South, Room 400C, 6120 Executive Blvd., Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Craig A. Jordan, PhD, Acting Director, NIH/NIDCD/DEA, Executive Plaza South, Room 400C, Bethesda, MD 20892–7180, 301–496–8693.

(Catalogue of Federal Domestic Assistance Program Nos. 93.173, Biological Research Related to Deafness and Communicative Disorders, National Institutes of Health, HHS)

Dated: March 9, 1999.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 99–6407 Filed 3–16–99; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Library of Medicine; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Library of Medicine Special Emphasis Panel.

Date: March 31, 1999.

Time: 11:00 am to 1:00 pm.

Agenda: To review and evaluate grant applications.

Place: National Library of Medicine, 6705 Rockledge Drive, Suite 301, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Sharee Pepper, PhD, Scientific Review Administrator, Health Scientist Administrator, Office of Extramural Programs, National Library of Medicine, 6705 Rockledge Drive, Suite 301, Bethesda, MD 20892.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.879, Medical Library Assistance, National Institutes of Health, HHS)

Dated: March 11, 1999.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 99–6403 Filed 3–16–99; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Committee for Injury Prevention and Control Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following committee meeting.

Name: Advisory Committee for Injury Prevention and Control (ACIPC).

Times and Dates: 1:30 p.m.–4:30 p.m., March 30, 1999. 8:30 a.m.–3:30 p.m., March 31, 1999.

Place: Embassy Suites Atlanta Airport, 4700 Southport Rd, College Park, GA 30337–5613.

Status: Closed: 1:30 p.m.–2:30 p.m., March 30, 1999, and 8:30 a.m.–9 a.m., March 31, 1999; Open: 2:30 p.m.–4:30 p.m., March 30, 1999, and 9 a.m.–3:30 p.m., March 31, 1999.

Purpose: The Committee advises and makes recommendations to the Secretary, the Assistant Secretary for Health, and the Director, CDC, regarding feasible goals for the prevention and control of injury. The Committee makes recommendations regarding policies, strategies, objectives, and priorities, and reviews progress toward injury prevention and control. The Committee provides advice on the appropriate balance and mix of intramural and extramural research, including laboratory research, and provides guidance on intramural and extramural scientific program matters, both present and future, particularly from a long-range viewpoint. The Committee provides second-level scientific and programmatic review for applications for research grants, cooperative agreements, and training grants related to injury control and violence prevention, and recommends approval of projects that merit further consideration for funding support. The Committee recommends areas of research to be supported by contracts and provides concept review of program proposals and announcements.

Matters To Be Discussed: The meeting will convene in closed session from 1:30 p.m. to 2:30 p.m. on March 30, 1999. The purpose of this closed session is for the Science and Program Review Work Group (SPRWG) to consider Injury Control Research Center grant applications recommended for further consideration by the CDC Injury Research Grant Review Committee. On March 31, 1999, from 8:30 a.m. to 9 a.m., the ACIPC voting members will convene in closed session to vote on a funding recommendation. These portions of the meeting will be closed to the public in accordance with provisions set forth in section 552b(c)(4) and (6) title 5 U.S.C., and the Determination of the Associate Director for Management and Operations, CDC, pursuant to Pub. L. 92–463.

Following the SPRWG closed session, there will be a program oversight session which will include discussion of upcoming program announcements, upcoming requests for proposals, the grant review process, and progress on standing Work Group issues. The Committee will discuss (1) an update from the Director, National Center for Injury Prevention and Control (NCIPC); (2) a presentation on unintentional injury prevention; and reports from (3) SPRWG and (4) ACIPC's Subcommittee on Family and Intimate Violence Prevention.

Agenda items are subject to change as priorities dictate.

For Further Information Contact: Mr. Thomas E. Blakeney, Executive Secretary, ACIPC, NCIPC, CDC, 4770 Buford Highway, NE, M/S K61, Atlanta, GA 30341–3724. Telephone 770/488–1481.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

John Burckhardt,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 99–6309 Filed 3–16–99; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4443–N–04]

Announcement of OMB Approval Number for Part 990—Public Housing Performance Funding System Incentives

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Announcement of OMB approval number.

SUMMARY: The purpose of this notice is to announce the effectiveness of the approval of information collections

contained in provisions of HUD's public housing Performance Funding System (PFS) regulations by the Office of Management and Budget (OMB). The approval covers §§ 990.109, 990.114, and 990.116, which pertain to projecting operating income level, phase-down of subsidy for units approved for demolition, and three-year incentive adjustments approving information collections contained throughout those regulations. This notice is necessary to inform the public of the effectiveness of these provisions and to assure that the codified regulations for 24 CFR part 990 do not contain inaccurate notations about the effectiveness of the information collections.

FOR FURTHER INFORMATION CONTACT: Mildred Hamman, Reports Liaison Officer, Office of Public and Indian Housing, Department of Housing and Urban Development, Room 4244, 451 Seventh Street, SW, Washington, DC 20410, telephone (202) 708–3642, ext. 4128. (This is not a toll-free number.) For persons with hearing or speech impairments, this number may be accessed by TTY through the Federal Information Relay Service, (800) 877–8339.

SUPPLEMENTARY INFORMATION: On September 30, 1996, HUD published a final rule revising the regulations for the PFS to add §§ 990.114 and 990.116 and to revise § 990.109, to provide a mechanism to encourage Public Housing Agencies (PHAs) to demolish and replace obsolete units and to encourage its residents to increase earned income. In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended), this notice advises that the approval numbers for the new sections are as follows:

Section No.	OMB approval No.	Expiration date
990.114	2577–0075	07/31/2001
990.116	2577–02	12/31/1999

The OMB approval number for § 990.109, 2577–0066, has expired and HUD is in the process of reinstating it. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless it displays a currently valid OMB control number.

Catalog

The Catalog of Federal Domestic Assistance number for the program affected by this rule is 14.850.

Dated: March 11, 1999.

Camille E. Acevedo,

Assistant General Counsel for Regulations.

[FR Doc. 99–6470 Filed 3–16–99; 8:45 am]

BILLING CODE 4210–33–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4441–N–19]

Submission for OMB Review: Comment Request

AGENCY: Office of the Assistant Secretary for 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.

DATES: Comments due date: April 16, 1999.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments must be received within thirty (30) days from the date of this Notice. Comments should refer to the proposal by name and/or OMB approval number and should be sent to: Joseph F. Lackey, Jr., OMB Desk Officer, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Wayne Eddins, Reports Management Officer, Department of Housing and Urban Development, 451, 7th Street, Southwest, Washington, DC 20410, telephone (202) 708–1305. This is not a toll-free number. Copies of the proposed forms and other available documents submitted to OMB may be obtained from Mr. Eddins.

SUPPLEMENTARY INFORMATION: 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 OMB approval number, if applicable; (4) the description of the need for the information and its proposed use; (5) the agency form number, if applicable; (6) what members of the public will be affected by the proposal; (7) how frequently information submissions will be required; (8) 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; (9) whether the proposal is new, an extension, reinstatement, or revision of an information collection requirement; and (10) 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 of 1995, 44 U.S.C. 35, as amended.

Dated: March 10, 1999.

David S. Cristy,

Director, IRM Policy and Management Division.

Title of Proposal: Schedule of Subscribers and Ginnie Mae Guaranty/ Contractual Agreement.

Office: Government National Mortgage Association.

OMB Approval Number: 2503–0009.

Description of the Need for the Information and its Proposed Use: This form is used to provide Ginnie Mae with a listing of subscribers/purchasers of the mortgage-backed securities, as well as other information needed to prepare the securities. It also provides the contractual agreement between issuer and Ginnie Mae.

Form Number: HUD–11705.

Respondents: Business or Other For-Profit and the Federal Government.

Frequency of Submission:

Reporting of Burden:

	Number of respondents	×	Frequency of response	×	Hours per response	=	Burden hours
HUD–11705	900		59		.17		4,002

Total Estimated Burden Hours: 4,002.

Status: Reinstatement with changes.

Contact: Sonya Suarez, HUD, (202) 708–2772; Joseph F. Lackey, Jr., OMB, (202) 395–7316.

Dated: March 10, 1999.

[FR Doc. 99–6471 Filed 3–16–99; 8:45 am]

BILLING CODE 4120–01–M

DEPARTMENT OF THE INTERIOR

Office of the Secretary

Privacy Act of 1974; as Amended; Revisions to the Existing System of Records

AGENCY: Office of the Secretary, Department of the Interior.

ACTION: Proposed revisions to an existing system of records.

SUMMARY: In accordance with the Privacy Act of 1974, as amended (5 U.S.C. 552a), the Office of the Secretary is issuing public notice of its intent to modify an existing Privacy Act system of records notice, DOI–36, ''Telephone Call Detail Records.'' The revisions will update the addresses for the System Locations and the System Managers.

EFFECTIVE DATE: These actions will be effective on March 17, 1999.

FOR FURTHER INFORMATION CONTACT: Chief, Telecommunications Systems Division, Office of Information Resources Management, MS–5312, 1849 C Street NW, Washington, DC 20240.

SUPPLEMENTARY INFORMATION: In this notice, the Department of the Interior is amending the DOI–36, ''Telephone Call Detail Records,'' to update and more accurately identify the addresses of the System Locations and the System Managers. Accordingly, the Department of the Interior proposes to amend the ''Telephone Call Detail Records,'' DOI–36 in its entirety to read as follows:

Sue Ellen Sloca,

Office of the Secretary Privacy Act Officer, National Business Center.

INTERIOR/DOI–36

SYSTEM NAME:

Telephone Call Detail Records—Interior, DOI–36.

SYSTEM LOCATION:

(1) U.S. Department of the Interior, Office of Information Resources Management, Telecommunications Systems Division, MS–5312, 1849 C Street NW, Washington, DC 20240.

(2) Office of Bureau System Managers.

(3) Bureau offices nationwide.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals (generally Department, bureau/office, and contractor employees) who make long distance telephone calls and individual who receive long distance telephone calls placed from or charged to DOI telephones.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records relating to the use of DOI telephone systems to place long distance calls; records indicating assignment of telephone numbers of employees; and records relating to the location of telephones.

Note: Records of telephone calls made to the Department's Office of Inspector General Hotline number are excluded from the records maintained in this system pursuant to the provisions of 5 U.S.C., Appendix 3 Section 7(b) (Inspector General Act of 1978).

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

31 U.S.C. 1348(b), which prohibits agencies from using appropriated funds to pay for personal calls; 44 U.S.C. 3101, which authorizes agencies to create and preserve records documenting agency organizations, functions, procedures, and transactions; and 43 CFR 201–38.007, which limits the use of Government telephone systems to the conduct of official business.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSE OF SUCH USES:

Disclosures within the Department of the Interior may be made to employees of the Department to determine responsibility for long distance telephone calls, and to resolve disputes and facilitate the verification of discrepancies relating to the billing, payment, or reconciliation of telephone operational or accountability record.

Disclosures outside the Department of the Interior may be made: (1) To representatives of a telecommunications company providing telecommunications support to permit the servicing of the account; (2) To representatives of the General Services Administration or the National Archives and Records Administration to conduct records management inspections under authority of 44 U.S.C. 2904 and 2906; (3) To the U.S. Department of Justice or in a proceeding before a court or adjudicative body when (a) the United States, the Department of the Interior, a component of the Department, or, when represented by the government, an employee of the Department is a party to litigation or anticipated litigation or has an interest in such litigation, and (b) The Department of the Interior determines that the disclosure is relevant or necessary to the litigation and is compatible with the purpose of which the records were compiled; (4) Of information indicating a violation or potential violation of a statue, regulation, rule, order or license, to appropriate Federal, State, local or foreign agencies responsible for investigating or prosecuting the violation or for enforcing or implementing the stature, rule, regulation, order or license; (5) To a Federal agency that has requested information necessary or relevant to the hiring, firing, or retention of an employee, or the issuance of a security clearance, contract, license, grant or other benefit, but only to the extent that the information disclosed is relevant and necessary to the requesting agency's decision on the matter; and (6) To a congressional office from the record of an individual in response to an inquiry the individual has made to the congressional office.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Official records are stored in electronic form.

RETRIEVABILITY:

Records are retrieved by employee name, telephone number, identification number, or by account code.

SAFEGUARDS:

Access to the records is limited to Departmental employees who have an official need to use the records in the performance of their duties. Records are stored in a controlled area and maintained with safeguards meeting the requirements of 43 CFR 2.51 for computer and paper records. Automated records are protected from unauthorized access through password identification procedures and other system-based protection methods.

RETENTION AND DISPOSAL:

In accordance with National Archives and Records Administration's General Records Schedule 12, Item 4, official (electronic) records are retained for three (3) years and then destroyed. Paper reference copies are destroyed when no longer needed or, if not before, when three (3) years old.

SYSTEM MANAGER(S) AND ADDRESS:

(1) Chief, Telecommunications Systems Division, Office of Information Resources Management, MS–5312, MIB, 1849 C Street NW, Washington, DC 20240.

(2) Telecommunications Manager, Office of Facilities Management, Bureau of Indian Affairs, PO Box 1246, Albuquerque, NM 87103.

(3) Chief, Branch of Telecommunications, Bureau of Land Management, Denver Federal Center, MS–DW101, BLD. 50, PO Box 25047, Lakewood, CO 80225.

(4) Telecommunications Manager, Bureau of Reclamation, Denver Federal Center, MS–D–7190, PO Box 25007, Denver, CO 80225.

(5) Telecommunications Manager, U.S. Fish and Wildlife Service, IRM/TFO, PO Box 25207, Denver, CO 80225.

(6) Chief, Branch of Telecommunications Services, U.S. Geological Survey, MS–809, National Center, Reston, VA 22092.

(7) Chief, Safety and Facilities Management Branch, Minerals Management Service, MS–2000, 381 Elden Street, Herndon, VA 22070.

(8) Telecommunications Manager, Information and Telecommunications Division, National Park Service, MS–2505, 1849 C Street NW, Washington, DC 20240.

(9) Telecommunications Administrator, Office of Inspector General, MS–124, SIB, 1849 C Street NW, Washington DC 20240.

(10) Chief, Telecommunications Service Office, National Business Center, Office of the Secretary, MS–1445, MIB, 1849 C Street NW, Washington, DC 20240.

(11) Telecommunications Manager, Office of Surface Mining Reclamation and Enforcement, MS–10, SIB, 1849 C Street NW, Washington, DC 20240.

NOTIFICATION PROCEDURE:

A request for notification of the existence of records shall be addressed to the appropriate System Manager. The request shall be in writing, signed by the requester, and comply with the content requirements of 43 CFR 2.60.

RECORD ACCESS PROCEDURES:

A request for access to records shall be addressed to the appropriate System Manager. The request shall be in writing, signed by the requester, and comply with the content requirements of 43 CFR 2.63.

CONTESTING RECORD PROCEDURES:

A request for amendment of records shall be addressed to the appropriate System Manager. The request shall be in writing, signed by the requester, and comply with the content requirements of 43 CFR 2.71.

RECORD SOURCE CATEGORIES:

Telephone assignment records, call detail listings, and results of administrative inquiries relating to assignment of responsibility for placement of specific long distance calls.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. 99–6441 Filed 3–16–99; 8:45 am]
BILLING CODE 4310–94–M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Receipt of an Application for an Incidental Take Permit for construction of Oak Grove High School, in Lamar County, Mississippi.

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice.

SUMMARY: The Lamar County School Board District (Applicant), is seeking an incidental take permit (ITP) from the Fish and Wildlife Service (Service), pursuant to section 10(a)(1)(B) of the Endangered Species Act of 1973 (Act), as amended. The ITP would authorize the take of the threatened Gopher tortoise, *Gopherus polyphemus,* for a fifty (50) year period. The proposed taking is incidental to land clearing and other activities associated with the construction and use of Oak Grove High School, a public education facility for grades nine through twelve, occupying a 39-acre site in Lamar County, Mississippi (Project). Surveys on the Project site indicate that at least one adult Gopher tortoise inhabits the Project. A description of the mitigation and minimization measures outlined the Applicant's Habitat Conservation Plan (HCP or Plan) to address the effects of the Project to the protected species is as described further in the **SUPPLEMENTARY INFORMATION** section below.

Further, the Service has determined that the Applicant's Plan qualifies as a ''low-effect'' Plan as defined by the Service's Habitat Conservation Planning Handbook (November 1996). The Service has further determined that approval of the Plan qualifies as a categorical exclusion under the National Environmental Policy Act (NEPA), as provided by the Department of Interior Manual (516 DM 2, Appendix 1 and 516 DM 6, Appendix 1).

Copies of the Applicant's Plan may be obtained by making a request to the Regional Office (see **ADDRESSES**). Requests must be in writing to be processed. This notice is provided pursuant to Section 10 of the Act and NEPA regulations (40 CFR 1506.6).

The Service specifically requests information, views, opinions from the public via this Notice, including information regarding the adequacy of the Plan as measured against the Service's ITP issuance criteria found in 50 CFR Parts 13 and 17.

DATES: Written comments on the application and Plan should be sent to the Service's Regional Office (see **ADDRESSES**) and should be received on or before April 17, 1999.

ADDRESSES: Persons wishing to review the Plan may obtain a copy by writing the Service's Southeast Regional Office, Atlanta, Georgia. Documents will also be available for public inspection by appointment during normal business hours at the Regional Office, 1875 Century Boulevard, Suite 200, Atlanta, Georgia 30345 (Attn: Endangered Species Permits), or Field Supervisor, U.S. Fish and Wildlife Service, 6578 Dogwood View Parkway, Suite A, Jackson, Mississippi 39213. Written data or comments should be submitted to the Regional Office.

Requests for the documentation must be in writing to be processed. Comments must be submitted in writing to be processed. Please reference permit number TE–007399–0 in such comments, or in requests of the documents discussed herein.

FOR FURTHER INFORMATION CONTACT: Mr. Rick G. Gooch, Regional Permit Coordinator, (see **ADDRESSES** above), telephone: 404/679–7110, facsimile: 404/679–7081.

SUPPLEMENTARY INFORMATION: The Gopher tortoise (*Gopherus polyphemus*), is listed as a threatened species in the western part of its range, from the Tombigbee and Mobile Rivers in Alabama west to southeastern Louisiana. As a native burrowing species of the fire-maintained longleaf pine ecosystem, typical gopher tortoise habitat consists of frequently burned longleaf pine or longleaf pine/scrub oak uplands on moderately well drained to xeric soils. About 80 percent of the original habitat for gopher tortoises has been lost due to urbanization and agriculture. Certain forest management practices in remaining upland pine habitats have also adversely affected the gopher tortoise. Silvicultural systems using intensive site preparation, dense plantations and stands of loblolly pine or slash pine, and infrequent fire have reduced or eliminated the open forest and sunny forest floor of grasses and forbs where gopher tortoises burrow, nest, and feed. Though gopher tortoises are widely distributed in south Mississippi, most populations are fragmented, small in size, and functionally non-viable.

Section 9 of the Act, and implementing regulations, prohibits taking the gopher tortoise. Taking, in part, is defined as an activity that kills, injures, harms, or harasses a listed endangered or threatened species. Section 10(a)(1)(B) of the Act provides an exemption, under certain circumstances, to the Section 9

prohibition if the taking is incidental to, and not the purpose of otherwise lawful activities.

Gopher tortoise surveys conducted by the Applicant have identified at least one adult gopher tortoise within the Project. Land clearing, construction and heavy equipment operations can directly kill or injure tortoises as a result of their becoming crushed or entombed in burrows.

The Plan describes measures the Applicant will take to avoid and mitigate such taking, including: (1) Translocation of all resident tortoises from the Project to a suitable 25-acre recipient site which already contains a colony of the species; (2) management of the recipient site for the long term benefit of the relocated tortoise(s) and the resident population; and, (3) monitoring and reporting on the effectiveness of the chosen mitigation and minimization strategy.

As earlier stated, the Service has determined that the Plan qualifies as a ''low-effect'' Habitat Conservation Plan (HCP) as defined by the Service's Habitat Conservation Planning Handbook (November 1996). Low-effect HCPs are those involving: (1) Minor or negligible effects on federally listed and candidate species and their habitats, and (2) minor or negligible effects on other environmental values or resources. The Applicant's Plan qualifies for the following reasons:

1. Approval of the Plan would result in minor or negligible effects on the Gopher tortoise and its habitat. The Service does not anticipate significant direct or cumulative effects to the Gopher tortoise resulting from construction of the Project.

2. Approval of the Plan would not have adverse effects on known unique geographic, historic or cultural sites, or involve unique or unknown environmental risks.

3. Approval of the Plan would not result in any significant adverse effects on public health or safety.

4. The project does not require compliance with Executive Order 11988 (Floodplain Management), Executive Order 11990 (Protection of Wetlands), or the Fish and Wildlife Coordination Act, nor does it threaten to violate a Federal, State, local or tribal law or requirement imposed for the protection of the environment.

5. Approval of the Plan would not establish a precedent for future action or represent a decision in principle about future actions with potentially significant environmental effects.

The Service has therefore determined that approval of the Plan qualifies as a categorical exclusion under the NEPA, as provided by the Department of the Interior Manual (516 DM 2, Appendix 1 and 516 DM 6, Appendix 1). No further NEPA documentation will therefore be prepared. In the Service's continuing efforts to ensure compliance with section 106 of the National Historic Preservation Act, the Service's Regional Archaeologist will determine, after further investigations which are currently underway, the effect of the proposed construction on cultural resources that may be present within the project area. Results of these investigations will be considered and incorporated into the Service's final determinations on this Plan.

The Service will evaluate the Plan and comments submitted thereon to determine whether the application meets the requirements of section 10(a) of the Act. If it is determined that those requirements are met, an ITP will be issued for the incidental take of the Gopher Tortoise. The Service will also evaluate whether the issuance of a Section 10(a)(1)(B) ITP complies with Section 7 of the Act by conducting an intra-Service Section 7 consultation. The results of the consultation, in combination with the above findings, will be used in the final analysis to determine whether or not to issue the ITP; the final decision will be made no sooner than 30 days from the date of this notice.

Dated: March 11, 1999.

H. Dale Hall,

Deputy Regional Director.

[FR Doc. 99–6437 Filed 3–16–99; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Availability of an Environmental Assessment and Receipt of an Application for a Permit to Allow Incidental Take of Threatened and Endangered Species in Connection With the North Peak Development Project in the City of Lake Elsinore, Riverside County, California

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of Availability.

SUMMARY: North Peak Partners, L.P., (Partners) have applied to the Fish and Wildlife Service for an incidental take permit pursuant to the Endangered Species Act of 1973, as amended (Act). The Partners request a 30-year permit authorizing incidental take of certain species in connection with the development of a master planned community, road improvements, ongoing management on open space and facilities, and implementation of conservation measures in the planning area located in the City of Lake Elsinore, Riverside County, California. The proposed permit would allow take in the form of harm or harassment of 3 currently listed species [coastal California gnatcatcher (*Polioptila californica californica*), least Bell's vireo (*Vireo bellii pusillus*), and Stephens' kangaroo rat (*Dipodomys stephensi*)] and 30 sensitive species that may be listed as threatened or endangered during the period permit. The proposed permit also would allow take in the form of harassment of 16 bird and mammal species, primarily raptors and bats that forage in the area. In addition, the Partners anticipate that 12 additional species would need to be added to the permit (if found to be present and a taking would occur) and have proposed a streamlined amendment process to determine measures to avoid, minimize, mitigate, and authorize take of those species. As required under the Act, the Partners have prepared a habitat conservation plan (Plan) for the species that would be covered by the incidental take permit and have submitted the Plan to the Service, together with an Implementation Agreement. The Plan and Implementation Agreement are part of the permit application.

The Service announces the availability of the permit application and the Environmental Assessment for public review and comment. All comments received, including names and addresses, will become part of the administrative record and may be made available to the public.

DATES: Written comments on the permit application and the Environmental Assessment should be received on or before April 16, 1999.

ADDRESSES: Comments should be addressed to Jim Bartel, Assistant Field Supervisor, Fish and Wildlife Service, 2730 Loker Avenue West, Carlsbad, California 92008. Comments may be sent by facsimile to 760–431–9624.

FOR FURTHER INFORMATION CONTACT: Michelle Shaughnessy, Branch Chief, or Dan Brown, Fish and Wildlife Biologist, at the above address (telephone: 760–431–9440).

SUPPLEMENTARY INFORMATION:

Availability of Documents

If you would like a copy of the documents, contact the Service's Carlsbad Fish and Wildlife Office at the above referenced address or telephone. Documents also are available for public

inspection, by appointment, during normal business hours at the above address.

Background Information

Under section 9 of the Act and its implementing regulations, ''taking'' of threatened or endangered wildlife species is prohibited. That is, no one may harass, harm, pursue, hunt, shoot, wound, kill, trap, capture or collect listed animal species, or attempt to engage in such conduct (16 USC 1538). The Service, however, may issue permits to take such species if the taking is incidental to, and not the purpose of, otherwise lawful activities. Regulations governing such permits are in 50 CFR 17.32 for threatened species and 50 CFR 17.22 for endangered species.

The permit requested by the Partners would allow incidental take of up to 61 species in connection with direct and indirect effects of development and management activities identified in the Plan. The area covered by the proposed permit includes approximately 997 acres within a Specific Plan area and 23 acres along the road providing access to the site. It is estimated that 1 pair of California gnatcatchers, 1 acre of potential least Bell's vireo habitat, and 220 acres of Stephens' kangaroo rat habitat would be harmed. Take of other species covered by the Plan is estimated in terms of habitat removal and would range from 1 to 621 acres depending on the habitat of the species. To avoid, minimize, and mitigate the effects of take, the Partners propose to limit direct harm to species, conserve 511 acres of natural habitats (including 340 acres of coastal sage scrub and 19 acres of riparian/wetland habitats), provide for the ongoing management of onsite conserved habitat, and maintain wildlife corridors and habitat connections across the property and to other protected lands. Approximately 411 acres would be conserved onsite (including 36.6 acres revegetated with coastal sage scrub and 11 acres of created/enhanced riparian and wetland habitats). Onsite conserved habitat would include 1 coastal California gnatcatcher use area, 6 acres of least Bell's vireo habitat, and 290 acres providing regionally significant habitat connections for Stephens' kangaroo rat. Two parcels totaling 100 acres would be dedicated to existing wildlife reserves in the region.

The Environmental Assessment considers six alternatives, including No Action. The first alternative considers the effects of the development project on the species of concern assuming implementation of the Plan as proposed by the Applicant. The second alternative considers reduced habitat impacts and increased onsite conservation in the master planned community through elimination of one of two proposed golf courses. The third alternative considers preservation of the area proposed for the master planned community under a mitigation banking agreement. Two variations of the third alternative are presented: one that covers the plan area identified in the Partner's Plan, and one that would conserve an additional 773 acres in the Specific Plan area as part of the mitigation bank. The 773 acres that would be added under the second variation have already been proposed by the Partners as a mitigation bank. The fourth alternative considers additional residential development instead of two golf courses in the master planned community. The fifth alternative considers development and onsite conservation as proposed in the 1991 Specific Plan for the property. The sixth alternative (No Action) considers a continuation of existing conditions in the plan area.

This notice is provided pursuant to section 10 (a) of the Act and Service regulations for implementing the National Environmental Policy Act of 1969 (40 CFR 1506.6). The Service will evaluate the application, associated documents, and comments submitted thereon to determine whether the application meets the requirements of law. If the Service determines that the requirements are met, a permit will be issued for the incidental take of the listed species. A final decision on permit issuance will be made no sooner than 30 days from the date of this notice.

Dated: March 10, 1999.

Elizabeth H. Stevens,

Deputy Manager, California/Nevada Operation Office, Region 1, Sacramento, California.

[FR Doc. 99–6438 Filed 3–16–99; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

Notice of Fund Availability and Distribution Process of the FY 1999 Housing Improvement Program Appropriation

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice.

SUMMARY: The Fiscal Year (FY) 1999 Department of the Interior, Bureau of Indian Affairs (Bureau), Housing Improvement Program (HIP) appropriation is $18,780,383. This Notice of Fund Availability describes the process by which this appropriation will be distributed to Bureau Area Offices and subsequently for individual eligible grantees through Indian tribal governments for FY 1999.

FOR FURTHER INFORMATION CONTACT: June Henkel, Office of Tribal Services, Bureau of Indian Affairs, Department of the Interior, 1849 C Street, NW, MS–4603–MIB, Washington, D.C. 20240. Telephone 202–208–3667, Fax 202–208–2648.

SUPPLEMENTARY INFORMATION: The purpose of this notice is to identify the methodology that will be used to distribute the Housing Improvement Program FY 1999 Appropriation.

Background

The HIP provides housing services to individuals, in the form of a grant, and is available to the neediest of the needy Indian applicants residing on Indian reservations or within ''approved service areas.'' An Indian reservation means any federally recognized Indian tribe's reservation, Pueblo, or Colony, including former reservations in Oklahoma, Alaska Native regions established pursuant to the Alaska Native Claims Settlement Act, Pub. L. 92–203, and Indian allotments. Eligible individual Indian applicants are those with limited resources who do not qualify for or otherwise cannot receive assistance from other housing programs. The HIP provides a non-duplicative service and differs from the Department of Housing and Urban Development (HUD) Indian housing programs specifically because the recipients of HIP grants are unable to meet HUD's minimum income requirements.

Revised HIP regulations, published in the **Federal Register** on March 2, 1998, and effective on April 1, 1998 (63 FR 10134), establish the Bureau's housing policy that every American Indian family should have the opportunity for a decent home and suitable living environment. To the extent possible, the program will serve the neediest of the needy Indian applicants. Accordingly, the Bureau defines the HIP as a secondary safety net program which provides assistance to Indian applicants who have no other recourse for housing assistance.

The limited availability of funds for this program require the continued use of a needs based distribution methodology. Funds are made available to tribal governments based upon the submission of: (1) viable, annual work plans, containing (a) the identification of eligible applicants; (b) identification

of the category of assistance needed; and, (c) the estimated project costs for each eligible applicant; and, (2) a report of prior year accomplishments.

Basis for Distribution of the FY 1999 HIP Appropriation

Area Offices will distribute FY 1999 HIP funds to the tribes within their respective areas who: (1) Have eligible applicants as defined under the revised rule in 25 CFR 256, effective April 1, 1998; (2) have submitted their FY 1997 inventory of housing needs; (3) have viable work plans; (4) are in compliance with the intent of the program; (5) have an approved service area; and, (6) provide a report of prior year accomplishments.

A viable work plan means that planned work projects fall within the scope and framework of the HIP and that the tribe has eligible HIP applicants. Funds will be distributed only to tribes with eligible HIP applicants.

The HIP funds identified for the Office of Self-Governance (OSG) tribes with an annual funding agreement are provided under the same general guidance as for other tribes. HIP funding should only be made available to tribes with eligible HIP applicants and in accordance with the payment provision, Pub. L. 103–413, Sec. 403(g)(3), which requires the Secretary to ''* * * provide funds to the tribe under an agreement under this title for programs, services, functions, and activities, or portions thereof, in an amount equal to the amount that the tribe would have been eligible to receive under contracts and grants under the Act.''

Area Offices are to ensure that distributed amounts are sufficient to fund at least one complete project. Therefore, Area Offices must devise or follow a previously established plan to rotate funds between tribes with projects requiring two or more years funding. (The intention is to fund as many HIP projects as possible, while curtailing the amount of unexpended funds, to enable the Bureau to attain performance goals as outlined in the FY 1998 strategic plan). Accordingly, Area Offices are authorized to redistribute funds from those tribes unable to expend some or all of their FY 1998 funding, to other tribes capable of expending the funds. Area Offices must notify Central Office of such actions. In addition, the areas and the OSG will be required to submit a report to Central Office in May 1999, identifying the funds obligated/expended and the funds available to be withdrawn for reallocation to other locations because of the lack of HIP eligible applicants.

Reprogramming of HIP funds to other Tribal Priority Allocation (TPA) programs is prohibited; however, tribes may supplement their HIP funds from other funding within their TPA.

This Notice of Fund Availability and the Distribution Process for the FY 1999 Housing Improvement Program Appropriation does not include FY 1998 TPA funds that were prioritized by tribes to be used for HIP.

Dated: February 18, 1999.

Kevin Gover,

Assistant Secretary—Indian Affairs.

[FR Doc. 99–6399 Filed 3–16–99; 8:45 am]

BILLING CODE 4310–02–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[OR–010–1430–00; GP9–0119]

Call for Nominations for the Southeast Oregon Resource Advisory Council

AGENCY: Lakeview District, Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The Bureau of Land Management Oregon State Office is calling for nominations to fill two unexpired terms in the Group I category on the Southeast Oregon Resource Advisory Council. The Southeast Oregon Council currently provides advice and recommendations to the Bureau of Land Management (BLM) and the Forest Service (FS). The nomination period will close on Monday, April 26, 1999.

The purpose of Resource Advisory Councils is to enable State residents and local citizens to have a meaningful say in how federal lands are managed. The Councils, which were established in August, 1995, provide advice on the broad array of resource issues that face federal land managers.

The Southeast Oregon RAC advises federal officials on the management of federal lands in Southeast Oregon. The area covers most of Malheur, Harney, and Lake Counties and small portions of Klamath, Deschutes, Crook, Grant, and Baker Counties.

The Southeast Oregon RAC operates on principles of collaboration and consensus. Council members are sought who are committed to working with other interests for the long term benefit of public lands and national forests.

The Southeast Oregon RAC worked with the BLM on the development of draft standards for rangeland health and guidelines for grazing management and has been providing the BLM with recommendations on the development of a Southeastern Oregon Resource Management Plan.

Council members serve without monetary compensation, but are reimbursed for travel and per diem expenses. Prospective members are advised that membership on a Council calls for a substantial commitment of time and energy.

Individuals may nominate themselves or others. Council members may be renominated upon the expiration of their terms. The Southeast Oregon RAC is composed of 15 members who serve 3-year terms with one-third of the terms expiring each year. This provides an experienced panel of members at any given time. Nominees must be residents of the State of Oregon.

Nominees are being sought to fill the vacant Transportation/Right-of-Way representative and the Energy/Minerals representative positions, for terms which expire in August 2000 and September 1999, respectively. Nominees will be evaluated based on their experience working with the interest area they choose to represent, and their knowledge of the geographic area covered by the Council. Nominees must also have demonstrated a commitment to collaborative resource decision making. All nominations must be accompanied by letters of reference from represented interests or organizations, a completed background information nomination form, as well as any other information that speaks to the nominee's qualification. To obtain a nomination form or additional information, please contact Public Affairs, Bureau of Land Management, Oregon State Office, P.O. Box 2965, Portland, OR 97208 (503) 952–6027, or your local BLM District Office.

Completed nomination forms and letters of reference should be sent to Elaine Zielinski, State Director, Bureau of Land Management, Oregon State Office, P.O. Box 2965, Portland, OR 97208. The BLM State Director, the Forest Service Regional Forester, and the Governor's Office will forward these nominations to the Secretary of Interior, who will make the appointments to the Council.

Dated: February 26, 1999.

FOR FURTHER INFORMATION, CONTACT: Sonya Hickman, Bureau of Land Management, Lakeview District Office, HC 10 Box 337, Lakeview, OR 97630 (Telephone: 541/947–2177).

Joe Tague,

Acting Designated Federal Official.

[FR Doc. 99–6221 Filed 3–16–99; 8:45 am]

BILLING CODE 4310–33–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[NM–030–1430–00; NMNM 96531 & NMNM 98501]

Notice of Realty Action; Recreation and Public Purposes (R&PP) Act Classification; New Mexico

AGENCY: Bureau of Land Management (BLM), Interior.

ACTION: Correction notice.

SUMMARY: In **Federal Register** Volume 64, Page 6114, Number 25 of Monday, February 8, 1999, Notices, under the SUMMARY heading, change the legal description of ''Parcel 1'' to read:

Parcel 1

T. 29 S., R. 4 E., NMPM
Sec. 17, Lots 6, 8, and 9, W½E½NE¼.
Containing 138.88 acres, more or less.

Dated: March 11, 1999.

Tim L. Sanders,

Acting Assistant Field Manager, Las Cruces Field Office.

[FR Doc. 99–6439 Filed 3–16–99; 8:45 am]

BILLING CODE 4310–VC–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[OR–050–1150–00; GP9–0133]

Notice of Noncompetitive Sale of Public Lands in Grant County, Oregon

AGENCY: Bureau of Land Management, Prineville District Office.

ACTION: Notice of noncompetitive sale of public lands in Grant County, Oregon.

SUMMARY: The following land has been found suitable for direct sale under Section 203 of the Federal Land Policy and Management Act of 1976 (90 Stat. 2750, 43 U.S.C. 1713). The land will not be offered for sale until at least 60 days after the date of notice.

Willamette Meridian

T. 12 S., Range 33 E.,
Section 24: NW¼SW¼
Containing approximately 40 acres.

The land described is hereby segregated from appropriation under the public land laws, including mining laws, pending disposition of this.

A decision to convey the land to the city of Prairie City, Oregon was signed on February 23, 1999. The action would result in the disposal of the tract that contains the cities solid waste disposal landfill. The action has been determined to be a logical means to resolve Prairie City's continuing need for a solid waste disposal site in a reasonable location without incurring the major expenses to close the existing site and develop a new one.

For a period of 45 days from the date of publication of this notice in the **Federal Register** interested parties may submit comments to the District Manager, P.O. Box 550, Prineville, Oregon 97754. In the absence of timely objections, this proposal shall become the final determination of the Department of the Interior.

FOR FURTHER INFORMATION CONTACT: Ron Lane, P.O. Box 550, Prineville, Oregon 97754, or call (541) 416–6700.

Dated: March 5, 1999.

James L. Hancock,

District Manager.

[FR Doc. 99–6413 Filed 3–16–99; 8:45 am]

BILLING CODE 4310–33–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[MT–060–08–1220–00]

Notice of Upstream Travel Restrictions in ''Wild and Scenic'' Segments of the Upper Missouri National Wild and Scenic River

SUMMARY: Notice is hereby given that effectively immediately and in accordance with the Upper Missouri National Wild and Scenic River Management Plan Update, February 1993, seasonal boating restrictions are in effect on the ''Wild and Scenic'' segments of the Upper Missouri National Wild and Scenic River from the Saturday before the observed Memorial Day through the Sunday after Labor Day.

Open Segments: from Fort Benton (river mile 0) to Pilot Rock (river mile 52) and Deadman's Rapids (river mile 84.5) to Holmes Council Island (river mile 92.5). In these segments, motorized travel upstream and downstream allowed.

Seasonal Restricted Segments: from Pilot Rock (river mile 52) to Deadman's Rapids (river mile 84.5) and from Holmes Council Island (river mile 92.5) to Fred Robinson Bridge (river mile 149). In these seasonally restricted segments, extended upstream travel by motorized watercraft is limited to official administrative, emergency, or law enforcement watercraft only. Downstream travel by motorized craft is allowed in these segments, but cannot exceed a white water wake speed. A white water wake speed is defined as a speed where white water occurs in the path of the vessel or in waves created by the vessel.

These seasonal restrictions in the ''Wild and Scenic'' segments of the Upper Missouri National Wild and Scenic River Corridor are necessary to reduce user conflicts, limit noise impacts, protect all boaters from capsizing or collisions, and to protect boats and canoes tied at the rivers edge.

SUPPLEMENTARY INFORMATION: Any person convicted of violating these restrictions shall be punished by a fine not to exceed $500.00 or by imprisonment for a period not to exceed 6 months, or both, and shall be adjudged to pay all costs of the proceedings (43 CFR 8351.2–1).

FOR FURTHER INFORMATION CONTACT: Lewistown Field Manager, Lewistown Field Office, P.O. Box 1160, Lewistown, Montana 406/538–7461.

Dated: March 8, 1999.

David L. Mari,

Field Manager.

[FR Doc. 99–6412 Filed 3–16–99; 8:45 am]

BILLING CODE 4310–DN–P

DEPARTMENT OF THE INTERIOR

Minerals Management Service

Agency Information Collection Activities: Submitted for Office of Management and Budget Review; Comment Request

Title: Designation of Royalty Payment Responsibility, OMB Control Number 1010–0107.

Comments: This collection of information has been submitted to the Office of Management and Budget for approval. In compliance with the Paperwork Reduction Act of 1995, Section 3506 (c)(2)(A), we are notifying you, members of the public and affected agencies, of this collection of information, and are inviting your comments. Is this information collection necessary for us to properly do our job? Have we accurately estimated the public's burden for responding to this collection? Can we enhance the quality, utility, and clarity of the information we collect? Can we lessen the burden of this information collection on the respondents by using automated collection techniques or other forms of information technology?

Comments should be made directly to the Attention: Desk Officer for the Interior Department, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503; telephone (202) 395–7340. Copies of these comments should also be sent to us. The U.S.

Postal Service address is Minerals Management Service, Royalty Management Program, Rules and Publications Staff, P.O. Box 25165, MS 3021, Denver, Colorado, 80225–0165; the courier address is Building 85, Room A–613, Denver Federal Center, Denver, Colorado 80225; and the e:Mail address is RMP.comments@mms.gov. OMB has up to 60 days to approve or disapprove the information collection but may respond after 30 days; therefore, public comments should be submitted to OMB within 30 days in order to assure their maximum consideration.

Copies of the proposed information collection and related explanatory material may be obtained by contacting Dennis C. Jones, Rules and Publications Staff, telephone (303) 231–3046, FAX (303) 231–3385, e-Mail Dennis.C.Jones@mms.gov.

DATES: Written comments should be received on or before April 16, 1999.

SUMMARY: The Federal Oil and Gas Royalty Simplification and Fairness Act of 1996 (RSFA), Pub. L. 104–185, as corrected by Pub. L. 104–200, establishes the owners of operating rights and/or lease record title (who are jointly defined as ''lessees'' under RSFA) as responsible for making royalty and related payments on a Federal lease. Currently, it is common for a payor rather than a lessee to make royalty and related payments on a Federal lease. When a payor pays royalties on a Federal lease on behalf of a lessee, RSFA requires that the lessee certify to MMS in writing that a particular payor has been designated by the lessee to make such royalty and related payments to MMS on behalf of the lessee. RSFA made this payor designation requirement effective for lease production beginning September 1, 1996.

Description of Respondents: Federal lessees.

Frequency of Response: As necessary.

Estimated Reporting and Recordkeeping Burden: 45 minutes.

Annual Responses: 11,500.

Annual Burden Hours: 8,625 hours.

Bureau Clearance Officer: Jo Ann Lauterbach, (202) 208–7744.

Dated: February 17, 1999.

Lucy Querques Denett,

Associate Director for Royalty Management.

[FR Doc. 99–6450 Filed 3–16–99; 8:45 am]

BILLING CODE 4310–MR–P

DEPARTMENT OF THE INTERIOR

National Park Service

60 Day Notice of Intention To Request Clearance of Collection of Information: Opportunity for Public Comment

AGENCY: National Park Service, The Department of the Interior.

ACTION: Notice and request for comments.

SUMMARY: Under the provisions of the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C., Chapter 3507) and 5 CFR Part 1320, Reporting and Recordkeeping Requirements, the National Park Service invites public comments on a proposed information collection request (ICR). Comments are invited on: (1) The need for information including weather the information has practical utility; (2) the accuracy of the reporting burden estimate; (3) ways to enhance the quality, utility, and clarity of the information to be collected: and (4) ways to minimize the burden of information collection on respondents, including the use of automated collection techniques or other forms of information technology.

The primary purpose if the ICR is to nominate properties for listing in the National Register of Historic Places, the office list of the Nation's cultural resources worthy of preservation, which public law requires that the Secretary of the Interior maintain and expand. Properties are listed in the National Register upon nomination by State Historic Preservation Officers and Federal Preservation Officers. Law also requires Federal agencies to request determinations of eligibility for property under their jurisdiction of affected by their program and projects. The forms provide the historic documentation on which decisions for listing and eligibility are based.

DATES: Public comments will be accepted on or before May 17, 1999.

ADDRESSES: Send comments to Carol Shull, Keeper of the National Register, National Park Service, 1849 ''C'' Street NW, Rm. NC 400, Washington, DC 20240.

All responses to this notice will be summarized and included in the request for OMB approval. All comments will become a matter of public record. Copies of the proposed ICR requirement can be obtained from Carol Shull, Keeper of the National Register, National Park Service, 1849 ''C'' Street, Rm. NC 400, Washington, D.C. 20240.

FOR FURTHER INFORMATION CONTACT: Carol Shull, (202) 343–9504.

SUPPLEMENTARY INFORMATION:

Title: National Register of Historic Places Registration Form, National Register of Historic Places Continuation Sheet, and National Register of Historic Places Multiple Property Documentation Form.

Form: NPS 100, –a,–b.

OMB Number: NPS 1024–0018.

Type of Request: Renewal.

Description of need: The National Historic Act requires the Secretary of the Interior to maintain and expand the National Register of Historic Places, and to establish criteria and guidelines for including properties in the National Register. The National Register of Historic Places Registration Form documents properties nominated for listing in the National Register and demonstrates that they meet the criteria established for inclusion. The documentation is used to assist in preserving and protecting the properties and for heritage education and interpretation National Register properties must be considered in the planning for Federal or federally assisted projects. National Register listing is required for eligibility for the federal rehabilitation tax incentives.

Description of respondents: The affected public are State, tribal, and local governments, Federal agencies, business, non-profit organizations, and individuals. Nominations to the National Register of Historic Places are voluntary.

Estimated annual reporting burden: 56,700 hours.

Estimated average burden hours per response: 18 hours.

Estimated average number of respondents: 1,575.

Estimated frequency of response: 1,575 annually.

Leonard Stowe,

Information Collection Clearance Officer, National Park Service, WAPC.

[FR Doc. 99–6422 Filed 3–16–99; 8:45 am]

BILLING CODE 4310–70–M

DEPARTMENT OF THE INTERIOR

National Park Service

Notice of Boundary Revision, Cabrillo National Monument

AGENCY: National Park Service, DOI.

ACTION: Notice of boundary revision, Cabrillo National Monument.

SUMMARY: This notice announces a revision of the boundary of Cabrillo National Monument to include three parcels of land needed for (1) the proper care and management of the Monument and the historical landmarks and

historical objects therein (2) to provide public access to the intertidal area and (3) to preserve and protect US Fish and Wildlife Service designated sensitive coastal sage scrub habitat. The Department of the Navy has declared these parcels as excess to its needs and has recommended they be transferred to the National Park Service for inclusion in the boundary of the Monument in accordance with a Memorandum of Agreement dated January 12, 1970.

FOR FURTHER INFORMATION CONTACT: Sondra S. Humphries, Chief, Pacific Land Resources Program Center at (415) 427–1416.

SUPPLEMENTARY INFORMATION: Notice is hereby provided that the boundary of Cabrillo National Monument, established pursuant to Presidential Proclamation No. 1255 on October 14, 1913, as amended, is revised, effective as of the date of publication of this notice, to include three parcels of land situated in San Diego County, State of California. The above parcels aggregate 25.60 acres, more or less, and are identified as Tract Nos. 01–103, 01–104 and 01–106 on Boundary Proposal Map, Drawing No. 342/80,034, dated July, 1997. The map is on file at the National Park Service, Pacific Land Resources Program Center, 600 Harrison Street, Suite 600, San Francisco, California 94107–1372

Dated: February 26, 1999.

John Reynolds,

Regional Director, Pacific West Region.

[FR Doc. 99–6423 Filed 3–16–99; 8:45 am]

BILLING CODE 4310–70–P

DEPARTMENT OF THE INTERIOR

National Park Service, DOI

Notice of Intent To Prepare an Off-Road Vehicle Management Plan/ Supplement to the Final Environmental Impact Statement (ORVMP/SEIS), Big Cypress National Preserve, National Park Service

SUMMARY: A notice of intent for this action that omitted a reference to the SEIS component of the plan was published on January 22, 1996. One purpose of this notice is to correct this omission. Further, in accordance with Section 102(2)(C) of the Environmental Policy Act of 1969 (Pub. L. 91–190), the National Park Service has initiated a supplemental environmental impact analysis process to identify and assess potential impacts of alternative options for the management of off-road vehicles within the Big Cypress National Preserve. Key management concerns include the need to protect natural and cultural resources while providing recreational ORV access to the Preserve. A series of meetings, interviews, and surveys were conducted to gather information and the opinions of stakeholders in order to begin preparation of the ORVMP/SEIS.

DATES: Public comments will be accepted on or before April 16, 1999. Anyone wishing to provide comments or suggestions on the proposed action should provide comments to the Superintendent at the address stated below.

Following publication of a draft ORVMP/SEIS, representatives of Federal, Tribal, State and local agencies, private organizations and individuals from the general public will be afforded an opportunity to comment at a public meeting. The date, time, and location of the public meeting will be announced in local and regional news media.

ADDRESSES: Anyone wishing to provide comments or suggestions on the ORVMP/SEIS may send such information to: Superintendent, Big Cypress National Preserve, HCR 61, Box 110, Ochopee, FL 34141.

SUPPLEMENTARY INFORMATION: An ORV management plan was initially called for in the final General Management Plan/Environmental Impact Statement (1992) for the Preserve. An October 1995 Settlement Agreement filed in the U.S. District Court for the Middle District of Florida also required issuance of the ORVMP/SEIS.

Since 1995, working through a cooperative agreement with the Virginia Polytechnic Institute and State University, the National Park Service has been collecting data and public opinion for the development of an ORV plan for the Preserve. Efforts to collect data and information included meetings and interviews with groups, organizations and individuals from a variety of sectors including ORV and hunting groups, hiking clubs, environmental groups, employees or associates of the Miccosukee or Seminole Tribes, state agencies, and other federal agencies. Other methods used to gather and solicit information from the public included a mail-back ORV visitors-use survey, a Website and E-mail, and two newsletters, distributed in 1996 and 1997 to an estimated 1600 people.

The National Park Service has now entered that phase of the project in which alternatives for the management of ORVs in the Preserve will be developed and considered. In accordance with the aforementioned National Environmental Policy Act (NEPA), the National Park Service will utilize the public involvement procedures of NEPA to provide an opportunity for the public to receive information and express their views, and to meet with interested members of the public in assessing the potential effects of the alternative options of the ORVMP/SEIS.

The National Park Service will analyze alternatives so as to evaluate differing options for resource protection, visitor use, access, safety and operations. As a conceptual framework for formulating these alternatives, the purposes of the Preserve and associated significant natural and cultural resources, major visitor experiences and management objectives will be specified.

The subsequent availability of the ORVMP/SEIS will be announced by formal notice and via local and regional news media. The draft ORVMP/SEIS is anticipated to be completed and available for public review in 1999. The final ORVMP/SEIS is expected to be completed approximately four months later, with a Record of Decision published in the **Federal Register** not sooner than 30 days after distribution of the final ORVMP/SEIS documents.

Dated: March 10, 1999.

Danielle Brown,

Regional Director, Southeast Region.

[FR Doc. 99–6421 Filed 3–16–99; 8:45 am]

BILLING CODE 4310–70–M

DEPARTMENT OF THE INTERIOR

National Park Service

Notice of Availability of a Plan of Operations and Environmental Assessment for Existing Natural Gas Pipelines at Padre Island National Seashore, Kenedy and Kleberg Counties, Texas

The National Park Service has received, for approval, from Houston Pipe Line Company, a Plan of Operations for Existing Natural Gas Pipelines at Padre Island National Seashore. An approved Plan of Operations would serve as a permit for the pipeline operations.

Pursuant to § 9.52(b) of Title 36 of the Code of Federal Regulations, Part 9, Subpart B (36 CFR 9B); the Plan of Operations and Environmental Assessment are available for public review and comment for a period of 30 days from the publication date of this notice in the Office of the Superintendent, Padre Island National Seashore, 20301 Park Road 22, Corpus Christi, Texas. Copies of the documents

are available from the Superintendent, Padre Island National Seashore, P.O. Box 181300 Corpus Christi, Texas 78480–1300, Telephone (361) 949–8173, extension 224.

Jock Whitworth,

Superintendent.

[FR Doc. 99–6420 Filed 3–16–99; 8:45 am]

BILLING CODE 4310–70–P

DEPARTMENT OF THE INTERIOR

Bureau of Reclamation

Privacy Act of 1974, as Amended; System of Records

AGENCY: Bureau of Reclamation, Interior.

ACTION: Notice of minor changes to two systems of records.

SUMMARY: Pursuant to the provisions of the Privacy Act of 1974, as amended (5 U.S.C. 552a), notice is hereby given that the Department of the Interior proposes minor changes to two systems of records managed by the Bureau of Reclamation (Reclamation). These changes are to the systems of records:

''Claims, WBR–5''

''Acreage Limitation, WBR–31''

The above notices are published in their entirety below.

DATES: These actions are effective March 17, 1999.

FOR FURTHER INFORMATION CONTACT: For information regarding ''Claims, BOR–5'' contact Ms. Debra Lange, Property and Office Services, Policy and Systems Team at (303) 445–2030, or for information regarding ''Acreage Limitation, BOR–31'' contact Mr. Richard Rizzi, Reclamation Law, Contracts, and Repayment Office at (303) 445–2900. For general information regarding Reclamation's Privacy Act program, call Mr. Casey Snyder at (303) 445–2048.

SUPPLEMENTARY INFORMATION: Recent Privacy Act Compilations list the following systems of records with a prefix of ''Reclamation'' (e.g., Reclamation-5). When originally published in the **Federal Register** these systems of records were identified with an organization prefix of ''WBR'' (e.g., WBR–5). The content of the systems of records is the same; the prefixes on these systems were changed to reflect organizational changes.

The system of records notices being revised and the reason for revision are listed below:

- Claims, WBR–5, previously published in the **Federal Register** on September 27, 1984 (49 FR 38195). This publication revises the system location and the system manager's title and address. Federal Government organization titles have been updated and other minor editorial changes made.
- Acreage Limitation, WBR–31, previously published in the **Federal Register** on March 9, 1994 (59 FR 11085). This publication revises the retention and disposal statement to reflect the revisions to the Acreage Limitation Rules and Regulations, 43 CFR part 426, which became effective January 1, 1998. Specifically, the retention period of the certification and reporting forms (including verification forms) is changed from 3 to 6 years and the Code of Federal Regulations cited is changed from 43 CFR 426.10(h) to 43 CFR 426.19(e). The term ''Federal Employer's Identification Numbers'' is changed to ''Taxpayer's Identification Numbers'' in the categories of records in the system and the retrievability statements. In addition, the term ''Individual Taxpayer's Identification Numbers'' is added to both statements. Organization titles have been updated and other minor editorial changes made. All other changes proposed are editorial in nature.

Rayleen Cruz,

Manager, Property and Facilities Group.

INTERIOR/WBR–5

SYSTEM NAME:

Claims.

SYSTEM LOCATION:

Commissioner's Office, Reclamation Service Center, and Regional Offices: Pacific Northwest, Mid-Pacific, Lower Colorado, Upper Colorado, and Great Plains. See appendix for addresses.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals who have filed tort, employee, or appropriation act claims, and claims under the Teton Dam Disaster Assistance Act.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records include claims and supporting documents submitted, information developed during investigations of claims, and final disposition.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Federal Tort Claims Act, 28 U.S.C. 2671–2680; Military Personnel and Civilian Employees' Claims Act, 31 U.S.C. 3701, 3721; Public Works for Water and Power Development and Energy Research Appropriation Act, 1977, Pub. L. 94–355, 90 Stat. 889; Teton Dam Disaster Assistance Act, Pub. L. 94–400, 90 Stat. 1211; Supplemental Appropriation Act, 1977, Pub. L. 94–438, 90 Stat. 1415; and annual Energy and Water Development Appropriation Acts.

PURPOSE(S):

For settlement of damages relating to tort and non-tortious claims and for loss or damage to employee's personal property resulting from activities of Reclamation. Routine uses of records maintained in the system, including categories of users and the purposes of such uses:

The primary uses of the records are to establish the facts and circumstances of each claim, compile statistical data, and evaluate claims. Disclosures outside the Department of the Interior may be made: (1) To the Department of Justice when related to litigation or anticipated litigation; (2) of information indicating a violation or potential violation of a statute, regulation, rule, order, or license to appropriate Federal, State, local, or foreign agencies responsible for investigating or prosecuting the violation or for enforcing or implementing the statute, rule, regulation, order, or license; (3) from the record of an individual in response to an inquiry from a congressional office made at the request of that individual; (4) where relevant or necessary to the hiring or retention of an employee, or the issuance of a security clearance, license, contract, grant, or other benefit, information may be disclosed: (a) To a Federal agency that has requested the information, or (b) to a Federal, State, or local agency to enable the Department of the Interior to obtain information from such agency; (5) to the Soil Conservation Service, and Farm Service Agency of the Department of Agriculture (USDA); Federal Emergency Management Agency, Army Corps of Engineers, and Department of Housing and Urban Development to assure that benefits to claimants have not been duplicated by the several agencies involved in disaster programs; (6) to the Department of Treasury, Internal Revenue Service, and State revenue and taxation departments relative to compensation for loss of salary or income; (7) to the Small Business Administration, Farm Service Agency, and Department of Housing and Urban Development regarding loans secured through those agencies; and (8) to General Services Administration (GSA) to document problems with GSA contract movers which result in claims against Reclamation.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Maintained in manual form in file folders.

RETRIEVABILITY:

By claimant's name.

SAFEGUARDS:

Records are maintained with safeguards in accordance with the requirements of 43 CFR 2.51 for manual records.

RETENTION AND DISPOSAL:

In accordance with approved retention and disposal schedules.

SYSTEM MANAGER(S) AND ADDRESS:

Claims Officers in the Reclamation Service Center, Commissioner's Office, and Regional Offices: Pacific Northwest, Mid-Pacific, Lower Colorado, Upper Colorado, and Great Plains. See appendix for addresses.

NOTIFICATION PROCEDURE:

Inquiries regarding the existence of a record(s) should be addressed to the System Manager at the appropriate address listed in the appendix. See 43 CFR 2.60.

RECORD ACCESS PROCEDURES:

Same as Notification above. See 43 CFR 2.63.

CONTESTING RECORD PROCEDURES:

Written petitions for amendment should be sent to the System Manager at the appropriate address listed in the appendix. See 43 CFR 2.71.

RECORD SOURCE CATEGORIES:

Claimants. Investigations conducted by Reclamation officials and contractors, officials of the Department of the Interior, and State and local governments.

INTERIOR/WBR–31

SYSTEM NAME:

Acreage Limitation.

SYSTEM LOCATION:

(1) District offices in which subject individuals submitted certification and reporting forms (addresses may be obtained from the applicable regional office); (2) Regional offices listed in the appendix; and (3) Bureau of Reclamation, PO Box 25007, Denver, Colorado 80225–0007.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals that directly or indirectly own or lease land that is subject to the acreage limitation provisions of Federal reclamation law, and individuals that operate such land.

Note: Records pertaining to corporate or other commercial entities are also maintained in the system. Only records pertaining to individuals are protected by the Privacy Act.

CATEGORIES OF RECORDS IN THE SYSTEM:

For owners, lessees, and operators: Names, addresses, and telephone numbers.

For owners and lessees: Taxpayer's Identification Numbers; Individual Taxpayer's Identification Numbers; Social Security Numbers; citizenship status; status pursuant to Federal reclamation law; legal descriptions or assessor parcel numbers; deeds; contracts or agreements relative to the transfer of land ownerships, including excess land sales and pertinent details of such sales; signature authorization documents; power-of-attorney documents; irrevocable elections; terms and effective dates of leases; leases; lease/purchase options; trust agreements; partnership agreements; and corporate resolutions.

For farm operators: Farm operating agreements, type of services provided, acreage operated by farm operators, and other pertinent details.

Authority for maintenance of the system: Reclamation Act of 1902, as amended and supplemented (43 U.S.C. 371), especially sections 206, 224(c), 224(g), and 228 of the Reclamation Reform Act of 1982 (43 U.S.C. 390aa).

PURPOSE(S):

The primary purpose of the system is to obtain from landowners and lessees written information on their landholdings that is pertinent to their compliance with the ownership and full-cost pricing provisions of Federal reclamation law.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

The data collected are used by district and Bureau of Reclamation personnel to determine compliance with Federal reclamation law.

Disclosures outside the Department of the Interior may be made pursuant to 43 CFR 2.56 and: (1) To the U.S. Department of Justice or in a proceeding before a court or adjudicative body when (a) the United States, the Department of the Interior, a component of the Department, or when represented by the Government, an employee of the Department is a party to litigation or anticipated litigation or has an interest in such litigation, and (b) the Department of the Interior determines that the disclosure is relevant or necessary to the litigation and is compatible with the purpose for which the records were compiled; (2) Of information indicating a violation or potential violation of a statute, regulation, rule, order, lease, license, contract, grant, or other agreement to appropriate Federal, State, tribal, territorial, local, or foreign agencies responsible for investigating or prosecuting the violation of, or for enforcing, implementing, or administering a statute, regulation, rule, order, lease, license, contract, grant, or other agreement; (3) To a congressional office from the record of an individual in response to an inquiry the individual has made to the congressional office; (4) To non-Federal auditors under contract with the Department of the Interior to perform audits relating to the acreage limitation program; (5) To the Internal Revenue Service for the purpose of reporting the existence of ''illegal Federal irrigation subsidies'' as defined by Section 90 of the Internal Revenue Code; and (6) To financial institutions for the purpose of acquiring information needed by the lender to complete the certification and reporting requirements of the Reclamation Reform Act of 1982 (43 U.S.C. 390aa) for involuntarily acquired irrigable or irrigation land.

DISCLOSURE TO CONSUMER REPORTING AGENCIES:

Disclosure pursuant to 5 U.S.C. 552a(b)(12). Disclosures may be made from this system to consumer reporting agencies as defined in the Fair Credit Reporting Act (15 U.S.C. 1681a(f)) or the Federal Claims Collection Act of 1966 (31 U.S.C. 3701(a)(3)).

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are maintained in manual form in file folders and, where automated, on magnetic media.

RETRIEVABILITY:

Manual records are retrieved by district and/or landholder name, by assessor parcel number, by excess land sale number, and/or by acreage limitation topic (e.g., trusts, farm operators, etc.). Automated records are retrieved by district identification number; sale number; landholder name; operator name; Social Security Number (if available); Taxpayer's Identification Number; Individual Taxpayer's Identification Number; telephone number; address; and/or identifying property characteristics, such as an assessor's parcel number.

SAFEGUARDS:

Records are maintained with safeguards in accordance with requirements of 43 CFR 2.51 for manual and computer records, and 43 CFR 2.52 for conduct of employees handling records subject to the Act.

RETENTION AND DISPOSAL:

Certiification and reporting forms (including verification forms) are retained for 6 years, at a minimum. The most current fully completed certification and reporting forms are maintained on file with the most current verification form, in accordance with 43 CFR 426.19(e). All other records are retained in compliance with Bureau of Reclamation retention schedules that have been approved by the National Archives and Records Administration.

SYSTEM MANAGER(S) AND ADDRESS:

Manager, Reclamation Law, Contracts, and Repayment Office, Bureau of Reclamation, Denver Federal Center, PO Box 25007, Denver, Colorado 80225–0007.

NOTIFICATION PROCEDURE:

For inquiries regarding the existence of their own certification and reporting forms, individuals should contact the districts in which they have filed forms. For requests for access to other records in the system, individuals may send a written request to the appropriate office listed under ''System Location.'' If you are unable to determine which office has the records, you may address your inquiry to the nearest Reclamation office listed in the appendix, or to the System Manager. Requests for notification of the existence of records shall be in writing, signed by the requester, and in compliance with the content requirements of 43 CFR 2.60.

RECORDS ACCESS PROCEDURES:

For requests for access to their own certification and reporting forms, individuals may contact the district(s) in which they have filed forms. For requests for access to other records in the system, individuals may send a written request to the appropriate office listed under ''System Location.'' If you are unable to determine which office has the records, you may address your inquiry to the nearest Reclamation office listed in the appendix, or to the System Manager. Requests for access to records shall be in writing, signed by the requester, and in compliance with the content requirements of 43 CFR 2.63.

CONTESTING RECORD PROCEDURES:

For requests for amendment of their own certification and reporting forms, individuals shall contact the district(s) in which they have filed forms. For request for amendment of other records in this system, individuals may send a written request to the appropriate office listed under ''System Location.'' If you are unable to determine which office has the records, you may address your inquiry to the nearest Reclamation office listed in the appendix, or to the System Manager. Requests for amendment of records shall be in writing, signed by the requester, and in compliance with the content requirements of 43 CFR 2.71.

RECORD SOURCE CATEGORIES:

Individuals on whom records are maintained, certain Federal agencies, State and local governmental units, and land appraisers.

[FR Doc. 99–6470 Filed 3–12–99; 8:45 am]
BILLING CODE 4310–10–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

Notice of Proposed Information Collection

AGENCY: Office of Surface Mining Reclamation and Enforcement.

ACTION: Notice and request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the Office of Surface Mining Reclamation and Enforcement (OSM) is announcing that the information collection requests for the titles described below have been forwarded to the Office of Management and Budget (OMB) for review and comment. The information collection requests describe the nature of the information collections and the expected burden and cost for 30 CFR Parts 750 and 877.

DATES: OMB has up to 60 days to approve or disapprove the information collections but may respond after 30 days. Therefore, public comments should be submitted to OMB by April 16, 1999 in order to be assured of consideration.

FOR FURTHER INFORMATION CONTACT: To request a copy of either information collection request, explanatory information and related forms, contact John A. Trelease at (202) 208–2783, or electronically to jtreleas@osmre.gov.

SUPPLEMENTARY INFORMATION: The Office of Management and Budget (OMB) regulations at 5 CFR 1320, which implement provisions of the Paperwork Reduction Act of 1995 (Pub. L. 104–13), require that interested members of the public and affected agencies have an opportunity to comment on information collection and recordkeeping activities [see 5 CFR 1320.8(d)]. OSM has submitted two requests to OMB to renew its approval of the collections of information contained in: 30 CFR Part 750, Requirements for surface coal mining and reclamation operations on Indian Lands; and 30 CFR Part 877, Rights of entry. OSM is requesting a 3-year term of approval for each information collection activity.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for these collections of information are 1029–0091 for Part 750, and 1029–0055 for Part 877.

As required under 5 CFR 1320.8(d), a **Federal Register** notice soliciting comments for these collections of information was published on January 4, 1999 (64 FR 179). No comments were received. This notice provides the public with an additional 30 days in which to comment on the following information collection activities:

Title: Requirements for surface coal mining and reclamation operations on Indian Lands—30 CFR Part 750.

OMB Control Number: 1029–0091.

Summary: Operators who conduct or propose to conduct surface coal mining and reclamation operations on Indian lands must comply with the requirements of 30 CFR 750 pursuant to Section 710 of SMCRA.

Bureau Form Number: None.

Frequency of Collection: On occasion.

Description of Respondents: Applicants for coal mining permits.

Total Annual Responses: 75.

Total Annual Burden Hours: 1,400.

Title: Rights of Entry—30 CFR Part 877.

OMB Control Number: 1029–0055.

Summary: This regulation establishes procedures for non-consensual entry upon private lands for the purpose of abandoned mine land reclamation activities or exploratory studies when the landowner refuses consent or is not available.

Bureau Form Number: None.

Frequency of Collection: On occasion.

Description of Respondents: State abandoned mine land reclamation agencies.

Total Annual Responses: 30.

Total Annual Burden Hours: 30.

Send comments on the need for the collections of information for the performance of the functions of the agency; the accuracy of the agency's burden estimates; ways to enhance the

quality, utility and clarity of the information collections; and ways to minimize the information collection burdens on respondents, such as use of automated means of collections of the information, to the following addresses. Please refer to the appropriate OMB control numbers in all correspondence.

ADDRESSES: Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Department of Interior Desk Officer, 725 17th Street, NW, Washington, DC 20503. Also, please send a copy of your comments to John A. Trelease, Office of Surface Mining Reclamation and Enforcement, 1951 Constitution Ave, NW, Room 210—SIB, Washington, DC 20240, or electronically to jtreleas@osmre.gov.

Dated: March 12, 1999.

Richard G. Bryson,

Chief, Division of Regulatory Support.

[FR Doc. 99–6443 Filed 3–16–99; 8:45 am]

BILLING CODE 4310–05–M

DEPARTMENT OF JUSTICE

Immigration and Naturalization Service

Agency Information Collection Activities

ACTION: Notice of Information Collection Under Review; Guam Visa Waiver Agreement.

The Office of Management and Budget (OMB) approval is being sought for the information collection listed below. This proposed information collection was previously published in the **Federal Register** on August 13, 1998 at 63 FR 43420, allowing for a 60-day public comment period. No comments were received by the Immigration and Naturalization Service. The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until April 16, 1999. This process is conducted in accordance with 5 CFR Part 1320.10.

Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention: Stuart Shapiro, 202–395–7316, Department of Justice Desk Officer, Washington, DC 20503. Additionally, comments may be submitted to OMB via facsimile to 202–395–7285. Comments may also be submitted to the Department of Justice (DOJ), Justice Management Division, Information Management and Security Staff, Attention: Department Clearance Officer, Suite 850, 1001 G Street, NW., Washington, DC 20530. Comments may also be submitted to DOJ via facsimile to 202–514–1534.

Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of this Information Collection

(1) *Type of Information Collection:* Reinstatement without change of previously approved information collection.

(2) *Title of the Form/Collection:* Guam Visa Waiver Agreement.

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Form I–760. Inspections Division, Immigration and Naturalization Service.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Business or other for-profit. Public Law 99–396 provides for certain aliens to be exempt from the nonimmigrant visa requirements if seeking entry into and stay on Guam as a visitor under certain conditions. This form is the agreement between the carrier of the alien and the United States.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 5 responses at 15 minutes (.25 hours) per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 1 annual burden hour.

If you have additional comments, suggestions, or need a copy of the proposed information collection instrument with instructions, or additional information, please contact Mr. Richard A. Sloan, 202–514–3291, Director, Policy Directives and Instructions Branch, Immigration and Naturalization Service, U.S. Department of Justice, Room 5307, 425 I Street, NW., Washington, DC 20536.

If additional information is required contact: Mr. Robert B. Briggs, Clearance Officer, United States Department of Justice, Information Management and Security Staff, Justice Management Division, Suite 850, Washington Center, 1001 G Street, NW, Washington, DC 20530.

Dated: March 9, 1999.

Richard A. Sloan,

Department Clearance Officer, United States Department of Justice, Immigration and Naturalization Service.

[FR Doc. 99–6462 Filed 3–16–99; 8:45 am]

BILLING CODE 4410–10–M

DEPARTMENT OF JUSTICE

Immigration and Naturalization Service

Agency Information Collection Activities:

ACTION: Notice of Information Collection Under Review; ABC Change of Address form and Special Filing Instructions for ABC Class Members.

The Office of Management and Budget (OMB) approval is being sought for the information collection listed below. This proposed information collection was previously published in the **Federal Register** on June 22, 1998 at 63 FR 33951, allowing for a 60-day public comment period. No comments were received by the Immigration and Naturalization Service. The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until; April 16, 1999. This process is conducted in accordance with 5 CFR Part 1320.10.

Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention: Stuart Shapiro, 202–395–7316, Department of Justice Desk Officer, Washington, DC 20503. Additionally, comments may be submitted to OMB via facsimile to 202–395–7285. Comments may also be submitted to the Department of Justice (DOJ), Justice Management Division, Information Management and Security

Staff, Attention: Department Clearance Officer, Suite 850, 1001 G Street, NW., Washington, DC 20530. Comment may also be submitted to DOJ via facsimile to 202–514–1534.

Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of this Information Collection

(1) *Type of Information Collection:* Reinstatement without change of previously approved information collection.

(2) *Title of the Form/Collection:* ABC Change of Address Form and Special Filing Instructions for ABC Class Members.

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Forms I–855 and M–426. Office of International Affairs, Asylum Division, Immigration and Naturalization Service.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Individuals or Households. This form is mandated by *the American Baptist Churches* v. *Thornburgh,* 760 F. Supp. 796 (N.D. Cal. 1991) and will be used by class members to inform the INS of address changes.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 250,000 I–855 responses at 30 minutes (.50 hours) per response; and 250,000 M–426 responses at 2 hours per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 625,000 annual burden hours.

If you have additional comments, suggestions, or need a copy of the proposed information collection instrument with instructions, or additional information, please contact Mr. Richard A. Sloan, 202–514–3291, Director, Policy Directives and Instructions Branch, Immigration and Naturalization Service, U.S. Department of Justice, Room 5307, 425 I Street, NW., Washington, DC 20536.

If additional information is required contact: Mr. Robert B. Briggs, Clearance Officer, United States Department of Justice, Information Management and Security Staff, Justice Management Division, Suite 850, Washington Center, 1001 G Street, NW., Washington, DC 20530.

Dated: March 9, 1999.

Richard A. Sloan,

Department Clearance Officer, United States Department of Justice, Immigration and Naturalization Service.

[FR Doc. 99–6463 Filed 3–16–99; 8:45 am]

BILLING CODE 4410–10–M

NUCLEAR REGULATORY COMMISSION

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: U.S. Nuclear Regulatory Commission (NRC).

ACTION: Notice of pending NRC action to submit an information collection request to OMB and solicitation of public comment.

SUMMARY: The NRC is preparing a submittal to OMB for review of continued approval of information collections under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

Information pertaining to the requirement to be submitted:

1. *The title of the information collection:* U.S. Nuclear Regulatory Commission Acquisition Regulation (NRCAR).

2. *Current OMB approval number:* 3150–0169.

3. *How often the collection is required:* On occasion; one time.

4. *Who is required to report:* Offerors responding to NRC solicitations and contractors receiving contract awards from NRC.

5. *The number of annual respondents:* 750.

6. *The number of hours needed annually to complete the requirement or request:* 120,449 (10.6 hours per response).

7. *Abstract:* The mandatory requirements of the NRCAR implement and supplement the government-wide Federal Acquisition Regulation, and ensure that the regulations governing the procurement of goods and services within the NRC satisfy the needs of the agency.

Submit by (May 17, 1999), comments that address the following questions:

1. Is the proposed collection of information necessary for the NRC to properly perform its functions? Does the information have practical utility?

2. Is the burden estimate accurate?

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

4. How can the burden of the information collection be minimized, including the use of automated collection techniques or other forms of information technology?

A copy of the supporting statement may be viewed free of charge at the NRC Public Document Room, 2120 L Street, NW (lower level), Washington, DC. OMB clearance requests are available at the NRC worldwide website (*http://www.nrc.gov/NRC/PUBLIC/OMB/index.html*). The document will be available on the NRC home page site for 60 days after the signature date of this notice.

Comments and questions should be directed to the NRC Clearance Officer, Brenda Jo Shelton, U.S. Nuclear Regulatory Commission, T–6 F33, Washington, DC. 20555–0001, or by telephone at (301) 415–7233, or by Internet electronic mail at BJS@NRC.GOV.

Dated at Rockville, Maryland, this 11th day of March, 1999.

For the Nuclear Regulatory Commission.

Brenda Jo Shelton,

NRC Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 99–6453 Filed 3–16–99; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: U. S. Nuclear Regulatory Commission (NRC).

ACTION: Notice of the OMB review of information collection and solicitation of public comment.

SUMMARY: The NRC has recently submitted to OMB for review the following proposal for the collection of information under the provisions of the

Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). The NRC hereby informs potential respondents that an agency may not conduct or sponsor, and that a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

1. Type of submission, new, revision, or extension: Revision.

2. The title of the information collection: 10 CFR Part 72, Licensing Requirements for the Independent Storage of Spent Nuclear Fuel and High-Level Radioactive Waste.

3. How often the collection is required: Required reports are collected and evaluated on a continuing basis as events occur. Applications for new licenses and amendments may be submitted at any time. Applications for renewal of licenses would be required every 20 years for an Independent Spent Fuel Storage Installation (ISFSI) and every 40 years for a Monitored Retrievable Storage (MRS) facility.

4. Who will be required or asked to report: Vendors of casks for the storage of spent fuel, licensees and applicants for a license to possess power reactor spent fuel and other radioactive materials associated with spent fuel storage in an ISFSI, and the Department of Energy for licenses to receive, transfer, package and possess power reactor spent fuel, high-level waste, and other radioactive materials associated with spent fuel and high-level waste storage in an MRS.

5. The number of annual respondents: 8.

6. The number of hours needed annually to complete the requirement or request: 21,529 (an average of approximately 167 hours per response for applications and reports, plus approximately 765 hours annually per recordkeeper).

7. An indication of whether Section 3507(d), Pub. L. 104–13 applies: Not applicable.

8. Abstract: 10 CFR Part 72 establishes requirements, procedures, and criteria for the issuance of licenses to receive, transfer, and possess power reactor spent fuel and other radioactive materials associated with spent fuel storage in an ISFSI, and requirements for the issuance of licenses to the Department of Energy to receive, transfer, package, and possess power reactor spent fuel and high-level radioactive waste, and other associated radioactive materials, in an MRS. The information in the applications, reports and records is used by NRC to make licensing and other regulatory determinations. The revised estimate of burden reflects an increase primarily because of the addition of requirements for decommissioning funding requirements, financial assurance provisions, documentation additions for decommissioning and license termination, and notification of incidents.

A copy of the final supporting statement may be viewed free of charge at the NRC Public Document Room, 2120 L Street, NW (lower level), Washington, DC. OMB clearance requests are available at the NRC worldwide web site (http://www.nrc.gov/NRC/PUBLIC/OMB/index.html). The document will be available on the NRC home page site for 60 days after the signature date of this notice.

Comments and questions should be directed to the OMB reviewer listed below by April 16, 1999. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given to comments received after this date.

Erik Godwin, Office of Information and Regulatory Affairs (3150–0135), NEOB–10202, Office of Management and Budget, Washington, DC 20503.

Comments can also be submitted by telephone at (202) 395–3084.

The NRC Clearance Officer is Brenda Jo. Shelton, 301–415–7233.

Dated at Rockville, Maryland, this 11th day of March 1999.

For the Nuclear Regulatory Commission.

Brenda Jo. Shelton,

NRC Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 99–6452 Filed 3–16–99; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 40–2259]

Pathfinder Mines Corporation

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Final finding of no significant impact notice of opportunity for hearing.

SUMMARY: Notice is hereby given that the U.S. Nuclear Regulatory Commission (NRC) proposes to amend NRC Source Material License SUA–672, approving Pathfinder Mines Corporation's (PMC's ''no action'' proposal on cleanup of Reid Draw located downgradient of the Lucky Mc tailings system at Gas Hills, Wyoming. This license currently authorizes PMC to possess byproduct material in the form of uranium waste tailings generated by the licensee's milling operations at the site. In accordance with the requirements of 10 CFR Part 51, an Environmental Assessment (EA) was performed by the NRC staff in support of its review of PMC's Environmental Report (ER) on the status of Reid Draw. The conclusion of the Environmental Assessment is a Finding of No Significant Impact (FONSI) of ''no action'' proposal on cleanup of Reid Draw.

SUPPLEMENTARY INFORMATION:

Background

By its letter dated August 28, 1998, PMC submitted an ER on the status of radiological contamination of Reid Draw. The draw is downgradient of the Lucky Mc tailings system at Gas Hills, Wyoming. PMC presented three action alternatives in the ER, and requested the NRC concurrence on its proposed ''no action'' alternative.

Reid Draw developed as a result of surface water erosion in the general area of the current Lucky Mc uranium mill site and portions of the uranium mine site that lie further to the south. Upon developing the mill, the mill tailings management structures were built at the head of Reid Draw. In the early days of mill operation, there was only one embankment, the No. 1 solid tailings dam. It served as the sole tailings storage facility from the inception of milling in 1958 until 1960 when the No. 2 dam was constructed. A review of early company records indicates that excess tailings solution was routinely discharged down Reid Draw from the No. 1 dam until June 1, 1960, when the No. 2 dam was commissioned. Apparently, this discharge was considered acceptable and normal practice in those days since the site was subject to Atomic Energy Commission inspections during the timeframe of interest. The furthest down-gradient embankment in the tailings system, the No. 4 dam was constructed in 1961.

Reid Draw is subject to only intermittent flows. However, a period of unusually rainy weather in June 1963 culminated with a protracted storm on June 15. The No. 4 solution pond capacity had been taxed due to the earlier precipitation, and the three inches of rain on June 15 proved too much for the system. Out of concern for the integrity of the No. 4 dam in the imminent event of an uncontrolled overtopping, the decision was made to cut a relief overflow, allowing some of the impounded water to escape. The licensee documentation at the time indicates that an estimated 23 million gallons of water were released. It should

be noted that this released water was significantly diluted due to the precipitation runoff.

The early releases and the single No. 4 dam breach event account at least in part for the levels of radionuclides found in Reid Draw at the present time. It is also likely that there is a natural contribution to the radionuclide levels in Reid Draw due to the fact that Reid Draw heads at the outcrop of a naturally mineralized area. It is reasonable to hypothesize that the erosion forces that created Reid Draw over time carried some of this mineralization down the draw. Since the controlled release during June 1963, there have been no other releases of tailings solutions to Reid Draw.

The No. 4 dam underwent a major reconstruction during 1980–1981 that entailed excavation down to competent Cody Shale in order to key the dam into impermeable material, and the overall size of the dam was expanded greatly. There is no evidence of ground-water impacts from seepage through the reconstructed dam, based upon the monitoring data from the piezometers, and the monitoring of water quality in the immediately down-gradient point of compliance well R–2 located in Reid Draw.

The Reid Draw gamma surveys conducted down-gradient from tailings dam No. 4 and beyond Reid Reservoir, located on the draw owned by Philp Sheep Company, indicate that the measurable contamination terminates just above Reid Reservoir. Reid Reservoir is some 3,000 meters (1.9 miles) down the draw from the toe of No. 4 dam. The reservoir existed prior to any up-gradient milling activity.

Additionally, radionuclide analysis of surface water and a sample of water taken from Reid Reservoir indicate that the concentrations are well within the NRC effluent water concentration limits for radionuclides, as specified in 10 CFR Part 20, Appendix B, Table 2. Cleanup criteria for off-pile areas of uranium mill sites are specified in 10 CFR Part 40, Appendix A, Technical Criteria.

Summary of the Environmental Assessment

In accordance with 10 CFR Part 51, Licensing and Regulatory Policy Procedures for Environmental Protection, the NRC staff performed an appraisal of the environmental impacts associated with the ''no action'' proposal on cleanup of Reid Draw. In conducting its appraisal, the NRC staff considered the following information: (1) PMC's ER on remediation of Reid Draw, and its subsequent submittal providing additional information and revised pages to the ER; (2) results of NRC staff site visits and inspections of the facility; and (3) consultation with the Wyoming Department of Environmental Quality, Bureau of Land Management, and Philp Sheep Company. The technical aspects of the proposal will be discussed separately in a Technical Evaluation Report (TER) that will accompany the final agency licensing action.

The results of the staff's appraisal are documented in an EA placed in the docket file. Based on its review, the NRC staff has concluded that there are no significant environmental impacts associated with the ''no action'' proposal.

Conclusions

The NRC staff has examined actual and potential impacts associated with PMC's ''no action'' proposal on cleanup of Reid Draw, and has determined that authorizing implementation of the ''no action'' proposal will not have long-term detrimental impacts on the environment. The following statements summarize the conclusions resulting from the staff's environmental assessment, and support the FONSI:

(1) Present and potential risks were assessed. The NRC staff determined that the risk factors for health and environmental hazards are insignificant in the licensee proposed ''no action'' alternative; and

(2) Remediation would cause irreversible damage to the current, very stable, environment of Reid Draw.

Because the staff has determined that there will be no significant impacts associated with approval of the ''no action'' proposal, there can be no disproportionally high and adverse effects or impacts on minority and low-income populations. Consequently, further evaluation of Environmental Justice concerns, as outlined in Executive Order 12898 and NRC's Office of Nuclear Material Safety and Safeguards Policy and Procedures Letter 1–50, Revision 1, is not warranted.

Alternatives to the Proposed Action

The proposed action is to amend NRC Source Material License SUA–672 authorizing PMC to implement ''no action'' proposal on cleanup of Reid Draw, as requested by PMC. Therefore, the principal alternatives available to NRC are to:

(1) Approve the licensee's ''no action'' alternative, as proposed; or (2) Amend the license with such additional conditions as are considered necessary or appropriate to protect public health and safety and the environment; or (3) Deny the licensee's request.

Based on its review, the NRC staff has concluded that the environmental impacts associated with the ''no action'' proposal on cleanup of Reid Draw do not warrant either the limiting of PMC's future operations or the denial of the licensee's request. Additionally, in the TER for this action, the staff will document its evaluation of the licensee's proposal with respect to the criteria for cleanup of off-pile areas of uranium mill sites as specified in 10 CFR Part 40, Appendix A. Therefore, the staff considers that Alternative 1 is the appropriate alternative for selection.

Finding of No Significant Impact

The NRC staff has prepared an EA for the ''no action'' proposal on cleanup of Reid Draw. On the basis of this assessment, the NRC staff has concluded that the environmental impacts that may result from the ''no action'' proposal would not be significant and, therefore, preparation of an Environmental Impact Statement is not warranted.

The EA and other related documents are available for public inspection and copying at the NRC Public Document Room, in the Gelman Building, 2120 L Street NW, Washington, DC 20555.

Notice of Opportunity for Hearing

The NRC hereby provides notice that this is a proceeding on an application for a licensing action falling within the scope of Subpart L, ''Informal Hearing Procedures for Adjudications in Materials and Operators Licensing Proceedings,'' of the Commission's Rules of Practice for Domestic Licensing Proceedings and Issuance of Orders in 10 CFR Part 2 (54 FR 8269). Pursuant to § 2.1205(a), any person whose interest may be affected by this proceeding may file a request for a hearing. In accordance with § 2.1205(c), a request for a hearing must be filed within thirty (30) days from the date of publication of this **Federal Register** notice. The request for a hearing must be filed with the Office of the Secretary either:

(1) By delivery to the Rulemakings and Adjudications Staff of the Office of the Secretary at One White Flint North, 11555 Rockville Pike, Rockville, MD 20852; or

(2) By mail or telegram addressed to the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Rulemakings and Adjudications Staff.

Each request for a hearing must also be served by delivering it personally or by mail to:

(1) The applicant, Pathfinder Mines Corporation, 935 Pendell Boulevard, P.O. Box 730, Mills, Wyoming 82644, Attention: Tom Hardgrove; and

(2) The NRC staff, by delivery to the Executive Director of Operations, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852, or by mail addressed to the Executive Director for Operations, U.S. Nuclear Regulatory Commission, Washington, DC 20555.

In addition to meeting other applicable requirements of 10 CFR Part 2 of the Commission's regulations, a request for a hearing filed by a person other than an applicant must describe in detail:

(1) the interest of the requestor in the proceeding;

(2) how that interest may be affected by the results of the proceeding, including the reasons why the requestor should be permitted a hearing, with particular reference to the factors set out in § 2.1205(g);

(3) the requestor's areas of concern about the licensing activity that is the subject matter of the proceeding; and

(4) the circumstances establishing that the request for a hearing is timely in accordance with § 2.1205(c).

The request must also set forth the specific aspect or aspects of the subject matter of the proceeding as to which petitioner wishes a hearing.

FOR FURTHER INFORMATION CONTACT: Mohammad Haque, Uranium Recovery Branch, Division of Waste Management, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Mail Stop T7-J8, Washington, D.C. 20555. Telephone 301/415–6640.

Dated at Rockville, Maryland, this 11th day of March 1999.

For the Nuclear Regulatory Commission.

N. King Stablein,

Acting Chief, Uranium Recovery Branch, Division of Waste Management, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 99–6454 Filed 3–16–99; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Sunshine Act Meeting

DATE: Weeks of March 15, 22, 29, and April 5, 1999.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public and Closed.

MATTERS TO BE CONSIDERED:

Week of March 15

Tuesday, March 16

1:00 p.m.
Briefing on Status of DOE High Level Waste Viability Assessment (Public Meeting)
(Contact: Mike Bell, 301–415–7252)

Wednesday, March 17

9:00 a.m.
Meeting with Advisory Committee on Nuclear Waste and Nuclear Waste Technical Review Board (Public Meeting)
Contact: John Larkins, 301–415–7360)

11:30 a.m.
Affirmation Session (Public Meeting)
*(Please Note: This item will be affirmed immediately following the conclusion of the preceding meeting.)
a: Radiological Criteria for License Termination of Uranium Recovery Facilities.

1:30 p.m.
Briefing on Part 50 Decommissioning Issues (Public Meeting)
(Contact: Seymour Weiss, 301–415–2170)

Thursday, March 18

9:30 a.m.
Briefing on Design Basis Threat (Closed—ex. 1)

2:00 p.m.
Briefing by Executive Branch (Closed—ex. 1)

Friday, March 19

9:00 a.m.
Briefing on Status of External Regulation of DOE Facilities (Public Meeting)
(Contact: Charlie Haughney, 301–415–7198)

Week of March 22—Tentative

Thursday, March 25

1:00 p.m.
Briefing on Part 35 Rulemaking (Public Meeting)
(Contact: Patricia Holahan, 301–415–8125)

Friday, March 26

9:00 a.m.
Briefing on Proposed Reactor Oversight Process Improvements & Enforcement (Public Meeting)
(Contact: William Dean, 301–415–2240)

12:00 p.m.
Affirmation Session (Public Meeting) (If needed)

Week of March 29—Tentative

There are no meetings scheduled for the Week of March 29.

Week of April 5—Tentative

There are no meetings scheduled for the Week of April 5.

*The Schedule for Commission meeting is subject to change on short notice. To verify the status of meetings call (recording)—(301) 415–1292.

CONTACT PERSON FOR MORE INFORMATION: Bill Hill (301) 415–1661.

* * * * *

Additional Information

By a vote of 5–0 on March 5, the Commission determined pursuant to U.S.C. 552b(e) and § 9.107(a) of the Commission's rules that ''Affirmation of North Atlantic Energy Service Corp., et al. (Seabrook Station Unit 1) Docket No. 50–443, Draft Commission Memorandum and Order Addressing Intervention Petitions and Hearing Requests of New England Power Company (NEPCO) and United Illuminating Co.'' (Public Meeting) be held on March 5, and on less than one week's notice to the public.

* * * * *

The NRC Commission Meeting Schedule can be found on the Internet at: http://www.nrc.gov/SECY/smj/schedule.htm.

* * * * *

This notice is distributed by mail to several hundred subscribers; if you no longer wish to receive it, or would like to be added to it, please contact the Office of the Secretary, Attn: Operations Branch, Washington, D.C. 20555 (301–415–1661). In addition, distribution of this meeting notice over the Internet system is available. If you are interested in receiving this Commission meeting schedule electronically, please send an electronic message to wmh@nrc.gov or dkw@nrc.gov.

Dated: March 12, 1999.

William M. Hill, Jr.,

SECY Tracking Officer, Office of the Secretary.

[FR Doc. 99–6571 Filed 3–15–99; 11:36 am]

BILLING CODE 7590–01–M

RAILROAD RETIREMENT BOARD

Proposed Collection: Comment Request

SUMMARY: In accordance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 which provides opportunity for public comment on new or revised data collections; the Railroad Retirement Board (RRB) will publish periodic summaries of proposed data collections.

Comments are Invited On

(a) Whether the proposed information collection is necessary for the proper performance of the functions of the agency, including whether the information has practical utility; (b) the accuracy of the RRB's estimate of the burden of the collection of the information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden related to the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

Title and Purpose of Information Collection

Application for Reimbursement for Hospital Insurance Services in Canada; OMB 3220–0086.

Under section 7(d) of the Railroad Retirement Act (RRA), the RRB administers the Medicare program for persons covered by the railroad retirement system. Payments are provided under section 7(d)(4) of the RRA for medical services furnished in Canada to the same extent as for those furnished in the United States. However, payments for the services furnished in Canada are made from the Railroad Retirement Account rather than from the Federal Hospital Insurance Trust Fund, with the payment limited to the amount by which insurance benefits under Medicare exceed the amounts payable under Canadian Provincial plans.

Form AA–104, Application for Canadian Hospital Benefits Under Medicare—Part A, is provided by the RRB for use in claiming benefits for covered hospital services received in Canada. The form obtains information needed to determine eligibility for, and the amount of any reimbursement due the applicant. One response is requested of each respondent. Completion is required to obtain a benefit. No changes are proposed to Form AA–104.

Number of respondents: 35.

Estimated Completion Time: 10 minutes.

Estimated annual burden hours: 6.

ADDITIONAL INFORMATION OR COMMENTS: To request more information or to obtain a copy of the information collection justification, forms, and/or supporting material, please call the RRB Clearance Officer at (312) 751–3363. Comments regarding the information collection should be addressed to Ronald J. Hodapp, Railroad Retirement Board, 844 N. Rush Street, Chicago, Illinois 60611–2092. Written comments should be received within 60 days of this notice.

Chuck Mierzwa,

Clearance Officer.

[FR Doc. 99–6493 Filed 3–16–99; 8:45 am]

BILLING CODE 7905–01–M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–41153; File No. SR–GSCC–99–02]

Self-Regulatory Organizations; Government Securities Clearing Corporation; Notice of Filing and Order Granting Accelerated Approval of a Proposed Rule Change Regarding Year 2000 Testing

March 10, 1999.

Pursuant to Section 19(b)(1) of the Security Exchange Act of 1934 (''Act''),[1] notice is hereby given that on February 5, 1999, the Government Securities Clearing corporation (''GSCC'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which items have been prepared primarily by GSCC. The Commission is publishing this notice and order to solicit comments from interested persons and to grant accelerated approval of the proposal.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The propose of the proposed rule change is to clarify that GSCC's rules on operational capability include certain reporting and testing requirements such as the requirement that all GSCC members conduct Year 2000 testing with GSCC.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, GSCC included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule changes. The text of these statements may be examined at the places specified in Item IV below. GSCC has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statements.[2]

(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

The proposed rule change requires all GSCC members to participate in Year 2000 testing with GSCC. GSCC believes that its rules on operational requirements for members provide GSCC with the authority to require such testing. Nonetheless, GSCC proposes to supplement its rules on operational capability standards to clarify that these standards include the fulfillment of testing and related reporting requirements that may be imposed on members by GSCC from time to time to ensure the continuing operational capability of each member. The scope of such Year 2000 testing and reporting requirements have been determined by GSCC in its sole discretion and have been conveyed to members through Important Notices. GSCC believes that the rule change is broad enough to cover Year 2000 testing without specifically referring to Year 2000 in order to alleviate the need to rescind the rule when Year 2000 testing is no longer relevant and also to enable GSCC to apply it to other contexts in which testing might be required.

GSCC expressly reserves the right to take remedial action against members that do not fulfill the testing and related reporting requirements referred to above within the time frames established by GSCC. The proposed rule change provides generally that GSCC may take the remedial actions already available to it in its rules (*i.e.*, increased clearing fund deposit and termination of membership) in the event a member does not fulfill the operational testing and related reporting requirements within the time frames specified by GSCC. GSCC has specified these time frames in an Important Notice to members.

GSCC believes that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder. In particular, the proposed rule change is consistent with Section 17A(b)(3)(F) of the Act[3] which requires that the rules of a clearing agency be designed to promote the prompt and accurate clearance and settlement of securities transactions and, in general, to protect investors and the public interest.

(B) Self-Regulatory Organization's Statement on Burden on Competition

GSCC does not believe that the proposed rule change will have an impact, or impose a burden, on competition.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants, or Others

Written comments relating to the proposed rule change have not yet been solicited or received. GSCC will notify

[1] 15 U.S.C. 78s(b)(1).

[2] The Commission has modified the text of the summaries prepared by GSCC.

[3] 15 U.S.C. 78q-1(b)(3)(F).

the Commission of any written comments received by GSCC.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Section 17A(b)(3)(F) of the Act [4] requires that the rules of a clearing agency be designed to promote the prompt and accurate clearance and settlement of securities transactions. The Commission believes that the proposed rule change is consistent with this obligation because the required Year 2000 testing should allow GSCC to address potential problems associated with its members' Year 2000 readiness. As a result, GSCC should be able to continue to provide prompt and accurate clearance and settlement of securities transactions before, on, and after Year 2000 without interruption.

GSCC requested that the Commission find good cause for approving the proposed rule change prior to the thirtieth day after the publication of notice of the filing. The Commission finds good cause for approving the proposed rule change prior to the thirtieth day after the publication of notice of the filing because such approval will allow GSCC to implement its mandatory Year 2000 testing program in a timely manner.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, N.W., Washington, D.C. 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. § 552, will be available for inspection and copying in the Commission's Public Reference Room, 450 Fifth Street, N.W., Washington, D.C. 20549. Copies of such filing will also be available for inspection and copying at the principal office of GSCC. All submissions should refer to the File No. SR–GSCC–99–02 and should be submitted by April 7, 1999.

[4] 15 U.S.C. 78q–1 (b)(3)(F).

It is therefore ordered, pursuant to Section 19(b)(2) of the Act, [5] that the proposed rule change (File No. SR–GSCC–99–2) be and hereby is approved.

For the Commission by the Division of Market Regulation, pursuant to delegated authority. [6]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 99–6455 Filed 3–16–99; 8:45 am]

BILLING CODE 8010–01–M

SMALL BUSINESS ADMINISTRATION

[(License No. 02/72–0573)]

EOS Partners SBIC II, L.P.; Notice Seeking Exemption Under Section 312 of the Small Business Investment Act, Conflicts of Interest

Notice is hereby given that Eos Partners SBIC II, L.P. (''EOS II''), 320 Park Avenue, 22nd Floor, New York, New York 10022, a Federal Licensee under the Small Business Investment Act of 1958, as amended (''the Act''), in connection with the proposed financing of a small concern is seeking an exemption under section 312 of the Act and section 107.730, Financings which Constitute Conflicts of Interest of the Small Business Administration (''SBA'') Rules and Regulations (13 CFR 107.730 (1998)). An exemption may not be granted by SBA until Notices of this transaction have been published. EOS II proposes to provide equity financing to Providence Service Corporation, 620 N. Craycroft, Tucson, Arizona 85710. The financing is contemplated for funding growth and acquisitions.

The financing is brought within the purview of section 107.730 (a) (1) of the Regulations because Eos Partners SBIC, L.P., an Associate of EOS II, owns greater than 10 percent of Providence Service Corporation and therefore Providence Service Corporation is considered an Associate of EOS II as defined in section 107.50 of the Regulations.

Notice is hereby given that any interested person may, not later than fifteen (15) days from the date of publication of this Notice, submit written comments on the proposed transaction to the Associate Administrator for Investment, U.S. Small Business Administration, 409 Third Street, SW Washington, DC 20416.

A copy of this Notice shall be published, in accordance with section 107.730 (g), in the **Federal Register** by SBA.

[5] 15 U.S.C. 78s(b)(2).

[6] 17 CFR 200.30–3(a) (12).

Dated: March 10, 1999.

Don A. Christensen,

Associate Administrator for Investment.

[FR Doc. 99–6469 Filed 3–16–99; 8:45 am]

BILLING CODE 8025–01–P

SOCIAL SECURITY ADMINISTRATION

Finding Regarding the Social Insurance System of Hungary

AGENCY: Social Security Administration.

ACTION: Notice of finding regarding the Social Insurance System of Hungary.

Finding: Section 202(t)(1) of the Social Security Act (42 U.S.C. 402(t)(1)) prohibits payment of monthly benefits to any individual who is not a United States citizen or national for any month after he or she has been outside the United States for 6 consecutive months, and prior to the first month thereafter for all of which the individual has been in the United States. This prohibition does not apply to such an individual where one of the exceptions described in sections 202(t)(2) through 202(t)(5) of the Social Security Act (42 U.S.C. 402(t)(2) through 402(t)(5)) affects his or her case.

Section 202(t)(2) of the Social Security Act provides that, subject to certain residency requirements of section 202(t)(11), the prohibition against payment shall not apply to any individual who is a citizen of a country which the Commissioner of Social Security finds has in effect a social insurance system which is of general application in such country and which:

(a) Pays periodic benefits, or the actuarial equivalent thereof, on account of old age, retirement, or death; and

(b) Permits individuals who are United States citizens but not citizens of that country and who qualify for such benefits to receive those benefits, or the actuarial equivalent thereof, while outside the foreign country regardless of the duration of the absence.

The Commissioner of Social Security has delegated the authority to make such a finding to the Associate Commissioner for International Programs. Under that authority, the Associate Commissioner for International Programs has approved a finding that Hungary, as of January 1, 1996, has a social insurance system of general application which:

(a) Pays periodic benefits, or the actuarial equivalent thereof, on account of old age, retirement, or death; and

(b) Permits United States citizens who are not citizens of Hungary and who qualify for the relevant benefits to receive those benefits, or their actuarial

equivalent, while outside of Hungary, regardless of the duration of the absence of these individuals from Hungary.

Accordingly, it is hereby determined and found Hungary has in effect, as of January 1, 1996, a social insurance system which meets the requirements of section 202(t)(2) of the Social Security Act (42 U.S.C. 402(t)(2)).

On July 1, 1968, it was determined that the Hungarian system did not meet part B of section 202(t)(2) because its social insurance law did not permit payment of benefits to those who resided outside Hungary. Although a new law was passed in 1990 that allowed benefits to be paid abroad, the Hungarian Forint was not convertible at that time, thereby constituting a currency restriction for section 202(t)(2) purposes. Effective January 1, 1996, the Forint became fully convertible, and payments could be made to qualified United States citizens residing outside Hungary as required by section 202(t)(2)(B) of the Social Security Act.

FOR FURTHER INFORMATION CONTACT: Donna Powers, Room 1104, West High Rise Building, PO Box 17741, 6401 Security Boulevard, Baltimore, MD 21235, (410) 965–3568.

(Catalog of Federal Domestic Assistance: Program Nos. 96.001 Social Security—Disability Insurance; 96.002 Social Security—Retirement Insurance; 96.004 Social Security—Survivors Insurance)

Dated: March 9, 1999.

Barry L. Powell,

Acting Associate Commissioner for International Programs.

[FR Doc. 99–6400 Filed 3–16–99; 8:45 am]

BILLING CODE 4190–29–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[RTCA Special Committee 192]

National Airspace Review Planning and Analysis

Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (P.L. 92–463, 5 U.S.C., Appendix 2), notice is hereby given for a Special Committee 192 meeting to be held March 30–31, 1999, starting at 9:00 a.m. The meeting will be held at RTCA, Inc., 1140 Connecticut Avenue, NW., Suite 1020, Washington, DC, 20036.

The agenda will be as follows: (1) Chairman's Introductory Remarks; (2) Review/Approval of Meeting Agenda; (3) Review/Approval of Summary of the Previous Meeting; (4) Update on ATA's National Airspace Redesign Activities; (5) Update on the FAA's Activities Related to Airspace Design: a. Obstruction Evaluation; b. National Parks; c. Commercial Space; d. Special Use Airspace Management System (SAMS)/Military Airspace Management System (MAMS); (6) Update on Architecture and Free Flight Phase 1; (7) Briefings on Working Group Activities; (8) Tour of National Airspace Redesign Lab; (9) Work Group Breakout Sessions; (10) Set Agenda for Next Meeting; (11) Date and Location of Next Meeting.

Attendance is open to the interested public but limited to space availability. With the approval of the chairman, members of the public may present oral statements at the meeting. Persons wishing to present statements or obtain information should contact the RTCA Secretariat, 1140 Connecticut Avenue, NW., Washington, DC, 20036; (202) 833–9339 (phone), (202) 833–9434 (fax), or http://www.rtca.org (web site). Members of the public may present a written statement to the committee at any time.

Issued in Washington, DC, on March 9, 1999.

Janice L. Peters,

Designated Official.

[FR Doc. 99–6519 Filed 3–16–99; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Public Meeting; Satellite-based Navigation User Forum

AGENCY: Federal Aviation Administration, Office of System Architecture and Investment Analysis.

SUMMARY: The Federal Aviation Administration (FAA) Office of System Architecture and Investment Analysis (ASD) will hold a forum to obtain information from the aviation user community as part of the investment analysis process to determine navigation alternatives as we transition to a satellite-based navigation (Sat/Nav) infrastructure.

DATES: The Sat/Nav user forum public meeting will be held on April 6, 1999, at the Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC, in the third-floor auditorium from 8:30 am to 12 noon. Time will be made available for specific follow-on meetings, as necessary, in the afternoon.

FOR FURTHER INFORMATION CONTACT: Ms. Millie Butler-Harris, Investment Analysis and Operations Research, ASD–400, at (202) 358–5399 and via e:mail at *millie.butler-harris@faa.gov* or Dr. Robert Rovinsky, the SatNav Investment Analysis Team Lead, ASD–410, at (202) 358–5212 and via e:mail at *robert.rovinsky@faa.gov*.

SUPPLEMENTARY INFORMATION: The Federal Aviation Administration is reviewing its plan to transition to a totally satellite-based navigation (Sat/Nav) infrastructure. A Sat/Nav public meeting is planned to obtain input from the aviation community as the FAA considers alternatives and develops a business case for a particular approach to navigation within the Nation's airspace.

At this meeting, the FAA will provide organizations an opportunity to review the preliminary results of the alternatives analysis led by the MITRE Corporation's Center for Advanced Aviation System Development (CAASD). This is the second in a series of three public meetings. The first one was held on February 25 to solicit comments on the alternatives analysis. The next public meeting is tentatively scheduled for May 19 to review the economic analysis and preliminary findings. The FAA investment analysis team will incorporate user information from these meetings into the investment analysis process leading to an FAA Joint Resources Council investment decision by the end of June 1999.

The public is invited to attend the meeting as observers and/or to provide comment during the breakout sessions. Requests to attend this meeting and to obtain information should be directed to the contact persons listed above. Additional information will be posted on the Internet at *www.faa.gov/asd*.

Issued in Washington, DC., on March 11, 1999.

Janice L. Peters,

Designated Official.

[FR Doc. 99–6520 Filed 3–16–99; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–99–5207]

Notice of Receipt of Petition for Decision That Nonconforming 1986–1995 BMW R80 and R100 Motorcycles Are Eligible for Importation

AGENCY: National Highway Traffic Safety Administration, DOT.

ACTION: Notice of receipt of petition for decision that nonconforming 1986–1995 BMW R80 and R100 motorcycles are eligible for importation.

SUMMARY: This document announces receipt by the National Highway Traffic Safety Administration (NHTSA) of a petition for a decision that 1986–1995 BMW R80 and R100 motorcycles that were not originally manufactured to comply with all applicable Federal motor vehicle safety standards are eligible for importation into the United States because (1) they are substantially similar to vehicles that were originally manufactured for importation into and sale in the United States and that were certified by their manufacturer as complying with the safety standards, and (2) they are capable of being readily altered to conform to the standards.

DATES: The closing date for comments on the petition is April 16, 1999.

ADDRESSES: Comments should refer to the docket number and notice number, and be submitted to: Docket Management, Room PL–401, 400 Seventh St., SW, Washington, DC 20590. [Docket hours are from 10 am to 5 pm].

FOR FURTHER INFORMATION CONTACT: George Entwistle, Office of Vehicle Safety Compliance, NHTSA (202–366–5306).

SUPPLEMENTARY INFORMATION:

Background

Under 49 U.S.C. 30141(a)(1)(A), a motor vehicle that was not originally manufactured to conform to all applicable Federal motor vehicle safety standards shall be refused admission into the United States unless NHTSA has decided that the motor vehicle is substantially similar to a motor vehicle originally manufactured for importation into and sale in the United States, certified under 49 U.S.C. 30115, and of the same model year as the model of the motor vehicle to be compared, and is capable of being readily altered to conform to all applicable Federal motor vehicle safety standards.

Petitions for eligibility decisions may be submitted by either manufacturers or importers who have registered with NHTSA pursuant to 49 CFR Part 592. As specified in 49 CFR 593.7, NHTSA publishes notice in the **Federal Register** of each petition that it receives, and affords interested persons an opportunity to comment on the petition. At the close of the comment period, NHTSA decides, on the basis of the petition and any comments that it has received, whether the vehicle is eligible for importation. The agency then publishes this decision in the **Federal Register**.

Champagne Imports of Lansdale, Pennsylvania (''Champagne'') (Registered Importer 90–009) has petitioned NHTSA to decide whether non-U.S. certified 1986–1995 BMW R80 and R100 motorcycles are eligible for importation into the United States. The vehicles which Champagne believes are substantially similar are 1986–1995 BMW R80 and R100 motorcycles that were manufactured for importation into, and sale in, the United States and certified by their manufacturer, Bayerische Motoren Werke, A.G., as conforming to all applicable Federal motor vehicle safety standards.

The petitioner claims that it carefully compared non-U.S. certified 1986–1995 BMW R80 and R100 motorcycles to their U.S. certified counterparts, and found the vehicles to be substantially similar with respect to compliance with most Federal motor vehicle safety standards.

Champagne submitted information with its petition intended to demonstrate that non-U.S. certified 1986–1995 BMW R80 and R100 motorcycles, as originally manufactured, conform to many Federal motor vehicle safety standards in the same manner as their U.S. certified counterparts, or are capable of being readily altered to conform to those standards.

Specifically, the petitioner claims that non-U.S. certified 1986–1995 BMW R80 and R100 motorcycles are identical to their U.S. certified counterparts with respect to compliance with Standard Nos. 106 *Brake Hoses,* 111 *Rearview Mirrors,* 116 *Brake Fluid,* 119 *New Pneumatic Tires for Vehicles other than Passenger Cars,* and 122 *Motorcycle Brake Systems.*

Petitioner additionally contends that the vehicles are capable of being readily altered to meet the following standard, in the manner indicated:

Standard No. 108 *Lamps, Reflective Devices and Associated Equipment*: (a) installation of U.S.-model head lamp assemblies; (b) installation of U.S.-model reflectors on vehicles that are not already so equipped.

Standard No. 120 *Tire Selection and Rims for Vehicles other than Passenger Cars*: installation of a tire information label.

Standard No. 123 *Motorcycle Controls and Displays*: installation of a U.S.-model speedometer calibrated in miles per hour.

The petitioner also states that a vehicle identification number plate will be affixed to the vehicle to meet the requirements of 49 CFR Part 565.

Comments should refer to the docket number and be submitted to: Docket Management, Room PL–401, 400 Seventh Street, S.W., Washington, DC 20590. It is requested but not required that 10 copies be submitted.

All comments received before the close of business on the closing date indicated above will be considered, and will be available for examination in the docket at the above address both before and after that date. To the extent possible, comments filed after the closing date will also be considered. Notice of final action on the petition will be published in the **Federal Register** pursuant to the authority indicated below.

Authority: 49 U.S.C. 30141(a)(1)(A) and (b)(1); 49 CFR 593.8; delegations of authority at 49 CFR 1.50 and 501.8.

Issued on: March 11, 1999.

Marilynne Jacobs,

Director, Office of Vehicle Safety Compliance.

[FR Doc. 99–6472 Filed 3–16–99; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–99–5209]

Notice of Receipt of Petition for Decision That Nonconforming 1992–1993 Bentley Turbo R Passenger Cars Are Eligible for Importation

AGENCY: National Highway Traffic Safety Administration, DOT.

ACTION: Notice of receipt of petition for decision that nonconforming 1992–1993 Bentley Turbo R passenger cars are eligible for importation.

SUMMARY: This notice announces receipt by the National Highway Traffic Safety Administration (NHTSA) of a petition for a decision that 1992–1993 Bentley Turbo R passenger cars that were not originally manufactured to comply with all applicable Federal motor vehicle safety standards are eligible for importation into the United States because (1) they are substantially similar to vehicles that were originally manufactured for importation into and sale in the United States and that were certified by their manufacturer as complying with the safety standards, and (2) they are capable of being readily altered to conform to the standards.

DATES: The closing date for comments on the petition is April 16, 1999.

ADDRESSES: Comments should refer to the docket number and notice number, and be submitted to: Docket Management, Room PL–401, 400 Seventh St., SW, Washington, DC 20590. [Docket hours are from 9 am to 5 pm].

FOR FURTHER INFORMATION CONTACT: George Entwistle, Office of Vehicle Safety Compliance, NHTSA (202–366–5306).

SUPPLEMENTARY INFORMATION:

Background

Under 49 U.S.C. § 30141(a)(1)(A), a motor vehicle that was not originally manufactured to conform to all applicable Federal motor vehicle safety standards shall be refused admission into the United States unless NHTSA has decided that the motor vehicle is substantially similar to a motor vehicle originally manufactured for importation into and sale in the United States, certified under 49 U.S.C. § 30115, and of the same model year as the model of the motor vehicle to be compared, and is capable of being readily altered to conform to all applicable Federal motor vehicle safety standards.

Petitions for eligibility decisions may be submitted by either manufacturers or importers who have registered with NHTSA pursuant to 49 CFR Part 592. As specified in 49 CFR 593.7, NHTSA publishes notice in the **Federal Register** of each petition that it receives, and affords interested persons an opportunity to comment on the petition. At the close of the comment period, NHTSA decides, on the basis of the petition and any comments that it has received, whether the vehicle is eligible for importation. The agency then publishes this decision in the **Federal Register**.

Champagne Imports of Lansdale, Pennsylvania (''Champagne'') (Registered Importer 90–009) has petitioned NHTSA to decide whether 1992–1993 Bentley Turbo R passenger cars are eligible for importation into the United States. The vehicles which Champagne believes are substantially similar are 1992–1993 Bentley Turbo R passenger cars that were manufactured for importation into, and sale in, the United States and certified by their manufacturer as conforming to all applicable Federal motor vehicle safety standards.

The petitioner claims that it carefully compared non-U.S. certified 1992–1993 Bentley Turbo R passenger cars to their U.S. certified counterparts, and found the vehicles to be substantially similar with respect to compliance with most Federal motor vehicle safety standards.

Champagne submitted information with its petition intended to demonstrate that non-U.S. certified 1992–1993 Bentley Turbo R passenger cars, as originally manufactured, conform to many Federal motor vehicle safety standards in the same manner as their U.S. certified counterparts, or are capable of being readily altered to conform to those standards.

Specifically, the petitioner claims that non-U.S. certified 1992–1993 Bentley Turbo R passenger cars are identical to their U.S. certified counterparts with respect to compliance with Standards Nos. 102 *Transmission Shift Lever Sequence . . . .*, 103 *Defrosting and Defogging Systems,* 104 *Windshield Wiping and Washing Systems,* 105 *Hydraulic Brake Systems,* 106 *Brake Hoses,* 109 *New Pneumatic Tires,* 113 *Hood Latch Systems,* 116 *Brake Fluid,* 124 *Accelerator Control Systems,* 201 *Occupant Protection in Interior Impact,* 202 *Head Restraints,* 204 *Steering Control Rearward Displacement,* 205 *Glazing Materials,* 206 *Door Locks and Door Retention Components,* 207 *Seating Systems,* 209 *Seat Belt Assemblies,* 210 *Seat Belt Assembly Anchorages,* 212 *Windshield Retention,* 216 *Roof Crush Resistance,* 219 *Windshield Zone Intrusion,* and 302 *Flammability of Interior Materials.*

Petitioner also contends that the vehicles are capable of being readily altered to meet the following standards, in the manner indicated:

Standard No. 101 *Controls and Displays*: (a) substitution of a lens marked ''Brake'' for a lens with a noncomplying symbol on the brake failure indicator lamp; (b) installation of a seat belt warning lamp that displays the appropriate symbol; (c) recalibration of the speedometer/odometer from kilometers to miles per hour.

Standard No. 108 *Lamps, Reflective Devices and Associated Equipment*: (a) installation of U.S.-model headlamp assemblies that incorporate headlamps with DOT markings; (b) installation of U.S.-model front and rear sidemarker/reflector assemblies; (c) installation of U.S.-model taillamp assemblies; (d) installation of a center high mounted stop lamp on vehicles that are not already so equipped.

Standard No. 110 *Tire Selection and Rims*: installation of a tire information placard.

Standard No. 111 *Rearview Mirror*: replacement of the passenger side rearview mirror with a U.S.-model component.

Standard No. 114 *Theft Protection*: installation of a warning buzzer microswitch in the steering lock assembly and a warning buzzer.

Standard No. 118 *Power Window Systems*: rewiring of the power window system so that the window transport is inoperative when the ignition is switched off.

Standard No. 208 *Occupant Crash Protection*: (a) installation of a U.S.-model seat belt in the driver's position, or a belt webbing-actuated microswitch inside the driver's seat belt retractor; (b) installation of an ignition switch-actuated seat belt warning lamp and buzzer; (c) replacement of the driver's side air bag and knee bolster with U.S.-model components. The petitioner states that the vehicles are equipped with combination lap and shoulder restraints that adjust by means of an automatic retractor and release by means of a single push button at both front designated seating positions, with combination lap and shoulder restraints that release by means of a single push button at both rear outboard designated seating positions, and with a lap belt in the rear center designated seating position.

Standard No. 214 *Side Impact Protection*: installation of reinforcing beams.

Standard No. 301 *Fuel System Integrity*: installation of a rollover valve in the fuel tank vent line between the fuel tank and the evaporative emissions collection canister.

Additionally, the petitioner states that the bumpers on the non-U.S. certified 1992–1993 Bentley Turbo R passenger cars must be reinforced or U.S.-model bumper components must be installed to comply with the Bumper Standard found in 49 CFR Part 581.

The petitioner also states that a vehicle identification number plate must be affixed to the vehicle to meet the requirements of 49 CFR Part 565.

Interested persons are invited to submit comments on the petition described above. Comments should refer to the docket number and be submitted to: Docket Section, National Highway Traffic Safety Administration, Room 5109, 400 Seventh Street, S.W., Washington, DC 20590. It is requested but not required that 10 copies be submitted.

All comments received before the close of business on the closing date indicated above will be considered, and will be available for examination in the docket at the above address both before and after that date. To the extent possible, comments filed after the closing date will also be considered. Notice of final action on the petition will be published in the **Federal Register** pursuant to the authority indicated below.

Authority: 49 U.S.C. 30141 (a)(1)(A) and (b)(1); 49 CFR 593.8; delegations of authority at 49 CFR 1.50 and 501.8.

Issued on: March 11, 1999.

Marilynne Jacobs,

Director, Office of Vehicle Safety Compliance.

[FR Doc. 99–6473 Filed 3–17–99; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–99–5197]

Notice of Receipt of Petition for Decision That Nonconforming 1993–1996 Lexus GS300 Passenger Cars Are Eligible for Importation

AGENCY: National Highway Traffic Safety Administration, DOT.

ACTION: Notice of receipt of petition for decision that nonconforming 1993–1996 Lexus GS300 passenger cars are eligible for importation.

SUMMARY: This notice announces receipt by the National Highway Traffic Safety Administration (NHTSA) of a petition for a decision that 1993–1996 Lexus GS300 passenger cars that were not originally manufactured to comply with all applicable Federal motor vehicle safety standards are eligible for importation into the United States because (1) they are substantially similar to vehicles that were originally manufactured for importation into and sale in the United States and that were certified by their manufacturer as complying with the safety standards, and (2) they are capable of being readily altered to conform to the standards.

DATES: The closing date for comments on the petition is April 16, 1999.

ADDRESSES: Comments should refer to the docket number and notice number, and be submitted to: Docket Management, Room PL–401, 400 Seventh St., SW, Washington, DC 20590. [Docket hours are from 9 am to 5 pm].

FOR FURTHER INFORMATION CONTACT: George Entwistle, Office of Vehicle Safety Compliance, NHTSA (202–366–5306).

SUPPLEMENTARY INFORMATION:

Background

Under 49 U.S.C. § 30141(a)(1)(A), a motor vehicle that was not originally manufactured to conform to all applicable Federal motor vehicle safety standards shall be refused admission into the United States unless NHTSA has decided that the motor vehicle is substantially similar to a motor vehicle originally manufactured for importation into and sale in the United States, certified under 49 U.S.C. § 30115, and of the same model year as the model of the motor vehicle to be compared, and is capable of being readily altered to conform to all applicable Federal motor vehicle safety standards.

Petitions for eligibility decisions may be submitted by either manufacturers or importers who have registered with NHTSA pursuant to 49 CFR Part 592. As specified in 49 CFR 593.7, NHTSA publishes notice in the **Federal Register** of each petition that it receives, and affords interested persons an opportunity to comment on the petition. At the close of the comment period, NHTSA decides, on the basis of the petition and any comments that it has received, whether the vehicle is eligible for importation. The agency then publishes this decision in the **Federal Register**.

Wallace Environmental Testing Laboratories, Inc. of Houston, Texas (''Wallace'')(Registered Importer 90–005) has petitioned NHTSA to decide whether 1993–1996 Lexus GS300 passenger cars are eligible for importation into the United States. The vehicles which Wallace believes are substantially similar are 1993–1996 Lexus GS300 passenger cars that were manufactured for importation into, and sale in, the United States and certified by their manufacturer, Toyota Motor Corporation, as conforming to all applicable Federal motor vehicle safety standards.

The petitioner claims that it carefully compared non-U.S. certified 1993–1996 Lexus GS300 passenger cars to their U.S. certified counterparts, and found the vehicles to be substantially similar with respect to compliance with most Federal motor vehicle safety standards.

Wallace submitted information with its petition intended to demonstrate that non-U.S. certified 1993–1996 Lexus GS300 passenger cars, as originally manufactured, conform to many Federal motor vehicle safety standards in the same manner as their U.S. certified counterparts, or are capable of being readily altered to conform to those standards.

Specifically, the petitioner claims that non-U.S. certified 1993–1996 Lexus GS300 passenger care are identical to their U.S. certified counterparts with respect to compliance with Standards Nos. 102 *Transmission Shift Lever Sequence . . .*, 103 *Defrosting and Defogging Systems,* 104 *Windshield Wiping and Washing Systems,* 105 *Hydraulic Brake Systems,* 106 Brake Hoses, 109 New Pneumatic Tires, 113 Hood Latch Systems, 116 *Brake Fluid,* 118 *Power Window Systems, 124 Accelerator Control Systems,* 201 *Occupant Protection in Interior Impact,* 202 *Head Restraints,* 204 Steering Control Rearward Displacement, 205 *Glazing Materials,* 206 *Door Locks and Door Retention Components,* 207 *Seating Systems,* 209 *Seat Belt Assemblies,* 210 *Seat Belt Assembly Anchorages,* 212 *Windshield Retention,* 214 *Side Impact Protection,* 216 *Roof Crush Resistance,* 219 *Windshield Zone Intrusion,* and 302 *Flammability of Interior Materials.*

Additionally, the petitioner states that non-U.S. certified 1993–1996 Lexus GS300 passenger cars comply with the Bumper Standard found in 49 CFR Part 581.

Petitioner also contends that the vehicles are capable of being readily altered to meet the following standards, in the manner indicated:

Standard No. 101 *Controls and Displays*: substitution of a lens marked ''Brake'' for a lens with an ECE symbol on the brake failure indicator lamp. Petitioner claims that the odometer is labeled as reading in kilometers.

Standard No. 108 *Lamps, Reflective Devices and Associated Equipment*: replacement of nonconforming headlight and sidemarker assemblies.

Standard No. 110 *Tire Selection and Rims*: installation of a tire information placard.

Standard No. 111 *Rearview Mirror*: inscription of the required warning statement on the passenger side rearview mirror.

Standard No. 114 *Theft Protection*: installation of a warning buzzer microswitch and a warning buzzer in the steering lock assembly.

Standard No. 208 *Occupant Crash Protection:* (a) installation of a safety belt warning system through replacement of the driver's seat belt latch and the addition of a seat belt warning buzzer; (b) replacement of the driver's side (on 1993 models) and the driver's and passenger's side (on 1994 through 1996 models) air bags and knee bolsters with U.S.-model components on vehicles that are not already so equipped. The petitioner states that the vehicles are equipped with Type II seat belts at both front and rear outboard designated seating positions, and with a lap belt in the rear center designated seating position.

Standard No. 301 *Fuel System Integrity:* installation of a rollover valve in the fuel tank vent line between the fuel tank and the evaporative emissions collection canister.

Additionally, the petitioner states that all vehicles will be inspected prior to importation to assure compliance with the Theft Prevention Standard found in 49 CFR Part 541.

The petitioner also states that a vehicle identification number plate must be affixed to the vehicles to meet the requirements of 49 CFR Part 565.

Interested persons are invited to submit comments on the petition described above. Comments should refer to the docket number and be submitted

to: Docket Management, Room PL–401, 400 Seventh St., SW, Washington, DC 20590. [Docket hours are from 9 am to 5 pm]. It is requested but not required that 10 copies be submitted.

All comments received before the close of business on the closing date indicated above will be considered, and will be available for examination in the docket at the above address both before and after that date. To the extent possible, comments filed after the closing date will also be considered. Notice of final action on the petition will be published in the **Federal Register** pursuant to the authority indicated below.

Authority: 49 U.S.C. 30141(a)(1)(A) and (b)(1); 49 CFR 593.8; delegations of authority at 49 CFR 1.50 and 501.8.

Issued on: March 11, 1999.

Marilynne Jacobs,

Director, Office of Vehicle Safety Compliance.

[FR Doc. 99–6474 Filed 3–16–99; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–99–5208]

Notice of Receipt of Petition for Decision That Nonconforming 1997–1999 Ferrari Maranello 550 Passenger Cars Are Eligible for Importation

AGENCY: National Highway Traffic Safety Administration, DOT.

ACTION: Notice of receipt of petition for decision that nonconforming 1997–1999 Ferrari Maranello 550 passenger cars are eligible for importation.

SUMMARY: This notice announces receipt by the National Highway Traffic Safety Administration (NHTSA) of a petition for a decision that 1997–1999 Ferrari Maranello 550 passenger cars that were not originally manufactured to comply with all applicable Federal motor vehicle safety standards are eligible for importation into the United States because (1) they are substantially similar to a vehicles that were originally manufactured for importation into and sale in the United States and that were certified by their manufacturer as complying with the safety standards, and (2) they are capable of being readily altered to conform to the standards.

DATES: The closing date for comments on the petition is April 16, 1999.

ADDRESSES: Comments should refer to the docket number and notice number, and be submitted to: Docket Management, Room PL–401, 400 Seventh St., SW, Washington, DC 20590. [Docket hours are from 9 am to 5 pm].

FOR FURTHER INFORMATION CONTACT: George Entwistle, Office of Vehicle Safety Compliance, NHTSA (202–366–5306).

SUPPLEMENTARY INFORMATION:

Background

Under 49 U.S.C. § 30141(a)(1)(A), a motor vehicle that was not originally manufactured to conform to all applicable Federal motor vehicle safety standards shall be refused admission into the United States unless NHTSA has decided that the motor vehicle is substantially similar to a motor vehicle originally manufactured for importation into and sale in the United States, certified under 49 U.S.C. § 30115, and of the same model year as the model of the motor vehicle to be compared, and is capable of being readily altered to conform to all applicable Federal motor vehicle safety standards.

Petitions for eligibility decisions may be submitted by either manufacturers or importers who have registered with NHTSA pursuant to 49 CFR Part 592. As specified in 49 CFR 593.7, NHTSA publishes notice in the **Federal Register** of each petition that it receives, and affords interested persons an opportunity to comment on the petition. At the close of the comment period, NHTSA decides, on the basis of the petition and any comments that it has received, whether the vehicle is eligible for importation. The agency then publishes this decision in the **Federal Register**.

Champagne Imports of Lansdale, Pennsylvania (''Champagne'') (Registered Importer 90–009) has petitioned NHTSA to decide whether 1997–1999 Ferrari Maranello 550 passenger cars are eligible for importation into the United States. The vehicles which Champagne believes are substantially similar are 1997–1999 Ferrari Maranello 550 passenger cars that were manufactured for importation into, and sale in, the United States and certified by their manufacturer as conforming to all applicable Federal motor vehicle safety standards.

The petitioner claims that it carefully compared non-U.S. certified 1997–1999 Ferrari Maranello 550 passenger cars to their U.S. certified counterparts, and found the vehicles to be substantially similar with respect to compliance with most Federal motor vehicle safety standards.

Champagne submitted information with its petition intended to demonstrate that non-U.S. certified 1997–1999 Ferrari Maranello 550 passenger cars, as originally manufactured, conform to many Federal motor vehicle safety standards in the same manner as their U.S. certified counterparts, or are capable of being readily altered to conform to those standards.

Specifically, the petitioner claims that non-U.S. certified 1997–1999 Ferrari Maranello 550 passenger cars are identical to their U.S. certified counterparts with respect to compliance with Standards Nos. 102 *Transmission Shift Lever Sequence . . . ., 103 Defrosting and Defogging Systems*, 104 *Windshield Wiping and Washing Systems*, 105 *Hydraulic Brake Systems*, 106 *Brake Hoses*, 109 *New Pneumatic Tires*, 113 *Hood Latch Systems*, 116 *Brake Fluid*, 124 *Accelerator Control Systems*, 201 *Occupant Protection in Interior Impact*, 202 *Head Restraints*, 204 *Steering Control Rearward Displacement*, 205 *Glazing Materials*, 206 *Door Locks and Door Retention Components*, 207 *Seating Systems*, 209 *Seat Belt Assemblies*, 210 *Seat Belt Assembly Anchorages*, 212 *Windshield Retention*, 216 *Roof Crush Resistance*, 219 *Windshield Zone Intrusion*, and 302 *Flammability of Interior Materials.*

Petitioner also contends that the vehicles are capable of being readily altered to meet the following standards, in the manner indicated:

Standard No. 101 *Controls and Displays:* (a) substitution of a lens marked ''Brake'' for a lens with a noncomplying symbol on the brake failure indicator lamp; (b) installation of a seat belt warning lamp that displays the appropriate symbol; (c) recalibration of the speedometer/odometer from kilometers to miles per hour.

Standard No. 108 *Lamps, Reflective Devices and Associated Equipment:* (a) installation of U.S.-model headlamp assemblies that incorporate headlamps with DOT markings; (b) installation of U.S.-model front and rear sidemarker/reflector assemblies; (c) installation of U.S.-model taillamp assemblies; (d) installation of a center high mounted stop lamp on vehicles that are not already so equipped.

Standard No. 110 *Tire Selection and Rims:* installation of a tire information placard.

Standard No. 111 *Rearview Mirror:* replacement of the passenger side rearview mirror with a U.S.-model component.

Standard No. 114 *Theft Protection:* installation of a warning buzzer microswitch in the steering lock assembly and a warning buzzer.

Standard No. 118 *Power Window Systems:* rewiring of the power window

system so that the window transport is inoperative when the ignition is switched off.

Standard No. 208 *Occupant Crash Protection:* (a) Installation of a U.S.-model seat belt in the driver's position, or a belt webbing-actuated microswitch inside the driver's seat belt retractor; (b) installation of an ignition switch-actuated seat belt warning lamp and buzzer; (c) replacement of the driver's and passenger's side air bags and knee bolsters with U.S.-model components on vehicles that are not already so equipped. The petitioner states that the vehicles are equipped with combination lap and shoulder restraints that adjust by means of an automatic retractor and release by means of a single push button at both front designated seating positions.

Standard No. 214 *Side Impact Protection:* installation of reinforcing beams.

Standard No. 301 *Fuel System Integrity:* installation of a rollover valve in the fuel tank vent line between the fuel tank and the evaporative emissions collection canister.

Additionally, the petitioner states that the bumpers on the non-U.S. certified 1997–1999 Ferrari Maranello 550 passenger cars must be reinforced or U.S.-model bumper components must be installed to comply with the Bumper Standard found in 49 CFR Part 581.

The petitioner also states that a vehicle identification number plate must be affixed to the vehicle to meet the requirements of 49 CFR Part 565.

Interested persons are invited to submit comments on the petition described above. Comments should refer to the docket number and be submitted to: Docket Section, National Highway Traffic Safety Administration, Room 5109, 400 Seventh Street, S.W., Washington, DC 20590. It is requested but not required that 10 copies be submitted.

All comments received before the close of business on the closing date indicated above will be considered, and will be available for examination in the docket at the above address both before and after that date. To the extent possible, comments filed after the closing date will also be considered. Notice of final action on the petition will be published in the **Federal Register** pursuant to the authority indicated below.

Authority: 49 U.S.C. 30141(a)(1)(A) and (b)(1); 49 CFR 593.8; delegations of authority at 49 CFR 1.50 and 501.8.

Issued on: March 11, 1999.

Marilynne Jacobs,

Director, Office of Vehicle Safety Compliance.

[FR Doc. 99–6475 Filed 3–16–99; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 8697

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 8697, Interest Computation Under the Look-Back Method for Completed Long-Term Contracts.

DATES: Written comments should be received on or before May 17, 1999 to be assured of consideration.

ADDRESSES: Direct all written comments to Garrick R. Shear, Internal Revenue Service, room 5571, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Carol Savage, (202) 622–3945, Internal Revenue Service, room 5569, 1111 Constitution Avenue NW., Washington, DC 20224.

SUPPLEMENTARY INFORMATION:

Title: Interest Computation Under the Look-Back Method for Completed Long-Term Contracts.

OMB Number: 1545–1031.

Form Number: Form 8697.

Abstract: Taxpayers who are required to account for all or part of any long-term contract entered into after February 28, 1986, under the percentage of completion method must use Form 8697 to compute and report interest due or to be refunded under Internal Revenue Code section 460(b)(3). The IRS uses Form 8697 to determine if the interest has been figured correctly.

Current Actions: There are no changes being made to Form 8697 at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations and individuals.

Estimated Number of Respondents: 5,000.

Estimated Time Per Respondent: 13 hours, 40 minutes.

Estimated Total Annual Burden Hours: 68,360.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: March 11, 1999.

Garrick R. Shear,

IRS Reports Clearance Officer.

[FR Doc. 99–6514 Filed 3–16–99; 8:45 am]

BILLING CODE 4830–01–U

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 8825

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent

burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 8825, Rental Real Estate Income and Expenses of a Partnership or an S Corporation.

DATES: Written comments should be received on or before May 17, 1999 to be assured of consideration.

ADDRESSES: Direct all written comments to Garrick R. Shear, Internal Revenue Service, room 5571, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Faye Bruce, (202) 622–6665, Internal Revenue Service, room 5571, 1111 Constitution Avenue NW., Washington, DC 20224.

SUPPLEMENTARY INFORMATION:

Title: Rental Real Estate Income and Expenses of a Partnership or an S Corporation.

OMB Number: 1545–1186.

Form Number: 8825.

Abstract: Partnerships and S corporations file Form 8825 with either Form 1065 or Form 1120S to report income and deductible expenses from rental real estate activities, including net income or loss from rental real estate activities that flow through from partnerships, estates, or trusts. The IRS uses the information on the form to verify that partnerships and S corporations have correctly reported their income and expenses from rental real estate property.

Current Actions: There are no changes being made to the form at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 705,000.

Estimated Time Per Respondent: 8 hrs., 43 min.

Estimated Total Annual Burden Hours: 6,147,600.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: March 3, 1999.

Garrick R. Shear,

IRS Reports Clearance Officer.

[FR Doc. 99–6515 Filed 3–16–99; 8:45 am]

BILLING CODE 4830–01–U

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request For Form 8609

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 8609, Low-Income Housing Credit Allocation Certification and Schedule A (Form 8609), Annual Statement.

DATES: Written comments should be received on or before May 17, 1999, to be assured of consideration.

ADDRESSES: Direct all written comments to Garrick R. Shear, Internal Revenue Service, room 5571, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form(s) and instructions should be directed to Carol Savage, (202) 622–3945, Internal Revenue Service, room 5569, 1111 Constitution Avenue NW., Washington, DC 20224.

SUPPLEMENTARY INFORMATION:

Title: Low-Income Housing Credit Allocation Certification and Schedule A (Form 8609), Annual Statement.

OMB Number: 1545–0988.

Form Number: Form 8609 and Schedule A (Form 8609).

Abstract: Owners of residential low-income rental buildings may claim a low-income housing credit for each qualified building over a 10-year credit period. Form 8609 is used to obtain a housing credit allocation from the housing credit agency. The form, along with Schedule A, is used by the owner to certify necessary information required by the law.

Current Actions: There are no changes being made to Form 8609 or Schedule A at this time.

Type of Review: Extension of a current OMB approval.

Affected Public: Business or other for-profit organizations, individuals, and state, local or tribal governments.

Estimated Number of Respondents: 120,000.

Estimated Time Per Respondent: 20 hours, 24 minutes.

Estimated Total Annual Burden Hours: 2,447,400.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

REQUEST FOR COMMENTS: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d)

ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: March 10, 1999.

Garrick R. Shear,

IRS Reports Clearance Officer.

[FR Doc. 99–6516 Filed 3–16–99; 8:45 am]

BILLING CODE 4830–01–U

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 8842

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 8842, Election To Use Different Annualization Periods for Corporate Estimated Tax.

DATES: Written comments should be received on or before May 17, 1999, to be assured of consideration.

ADDRESSES: Direct all written comments to Garrick R. Shear, Internal Revenue Service, room 5571, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Faye Bruce, (202) 622–6665, Internal Revenue Service, Room 5577, 1111 Constitution Avenue NW., Washington, DC 20224.

SUPPLEMENTARY INFORMATION:

Title: Election To Use Different Annualization Periods for Corporate Estimated Tax.

OMB Number: 1545–1409.

Form Number: 8842.

Abstract: Form 8842 is used by corporations, tax-exempt organizations subject to the unrelated business income tax, and private foundations to annually elect the use of an annualization period under Internal Revenue Code section 6655(e)(2)(C)(i) or (ii) for purposes of figuring the corporation's estimated tax payments under the annualized income installment method.

Current Actions: There are no changes being made to Form 8842 at this time.

Type of Review: Extension of a current OMB approval.

Affected Public: Business, or other for-profit organizations.

Estimated Number of Respondents: 1700.

Estimated Time Per Respondent: 2 hrs., 8 min.

Estimated Total Annual Burden Hours: 3,638.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

REQUEST FOR COMMENTS: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: March 8, 1999.

Garrick R. Shear,

IRS Reports Clearance Officer.

[FR Doc. 99–6517 Filed 3–16–99; 8:45 am]

BILLING CODE 4830–01–U

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 8838

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 8838, Consent To Extend the Time To Assess Tax Under Section 367-Gain Recognition Agreement.

DATES: Written comments should be received on or before May 17, 1999, to be assured of consideration.

ADDRESSES: Direct all written comments to Garrick R. Shear, Internal Revenue Service, room 5571, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Faye Bruce, (202) 622–6665, Internal Revenue Service, Room 5577, 1111 Constitution Avenue NW., Washington, DC 20224.

SUPPLEMENTARY INFORMATION:

Title: Consent To Extend the Time To Assess Tax Under Section 367-Gain Recognition Agreement.

OMB Number: 1545–1395.

Form Number: 8838.

Abstract: Form 8838 is used to extend the statute of limitations for U.S. persons who transfer stock or securities to a foreign corporation. The form is filed when the transferor makes a gain recognition agreement. This agreement allows the transferor to defer the payment of tax on the transfer. The IRS uses Form 8838 so that it may assess tax against the transferor after the expiration of the original statute of limitations.

Current Actions: There are no changes being made to Form 8838 at this time.

Type of Review: Extension of a current OMB approval.

Affected Public: Business or other for-profit organizations and individuals.

Estimated Number of Respondents: 1000.

Estimated Time Per Respondent: 8 hrs., 14 min.

Estimated Total Annual Burden Hours: 8,440.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any Internal Revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

REQUEST FOR COMMENTS: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: March 8, 1999.

Garrick R. Shear,

IRS Reports Clearance Officer.

[FR Doc. 99–6518 Filed 3–16–99; 8:45 am]

BILLING CODE 4830–01–U

UNITED STATES INFORMATION AGENCY

Culturally Significant Objects Imported for Exhibition Determinations

AGENCY: United States Information Agency.

ACTION: Notice.

SUMMARY: Notice is hereby given of the following determinations: Pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985, 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978 (43 FR 13359, March 29, 1978), and Delegation Order No. 85–5 of June 27, 1985 (50 FR 27393, July 2, 1985). I hereby determine that the objects to be included in the exhibit ''Nainsukh: Painter from the Punjab Hills,'' imported from abroad for temporary exhibition without profit within the United States, is of cultural significance. These objects are imported pursuant to a loan agreement with the foreign lender. I also determine that the exhibition or display of the listed exhibit objects at the Arthur M. Sackler Gallery of Art, Smithsonian Institution, Washington, DC, from on or about April 25, 1999, to on or about July 18, 1999, is in the national interest. Public Notice of these determinations is ordered to be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Neila Sheahan, Assistant General Counsel, 202–619–5030, and the address is Room 700, U.S. Information Agency, 301 4th Street, SW., Washington, DC 20547–0001.

R. Wallace Stuart,

Deputy General Counsel.

[FR Doc. 99–6495 Filed 3–16–99; 8:45 am]

BILLING CODE 8230–01–M

Federal Register

Wednesday
March 17, 1999

Part II

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 201, et al.

Over-The-Counter Human Drugs; Labeling Requirements; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 201, 330, 331, 341, 346, 355, 358, 369, and 701

[Docket Nos. 98N–0337, 96N–0420, 95N–0259, and 90P–0201]

RIN 0910–AA79

Over-The-Counter Human Drugs; Labeling Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule establishing a standardized format and standardized content requirements for the labeling of over-the-counter (OTC) drug products. This final rule is intended to assist consumers in reading and understanding OTC drug product labeling so that consumers may use these products safely and effectively. This final rule will require all OTC drug products to carry the new, easy-to-read format and the revised content requirements within prescribed implementation periods.

DATES:

Effective Date: April 16, 1999.

Compliance Dates: For compliance dates see section V of the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Debra L. Bowen, Food and Drug Administration, Center for Drug Evaluation and Research (HFD–560), 5600 Fishers Lane, Rockville, MD 20852, 301–827–2222, or email ''BOWEND@cder.fda.gov''.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of February 27, 1997 (62 FR 9024), FDA proposed to establish a standardized format for the labeling of OTC drug products that included: (1) Specific headings and subheadings presented in a standardized order, (2) standardized graphical features such as Helvetica type style and the use of ''bullet points'' to introduce key information, and (3) minimum standards for type size and spacing. The proposal included an extensive list of ''connecting terms'' that manufacturers may omit from product labeling, and an expanded list of ''interchangeable terms'' to facilitate the use of more concise and easy to understand language in OTC drug product labeling. The agency also proposed to amend several specific warnings, including the required pregnancy-nursing warning, the ''keep out of reach of children'' warning, and the accidental overdose/ingestion warnings, to make these warnings as direct and understandable as possible. Finally, the agency proposed to preempt State and local rules that establish different requirements than those in the proposed rule, to promote a national, standardized format for all OTC drug product labeling.

The agency discussed at length its basis for proposing to improve labeling design (62 FR 9024 at 9027 through 9031). The agency stated that a standardized labeling format would significantly improve readability by familiarizing consumers with the types of information in OTC drug product labeling and the location of that information. In addition, a standardized appearance and standardized content, including various ''user-friendly'' visual cues, would help consumers locate and read important health and safety information and allow quick and effective product comparisons, thereby helping consumers to select the most appropriate product.

The agency reviewed literature studies that confirmed that OTC drug product labeling often lacks the graphical features and visual cues needed to ensure readability and comprehension. These and other studies recommended ways to make labeling easier to read and understand, described the importance of adherence to directions for use, and reported on a number of preventable adverse drug reactions from OTC drug products (see 62 FR 9024 at 9027 and 9028).

The agency also has benefitted significantly in this proceeding from the experience it gained in redesigning food labeling under the Nutrition Labeling and Education Act of 1990 (NLEA) (Pub. L. 101–535, November 8, 1990). The agency's required nutrition labeling panel (§ 101.9 (21 CFR 101.9)) provides a standardized graphic presentation for food nutrients, allowing consumers to judge the significance of the level of a particular nutrient in a product in the context of a total daily diet. Since its implementation in 1993, the agency has received praise from consumers and nutritionists, noting the impact and utility of the standardized food label.

The agency provided over 7 months for interested persons to comment on the OTC labeling proposal, which included an extension of the comment period from June 27, 1997, to October 6, 1997, published in the **Federal Register** on June 19, 1997 (62 FR 33379). In addition, the agency solicited public comment on two labeling studies it conducted. In the **Federal Register** of December 30, 1997 (62 FR 67770), the agency sought comment (until February 13, 1998) on a study entitled ''Evaluation of Revised Formats for Over-the-Counter (OTC) Drugs'' (Study B). Study B consisted of a survey of more than 900 respondents to evaluate consumer preference for design variations in drug labeling formats. In the **Federal Register** of February 13, 1998 (63 FR 7331), the agency solicited comment (until March 30, 1998) on a second study entitled ''Evaluation of Proposed Over-the-Counter (OTC) Label Format Comprehension Study'' (Study A). Study A consisted of a survey of more than 1,200 consumers on the influence of variations in labeling formats on the communication of directions for use and required warnings.

In response to the proposed rule and the publication of Studies A and B, the agency received more than 1,800 comments from health professionals and students, professional organizations, trade associations, manufacturers, consumers, and consumer organizations. An overwhelming majority of the comments supported the agency's initiative to standardize the format of OTC drug product labeling and to make the labeling easier to read and understand by requiring a minimum type size, user-friendly headings, and other well-accepted visual cues.

However, a number of specific points in the proposal generated extensive, and sometimes divergent, comment: (1) Whether pharmacists, nurses, or other health professionals should be specifically referenced in certain of the proposed headings; (2) an appropriate minimum type size for the required labeling information; (3) application of the proposed labeling format to products traditionally marketed in small containers and products marketed as both drugs and cosmetics; and (4) continued reference to Poison Control Centers in the required accidental ingestion warning. These and other comments are addressed at length in section IV of this document.

The agency has considered the information presented in the proposed rule, the comments received, the results from Studies A and B, and all other relevant information, and concludes that the standardized format and content requirements for OTC drug product labeling, as set forth in this final rule, will enable consumers to better read and understand the information presented and apply this

information to the safe and effective use of OTC drug products.

As discussed in the proposed rule, research on reading behavior and document simplification shows that the use of less complex terminology, presented in shorter sentences with an organized or ''chunked'' structure, is likely to improve consumer processing of the information (Refs. 1, 2, and 3). Research also shows that consumers are more likely to engage in behavior that they believe they can successfully complete than in behavior that appears overwhelming (Ref. 4) or that presents a ''cognitive load,'' such as the task of reading densely worded consumer information (Ref. 5).

The new OTC drug product labeling is expected to decrease ''cognitive load'' by, among other things, decreasing the memory demands necessary for processing the information. This, in turn, will allow consumers to process the information faster. In addition, the new format offers a more structured, organized, and compact presentation, which places fewer and less imposing processing demands on the reader. The consumer's self-perceived ability to read the labeling will increase significantly and, thereby, result in an improved overall understanding of the information presented. Finally, the new labeling is expected to provide clear signals regarding important information, leading to increased processing and communication of this information.

II. Prototype Labeling Based on This Final Rule

An outline of the various labeling provisions for OTC drug products is shown below:

BILLING CODE 4160–01–F

OTC Drug Product Labeling Outline

Drug Facts

Active ingredient (in each dosage unit) ***Purpose***

xxxxxxxxxxxxxxx mg.....xxxxxxxxx

Uses
- xxxxxxxxxxxxxx
- xxxxxxxxxxxxxx

Warnings

Do not use xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Ask a doctor before use if you have
- xxxxxxxxxxxxxx
- xxxxxxxxxxxxxx

Ask a doctor or pharmacist before use if you are xxxxxxxxxxxxx

When using this product
- xxxxxxxxxxxxxx
- xxxxxxxxxxxxxx

Stop use and ask a doctor if
- xxxxxxxxxxxxxx
- xxxxxxxxxxxxxx

If pregnant or breast-feeding, ask a health professional before use.
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Drug Facts (continued)

Directions
- xxxxxxxxxxxxxx
- xxxxxxxxxxxxxx

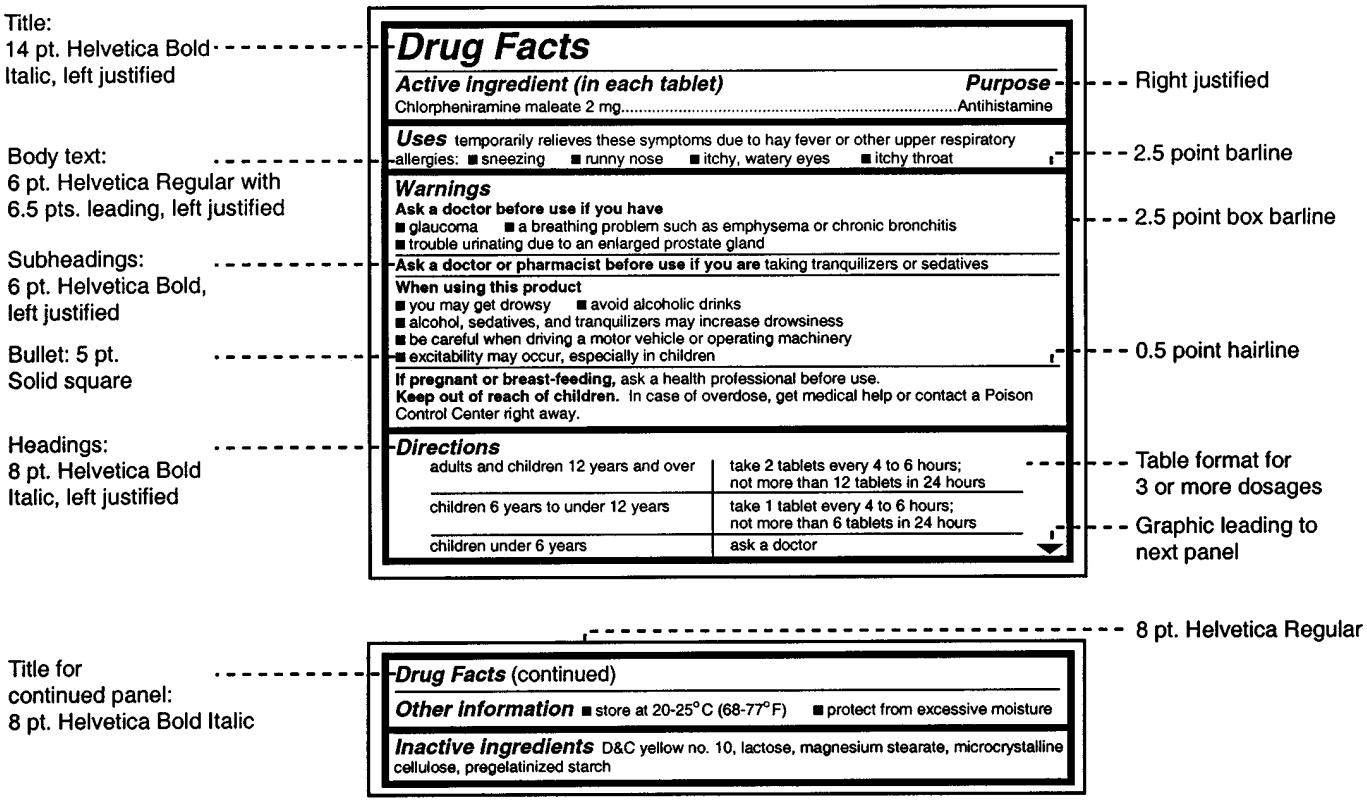
Other information
- xxxxxxxxxxxxxx
- xxxxxxxxxxxxxx

Inactive ingredients xxxxxxxxxxxxx

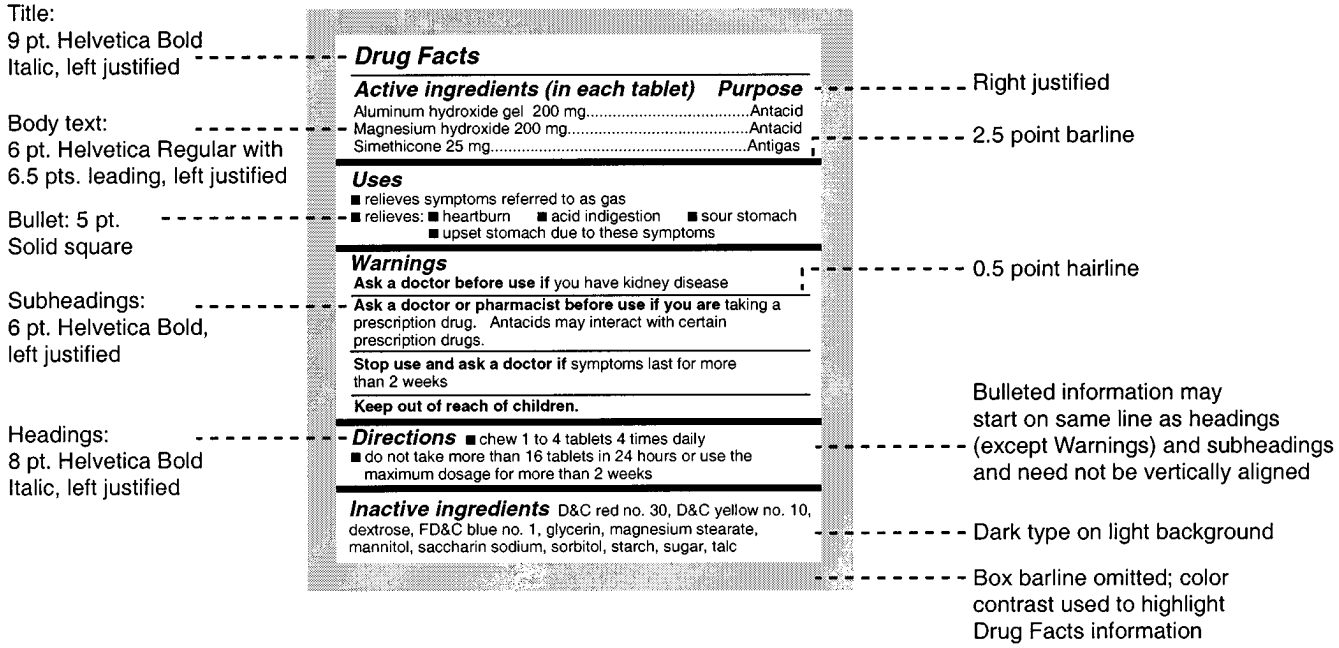
Questions? **123-555-1234**

BILLING CODE 4160–01–C

An example of labeling for a single ingredient antihistamine OTC drug product, annotated for illustrative purposes, is shown below. FDA recommends use of the type style and font sizes shown below:



An example of labeling for an antacid OTC drug product, applying the modified, small package labeling provisions in this final rule and annotated for illustrative purposes, is shown below. FDA recommends use of the type style and font sizes shown below:



BILLING CODE 4160–01–C

Examples of prototype OTC drug product labeling are attached in Appendix A of this document. The information in these examples is presented using ordinary package sizes for these types of products. These examples are for illustrative purposes only and are not intended to depict specific products. Some are based on proposed monograph requirements only. Example 1 depicts sample labeling for a single ingredient antihistamine product, using the format and content provisions set forth in this final rule. Example 2 depicts labeling for a combination cough/cold product using the format and content provisions set forth in this final rule. Example 3 demonstrates how the same information shown in Example 2 can be presented directly on the package label for an 8-ounce bottle of syrup, using the small package modifications specified in the final rule. Example 4 depicts a toothpaste that is marketed as a standing tube without an outer carton, using the format and content provisions set forth in this final rule. Example 5 demonstrates labeling for a drug product that is also marketed for cosmetic uses using the format and content provisions set forth in this final rule. Example 5 also demonstrates an acceptable ''similar enclosure'' to a box. Example 6 depicts labeling for a topical acne product that is marketed in a tube and packaged in a carton with a riser, in order to provide additional labeling space. Example 7 depicts labeling for an antacid product, applying the small package modifications.

III. Summary of Studies A and B

Studies A and B tested whether the proposed format improves the readability and understandability of OTC drug product labeling and investigated consumer preference for certain format variations. The studies confirm that the new labeling format will increase communication of OTC drug product information.

A. Study A

Study A examined the influence of labeling formats and the use of selective highlighting on the communication of directions for use and warnings. The study examined two levels of four independent variables in a factorial design: (1) Labeling format (prototypical existing format versus proposed new format), (2) drug type (cough-cold versus pain reliever), (3) the use of highlighting (more versus less emphasis on graphic design features), and (4) consumer attention (divided versus focused). Highlighting, label format, and drug type were varied in the design of the sample product label. Attention (focused or divided) was varied through instructions given to the respondents. Study participants were asked to read a food label, then a drug label to test for divided and focused attention. Half of the participants were told they would be asked questions about both labels (divided attention); the other half were told they would be tested only on the drug label (focused attention) and that the food label was to serve only as reading practice.

The study included 1,202 respondents in 8 geographically distributed shopping malls in the United States, with approximately equal numbers of respondents from each location. Respondents were asked to evaluate the presentation of label information on one OTC drug sample and were asked questions about the labeling to determine their knowledge, opinions, and willingness to read the labeling.

Dependent measures were analyzed using a general linear model analysis of variance. The study demonstrated that the proposed new format took less time and was easier to read and understand than a product that did not follow the new format. Study respondents indicated a general preference for the proposed format and, when their attention was divided, respondents felt more confident in their ability to use the proposed format labeling. When more graphical design features were used, respondents who were instructed to focus on the labeling made more correct product use decisions, compared to respondents whose attention was divided. There were no conditions under which a product with an existing labeling format outperformed the proposed new format.

The results from Study A suggest that consumers who are presented with the new labeling format will be: (1) More confident in their ability to use the information in the labeling, and (2) better able to make correct product use decisions.

B. Study B

This study investigated consumer preferences for format and graphical design variations. The study examined two levels of each of four independent variables in a factorial design: (1) The order of the ''Warning(s)'' and ''Direction(s)'' section (i.e., warnings before directions or warnings after directions), (2) the placement of the ''Active ingredients'' section at the top of the labeling versus bottom, (3) the use of a title as an introduction to the required information (''Medication Facts'' versus no title), and (4) the use of dividing lines between sections (thick versus thin lines).

This study included 904 respondents in 8 geographically distributed shopping malls in the United States, with approximately equal numbers of respondents from each location. The respondents were asked to evaluate 16 labeling variations of either a sample cough-cold or sunscreen drug product. The respondents were also asked to rank the randomly ordered labels from most to least preferred, to specify the reasons for their first and second choices, and to rate a current OTC drug product that did not follow the new format.

The study showed that the presence of a title was the most important factor in determining preference, as participants were more likely to choose labeling with a title than without. When asked why they preferred the label ranked as number one, the respondents indicated that it: (1) Was easy to read, and (2) begins with ''Medication Facts.''

The agency performed a primary conjoint analysis on the preference rankings. A conjoint analysis simultaneously weighs multiple variables and allows for a determination of the relative importance of each particular attribute of a variable, in addition to the level at which each attribute is preferred (SPSS Categories, 1994). Results indicated that, of the four factors examined, title had the greatest impact on rankings, with a utility range from -1.83 for no title and +1.83 for the ''Medication Facts'' title. In this primary analysis, the effect of the other three variables was not significant.

The agency also performed a secondary analysis of the data, to look at differences between variables, independent of context. For labeling with a title, the mean ranks were 6.67 and 10.33 ($Z=-20$, $SD=1.95$, $p<0.001$), clearly confirming that the presence of a title was the most important factor in determining preference rankings. The secondary analysis of the other three format variables showed mean ranks in the middle range (between 8.18 and 8.82, SDs=0.94 to 1.97). However, as stated previously, the primary analysis of these three variables showed that none had a statistically significant influence on preference when the variable was considered in context. Again, the presence of an introductory title proved to be the preferred variable.

IV. Summary and Response to Comments

This section summarizes each section of the final rule and provides the agency's response to comments.

A. Scope (§ 201.66(a))

Section 201.66(a) states that the content and format requirements in § 201.66 apply to the labeling of all OTC drug products. This would include products marketed under a final OTC drug monograph, an approved new drug application (NDA) or abbreviated new drug application (ANDA) under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355), and OTC products for which there is no final OTC drug monograph or approved drug application. Thus, for example, OTC drug products that are the subject of tentative final monographs will, in time, be required to comply with the new labeling requirements.

The proposed rule stated that the new labeling would apply to products that are the subject of a final monograph or an approved drug application. Under both the proposed and the final rule, all OTC drug products in time would be required to adopt the new labeling. The revised wording of the scope provision is consistent with and furthers two central themes of this proceeding. First, the agency has concluded that consistent, standardized labeling of OTC drug products will improve the selection and the safe and effective use of all OTC drug products. Second, all drug products, irrespective of their regulatory status, must bear labeling that is ''likely to be read and understood by the ordinary individual under customary conditions of purchase and use.'' (Section 502 of the act (21 U.S.C. 352(c)).) With all products following the new format, consumers will be able to readily distinguish OTC drug products from other categories of products (such as dietary supplements and foods), make product-to-product comparisons across all therapeutic classes, and will begin to recognize where to find information that is critical to the best use of any OTC drug product. The final rule ensures that by a date certain all OTC drug products will display the new labeling.

The agency has chosen an outside implementation date of 6 years for marketed OTC drug products that are not and do not become the subject of final OTC monographs (see section V of this document). Because most, if not all, drug products undergo at least one major labeling revision every 6 years (see section VIII of this document), the revised scope is not expected to impose any significant additional burdens.

1. Several comments asked that § 201.66 include an express exemption for homeopathic drug products, including those products listed in the Homeopathic Pharmacopeia of the United States. One comment recommended that the labeling requirements should apply to homeopathic drug products to promote their safe use.

Homeopathic drug products generally are subject to the drug provisions of the act, including the misbranding provisions in section 502 of the act, and therefore, the agency has concluded that an express exemption would not be appropriate. However, as emphasized in the proposed rule, the agency's stated policy is that such products ordinarily will not be recommended for regulatory action if the product is a homeopathic drug as described in Compliance Policy Guide 7132.15 entitled ''Conditions Under Which Homeopathic Drugs May Be Marketed'' (62 FR 9024 at 9031), and the product follows the labeling and all other recommendations outlined in that guidance document. By its terms, the policy of generally not recommending homeopathic products for regulatory action will extend to this rule.

B. Definitions (§ 201.66(b))

Section 201.66(b) contains applicable definitions, including explanations of certain printing, typesetting, and graphics terms applicable to this rule. The agency has also added definitions for the terms ''bullet,'' ''title,'' and ''inactive ingredient.'' The definition for inactive ingredient is identical to the definition in the agency's good manufacturing practice regulations in 21 CFR 210.3(b)(8).

C. Content Requirements (§ 201.66(c))

Section 201.66(c) contains the content requirements for the standardized labeling format and states that all information must be organized under the title, headings, and subheadings set forth in paragraphs (c)(1) through (c)(8), and it may contain the information under the heading in paragraph (c)(9), in the order prescribed. This information must appear on the outside container or wrapper of the retail package, or the immediate container label if there is no outside container or wrapper. As discussed below, the agency has amended some of the headings and subheadings and included additional headings and subheadings, including the title ''Drug Facts.''

2. Several comments supported the order for listing information, as prescribed in § 201.66(c). One comment stated that listing active ingredients and their purposes first allows consumers to compare ingredients, avoid certain ingredients for reasons of safety or personal preference, and helps to ensure that products with different active ingredients are not used for the same indication.

Several comments focused on the placement of the inactive ingredient section, with some suggesting that inactive ingredients should be listed separately from active ingredients because the inactive ingredients are of only minor concern to most consumers. Others were opposed to the separation of active and inactive ingredients.

Many comments addressed the relative placement of the ''Directions'' and ''Warnings'' sections. Consumer and professional groups and industry representatives generally preferred that the warnings be presented first, to ensure proper self-selection of the appropriate drug at the point of purchase. A smaller number of comments favored placing the directions first, based on the idea that this section would contain the most important information on the proper use of the product.

As discussed previously in section III.B of this document, the primary statistical analysis performed in Study B did not find a significant respondent preference for the placement of ''Warnings,'' ''Directions,'' and ''Active ingredients.'' Therefore, the order for the placement of information in the final rule is modeled after the decisionmaking process consumers would be expected to follow, and should follow, when selecting and using OTC drug products.

First, consumers need to know what the product is and what it is intended to do. This information often is not apparent from the principal display panel (PDP), especially for combination OTC drug products. This information also is critical to consumers' ability to select the most appropriate product. Therefore, the agency is requiring the listing of the active ingredients and their purposes as the first information presented under the title ''Drug Facts.'' Foremost, the agency believes that consumers need to be able to identify the active drug ingredients, to readily access that information, and to associate the ingredients with their respective purposes.

Next, the consumer needs to select an appropriate product for its intended uses. Therefore, this section, entitled ''Use(s),'' follows the active ingredient and purpose information.

The ''Warnings'' section, which follows the ''Use(s),'' contains information that is relevant to both the product selection decision and to proper use. This section contains information regarding when the product should absolutely not be used, drug-drug and drug-food interactions, when to consult

a doctor or pharmacist before taking the product, possible side effects, and when to stop use and contact a doctor after taking the product.

After a consumer selects an appropriate product, correct administration and dosing is essential. The ''Directions'' section contains dosage and administration information necessary for the safe and effective use of the product. Therefore, this section follows the ''Warnings'' section.

''Other information'' is listed in the next section, for products that need to provide additional information that is important for complete understanding of the product's use, including information for consumers who may be allergic to certain ingredients, such as aspartame, or who restrict the intake of dietary ingredients such as sodium.

The ''Inactive ingredients'' section is listed near the conclusion of the FDA-required information, because some products contain a large number of inactive ingredients. The location of this section will help maintain the systematic presentation of the information listed under the other headings.

Finally, the agency has included a location for a telephone number. The telephone number, if provided, would appear after the header ''Questions?'' (or ''Questions or comments?''), does not need to be a toll-free number, and may include the days of the week and time when someone is available to respond to questions.

As described in section III.B in this document, the agency examined the order of certain headings in Study B, including the relative placement of the ''Warnings'' and ''Directions'' sections and the placement of the ''Active ingredients'' section. When all of the design variables in the study were analyzed simultaneously, the variable placement of these three headings had little relative impact on preference or readability ratings of the entire labeling. The agency selected the order prescribed in § 201.66(c) because it most closely tracks a logical decisionmaking process that would allow for the best selection and best use of OTC drug products.

3. The agency sought comment on whether the new labeling should apply to the immediate container label even if the product is marketed with an outer package or wrapper (62 FR 9024 at 9037 and 9038). Several comments stated that the labeling requirements should not apply to the immediate container, or should be voluntary for the immediate container, when there is an outer package, because space is often especially limited on the container. Some comments supported requiring certain headings in a mandated order, but not imposing the type size and other type style requirements. Others, however, emphasized that the outer carton is often discarded, leaving the immediate container as the sole source for important warnings and dosage information.

For products that are sold with an outer package, the agency encourages manufacturers to try to meet all of the labeling requirements in this rule on the immediate container as well. If the immediate container is too small to meet the format requirements of § 201.66(d)(1) through (d)(9), the agency encourages manufacturers to include the required information as provided in the small package format in § 201.66(d)(10). In addition, manufacturers must include on the immediate container any information that is specifically required by regulation (including an OTC drug monograph) to appear on the immediate container, in the manner described in that regulation or monograph (see, e.g., § 201.314(h)(2) (21 CFR 201.314(h)(2))), requiring Reye's syndrome warning on the immediate container).

1. Title (§ 201.66(c)(1))

Section 201.66(c)(1) requires the title ''Drug Facts'' as the first heading in the standardized format. A title provides an important visual cue for introducing required information. The agency evaluated the use of a title as a graphical design feature in Study B and solicited comment on both the design of Study B and the results of the study. As summarized in section III of this document, respondents in Study B strongly preferred labeling that contained a title, such as ''Medication Facts,'' and considered such labeling to be more credible and reliable than labeling without a title. When the agency analyzed simultaneously the impact of all design variables tested in Study B, the introductory title had the greatest relative impact on preference rankings.

4. The existing regulations governing OTC monograph products allow manufacturers to use titles such as ''FDA Approved Uses'' and ''FDA Approved Information'' to introduce required monograph information. These titles, and the ability to enclose labeling information in a highlighted ''box,'' are available under FDA's ''exclusivity policy.'' Under the policy, manufacturers may include a specified title and box if they follow certain precise or ''exclusive'' language provided by FDA in a final OTC monograph (see § 330.1 (21 CFR 330.1)).

Most manufacturers, however, have preferred to use ''flexible'' language to describe the uses and other information required under the OTC drug monographs. Moreover, the proposed rule itself added more flexibility in selecting language, making it less likely that manufacturers would avail themselves of the labeling features specified in § 330.1. The agency therefore solicited comment on whether to retain the idea of allowing special titles and boxes for manufacturers who follow precise monograph language (62 FR 9024 at 9039).

The agency did not receive substantive comments on this issue. The agency did, however, receive one comment stating that the title ''FDA Approved Uses'' violated section 301(1) of the act and could create confusion between products marketed under new drug applications and similar products marketed under OTC drug monographs. The first issue was rendered moot by the repeal of section 301(1) of the act under section 421 of the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105–115), while the second issue was addressed by the agency in the rulemaking for § 330.1(c) (see 51 FR 16258 at 16260 and 16261, May 1, 1986).

The agency agrees, however, that the availability of a title should not be limited to products marketed under OTC drug monographs. The agency also finds, based in part on the strong support for a title under Study B, that consumers would benefit by having a title on all OTC drug products (rather than only on those few products that chose to use certain language specified under an OTC drug monograph). The agency has therefore included a title as part of this final rule to introduce the required information on all OTC drug products. In addition, the agency is revoking the titles and boxed labeling provisions from § 330.1(c).

5. Several comments contended that a title such as ''Medication Facts'' was not specifically discussed in the proposed rule and, therefore, should not be included in this final rule. The comments also contended that this title has not been shown to actually improve consumer use of OTC drug products and would take up too much space.

As discussed, the agency included the title ''Medication Facts'' as a key variable in Study B and provided ample opportunity for interested persons to comment on the design and on the results of the study.

A title on the information panel provides a strong cue to the consumer that important labeling information follows. This is similar to the highly

successful ''Nutrition Facts'' title required on the information panel for food products (§ 101.9). Indeed, respondents in Study B stated that they preferred a label with a title and that they considered the information to be more credible and reliable when introduced by a prominent title.

The agency does not believe that it must prove that the title alone improves consumer use of OTC drug products. A number of factors combined determine consumer use, including format variables, legibility, readability, comprehension, and consumer motivation. It is difficult to separate out the influence of each variable. Nevertheless, it is important to note that when all of the design variables in Study B were considered simultaneously, the title had the most significant impact in determining which label consumers preferred. Overall, a title creates an important, concise visual cue for consumers and serves to reinforce the importance of the information that follows.

The agency has decided to use the title ''Drug Facts,'' in place of the test title ''Medication Facts,'' because the phrase ''Drug Facts'' is short, concise, easy to print in large type, and best signals an OTC drug product. Consumers may use the term ''Medication'' to refer to remedies which may not be marketed as drug products. It is also a four syllable word which requires a higher level of reader comprehension. Consumers, for example, commonly use the term ''drug store'' to refer to a pharmacy. The agency therefore concludes that the word ''drug'' in this title is more precise, readable, comprehensible and, in response to the comments, will require less labeling space.

The title will take up one line of text on each panel that it appears. The previously allowed titles (''FDA APPROVED USES'' and ''FDA APPROVED INFORMATION'') also took up one line of text. Based in part on the results of study data and on the agency's experience with other forms of labeling, the agency concludes that the benefits of having a title outweigh the minimum space required.

2. Active Ingredient(s) (§ 201.66(c)(2))

Section 201.66(c)(2) requires the heading ''Active ingredient(s),'' followed by the established name and the quantity of each active ingredient per dosage unit. For products marketed without a discrete dosage unit, such as topical OTC drug products, the proportion of each active ingredient must be stated instead of the quantity, unless otherwise specified in an applicable monograph or approved drug application.

This provision incorporates a recent amendment to section 502(e) of the act under FDAMA. FDAMA amended section 502(e) of the act to require that the quantity (or the proportion, if determined to be appropriate by the Secretary of Health and Human Services (the Secretary)) of each active ingredient appear in the labeling of all OTC drug products intended for human use. In the proposed rule, the agency provided for the placement and formatting of the quantity of each active ingredient, but requested comment on whether to require all products to include this information. At that time, the agency's regulations encouraged (but did not require) manufacturers to include the quantity per dosage unit in the labeling (§ 330.1(j)). The vast majority of OTC drug products already include such information in their labeling. As a result of the statutory change, this final rule makes clear that the established name and quantity of each active ingredient must be included in the required information set forth in § 201.66(c), in the location and format established by the agency. In an agency guidance document titled ''National Uniformity for Nonprescription Drugs—Ingredient Listing for OTC Drugs (April 1998)'' (Ref. 6), the agency stated that it does not intend to object if manufacturers, packers, and distributors defer relabeling their products to comply with the statutory requirement until the earliest applicable implementation date specified in this final rulemaking document.

6. Several comments favored placing the active ingredient section on the PDP, rather than on another panel. The comments argued that product line extensions (i.e., OTC drug products with the same brand name that contain different active ingredients) invite the need for more prominent placement of the active ingredients. According to these comments, most consumers are able to recognize brand names but are unable to identify the relevant active ingredients. Placement of the active ingredients on the PDP would allow consumers to distinguish products sold under the same brand name.

This final rule requires the listing of active ingredients as the very first information within a clearly defined panel, immediately below a prominent title. This location will enable consumers to quickly and systematically compare ingredients within products for similar uses. In addition, because the respective purposes will be listed next to each active ingredient, consumers will know why the ingredient is in the product. Regardless of placement on the PDP, such uniform and prominent placement will help to ensure proper product selection, especially for product line extensions.

3. Purpose(s) (§ 201.66(c)(3))

Section 201.66(c)(3) requires the heading ''Purpose'' or ''Purposes,'' followed by the general pharmacological category(ies) or the principal intended actions of the drug or of each active ingredient, when more than one ingredient is listed. When an OTC drug monograph contains a statement of identity, the pharmacological action described in the statement of identity shall also be stated as the purpose of the active ingredient. Section 201.66(c)(3) of the final rule does not differ from the proposal.

4. Use(s) (§ 201.66(c)(4))

Section 201.66(c)(4) requires that all OTC drug product labeling include the heading ''Use'' or ''Uses'' followed by the indications for use of the drug product. Section 201.66(c)(4) of the final rule does not differ from the proposal.

5. Warning(s) (§ 201.66(c)(5))

Section 201.66(c)(5) requires the heading ''Warning'' or ''Warnings'' followed by the specific information and subheadings listed in §§ 201.66(c)(5)(i) through (c)(5)(x), as applicable.

7. Several comments requested that the warning ''For external use only'' appear immediately following the ''Warnings'' heading, on the same line of text as the heading. The agency agrees that for topical drug products not intended for ingestion, this warning should appear first. The agency, however, believes that the ''Warnings'' heading should signal the entire warning facts information and, therefore, disagrees with the request to display this statement on the same line as the heading. The agency is also specifying that the placement of the warnings ''For rectal use only'' or ''For vaginal use only,'' where applicable, immediately follow the ''Warning'' heading.

8. The proposed rule would have required certain ingredient-specific warnings, such as the Reye's syndrome warning in § 201.314(h)(1), to be listed first under the heading. Several comments recommended that the agency integrate such warnings into the various subheadings set forth in § 201.66(c)(5). Although the subheadings provide important visual and organizational cues, the agency believes that the warnings listed in § 201.66(c)(5)(ii) of the final rule need to

be given special prominence and should not be combined or grouped with other warnings under a subheading. An effective way to ensure that these special warnings are prominently displayed is to require that they be listed immediately under the ''Warnings'' heading, with a subheading that describes the key aspect of the warning. The agency has incorporated special subheadings for the warnings that will appear in this section. Some of the subheadings appear in current regulations or approved drug applications, and others are being added to provide consumers with signal words that describe the key aspect of the warning statement.

9. One comment suggested that the subheading ''Do not use'' include the word ''if,'' to read ''Do not use if.'' Another suggested listing allergic reaction warnings under this subheading.

The agency disagrees with adding ''if'' to this subheading because conditional words other than ''if'' may be part of certain warnings (e.g., ''on broken skin''). With respect to allergic reactions, the agency considers serious allergic reactions (e.g., immediate hypersensitivity reactions) to be of such importance that it is requiring these warnings to appear immediately under the ''Warnings'' heading, preceded by the subheading ''Allergy alert.''

In the labeling examples included in the proposed rule, the agency showed the prescription monoamine oxidase inhibitor (MAOI) warning under the ''Do Not Use'' subheading. No comments to the contrary were received, and the agency concludes that the warning should appear after this subheading.

The MAOI warning appears in several places in the cough-cold monograph (§§ 341.74(c)(4)(v) and (c)(4)(vi), 341.76(c)(4), and 341.80(c)(1)(i)(D) and (c)(1)(ii)(D) (21 CFR 341.74(c)(4)(v) and (c)(4)(vi), 341.76(c)(4), and 341.80(c)(1)(i)(D) and (c)(1)(ii)(D)). The agency has determined that the words ''Drug Interaction Precaution'' and ''this product,'' which are currently included in these sections, need not appear when the information appears after the new ''Do not use'' heading. Therefore, the agency is including the words ''Drug Interaction Precaution'' and ''this product'' in new § 330.1(j) in this final rule, which lists connecting terms that can be deleted from the labeling of OTC drug products. The MAOI warning would now appear in labeling as follows ''Do not use if you are now taking a prescription monoamine oxidase inhibitor (MAOI) * * * .''

10. The agency received numerous comments on the subheading, ''Ask a doctor before use.'' The agency specifically sought comment on whether the phrase ''or pharmacist,'' as in ''Ask your doctor or pharmacist,'' should be included in OTC drug product labeling and, if so, in what section of the labeling, and for which products (62 FR 9024 at 9039). A majority of the comments supported the inclusion of the pharmacist in OTC drug product labeling. Other comments suggested phrases such as ''other health professional,'' ''other healthcare professional,'' or ''other healthcare practitioner.''

Those comments favoring the phrase ''or pharmacist'' stated that pharmacists often are immediately accessible at the time of OTC drug purchase, are well equipped to provide information regarding benefits and risks associated with OTC drug products, have extensive training, and in many instances have immediate access to patient profiles and prescribing histories. The comments added that when pharmacists do not have enough information about a person's medical condition, or otherwise recognize the need to contact a doctor, they are trained to advise the consumer to speak with a doctor before taking an OTC drug product. Several comments noted that about 60 percent of OTC drug products are purchased in retail pharmacies.

Those supporting phrases such as ''other health professional'' or ''other healthcare professional'' or ''other healthcare practitioner'' stated that for many consumers the primary healthcare provider is a nurse practitioner, clinical nurse specialist, nurse midwife, physician assistant, or other healthcare professional, and not a physician. The comments argued that limiting the reference to ''doctor'' sends the message that only a ''doctor'' is qualified to know about a drug product's benefits, risks, side effects, and precautions.

A few comments stated that a subheading such as ''Ask a doctor or pharmacist before use'' would equate the role of a pharmacist with that of a doctor. These comments contended that pharmacists do not have the same level of knowledge or training regarding patient specific conditions, symptoms, side effects, and concomitant therapies. Further, only a physician is trained in medical history-taking, physical examination, and diagnosis. The comments stated that although a pharmacist may be qualified to help consumers select OTC drug products, a phrase such as ''or pharmacist'' is likely to confuse consumers about the role of their doctor and may seriously and adversely impact health.

This issue was also presented to the FDA's Nonprescription Drugs Advisory Committee at its July 14, 1997, meeting. The committee did not reach consensus whether ''pharmacist'' should be included in the labeling. However, several presenters suggested a specific consultative role for the pharmacist when considering drug-drug and drug-food interactions.

The agency has determined that warnings for persons with certain preexisting conditions (e.g., glaucoma) and symptoms (e.g., cough with fever, rash, or persistent headache) be listed under the subheading, ''Ask a doctor before use if you have,'' and that warnings concerning drug-drug or drug-food interactions be listed under the subheading, ''Ask a doctor or pharmacist before use if you are.'' However, the pregnancy/breast-feeding warning in § 201.63 (21 CFR 201.63) will continue to use the term ''health professional.''

As stated in the proposed rule, the agency recognizes that pharmacists are knowledgeable about OTC drug products. Also, pharmacists are readily accessible to a majority of consumers who purchase OTC drug products and are a valuable resource for general questions. Survey studies submitted to the docket for this proceeding suggest that direct consumer counseling by pharmacists may change initial OTC drug purchasing decisions and may prevent potential adverse events (Refs. 7 and 8). In addition, pharmacists are trained to provide advice about drug-drug and drug-food interactions and often have access to computer data bases which contain (and frequently update) this information. Therefore, the agency concludes that warnings concerning interactions be listed under the subheading, ''Ask a doctor or pharmacist before use if you are.'' The drug interaction precautions in 21 CFR 331.30(d) and 346.50(c)(7)(ii) have been revised to fit this new subheading.

If a consumer has a preexisting disease or clinical symptoms, the agency concludes that the subheading, ''Ask a doctor before use if you have,'' should be retained. The agency has decided not to include the phrase ''or pharmacist'' in this subheading because questions concerning preexisting diagnoses or clinical symptoms are best answered by a healthcare provider who is trained and licensed specifically to make differential diagnoses and to treat disease entities.

The agency has also decided to use only the term ''doctor'' in this subheading, rather than a longer list of

healthcare providers. The agency acknowledges that in addition to physicians, surgeons, and dentists, other licensed professionals play important roles in delivering clinical services directly to consumers and that nurse practitioners and physician's assistants may sometimes serve as primary medical care providers. However, the agency has decided not to endeavor to list each specific practitioner who is licensed and qualified in the clinical practice of medicine and in disease management. For OTC drug products, the term ''doctor'' in this subheading is sufficiently broad and inclusive (Ref. 9).

The agency is retaining the phrase, ''health professional'' in the revised pregnancy/breast-feeding warning in § 201.63(a), which requires, when appropriate, the warning, ''If pregnant or breast-feeding, ask a health professional before use.'' In establishing this warning (47 FR 54750, December 3, 1982), the agency noted that certain health professionals (e.g., physicians, nurses, certified nurse midwives, nurse practitioners, and physician's assistants) may be familiar with problems related to medication use during pregnancy and nursing because they receive specific training in this area and they directly deliver healthcare to women who are pregnant or nursing. As a consequence, for these specific physiologic conditions, these health professionals may be appropriately relied upon as sources of information advising caution concerning drug use while pregnant or nursing. The agency has amended § 201.63(a) in this final rule by requiring that the first four words of the warning appear in bold type, to ensure that this warning is as prominent and conspicuous as the required subheadings.

Finally, the agency is including in this final rule a conforming amendment to the MAOI warning (§§ 341.74(c)(4)(v) and (c)(4)(vi), 341.76(c)(4), and 341.80(c)(1)(i)(D) and (c)(1)(ii)(D)), substituting the words ''doctor or pharmacist'' for the words ''health professional.'' This change is consistent with the respective roles of pharmacists, doctors, and health professionals in assisting consumers of OTC drug products.

11. Several comments recommended consolidating the subheading ''Ask a doctor before use if you have'' (proposed § 201.66(c)(iii)(A)) with the subheading ''Ask a doctor before use if you are'' (proposed § 201.66(c)(iii)(B)), to allow greater flexibility in labeling design.

The subheading ''Ask a doctor before use if you have'' (§ 201.66(c)(5)(iv) in this final rule) cautions consumers about preexisting conditions when consumers should not use the product before a doctor is consulted. The subheading ''Ask a doctor or pharmacist before use if you are'' (§ 201.66(c)(5)(v) in this final rule) cautions consumers about potential drug-drug or drug-food interactions when consumers should not use the product before a doctor or pharmacist is consulted. Organizing or ''chunking'' the information under separate subheadings makes it more likely that the information will be read and understood by consumers who have certain conditions or are taking other drugs.

12. Section 201.66(c)(5)(vi) requires the subheading ''When using this product,'' followed by any side effects that the consumer may experience and the substances (e.g., alcohol) or activities (e.g., operating machinery, driving a car) to avoid while using the product. One comment suggested that because this subheading is not parallel in grammar with the other subheadings, it should read, ''Be aware when using this product.'' Another comment requested that warnings for drugs in dispensers pressurized by gaseous propellants be included under this subheading.

Although the subheading ''When using this product'' is not grammatically parallel with the other subheadings, the phrase ''Be aware'' is implied in the subheading because it appears under the general heading, ''Warnings.'' Consumers are already cautioned that they need to read and take note of the warning information that follows. In addition, the words ''Be aware'' would unnecessarily lengthen the subheading.

The agency agrees with the comment that the warnings for drugs in dispensers pressurized by gaseous propellants (§ 369.21 (21 CFR 369.21), 21 CFR 310.201(a)(11) and (a)(18)) would appear under this subheading.

13. Section 201.66(c)(5)(vii) requires the subheading ''Stop use and ask a doctor if,'' followed by any signs of toxicity or other serious reactions that would necessitate immediately discontinuing use of the product. This subheading, as proposed, read ''Stop using this product if,'' followed by the required warnings, followed by ''Ask a doctor. These may be signs of a serious condition.'' Several comments raised the concern that the ''Ask a doctor'' portion of this warning may be de-emphasized within the proposed labeling format. The agency agrees and has amended the subheading to ensure that consumers are adequately advised to contact a doctor if they experience certain signs of toxicity or other reactions.

The agency has also added to the final rule a ''catch-all'' provision in § 201.66(c)(5)(viii) that directs the placement of any other required warning that does not fit within the categories listed in § 201.66(c)(5)(i) through (c)(5)(vii), (c)(5)(ix), and (c)(5)(x), to appear following the warnings described in (c)(5)(vii).

14. Many comments disagreed with the proposal to eliminate the reference to Poison Control Centers in the accidental overdose/ingestion warning in § 330.1(g), which is incorporated by reference in § 201.66(c)(5)(x) of the final rule. The comments cited several factors, including: (1) Medical professionals may lack complete knowledge about treating an accidental overdose of an OTC drug product; (2) advising consumers to ''get medical help right away'' is likely to encourage consumers to proceed immediately to a hospital emergency room when Poison Control Centers can often help treat such exposures at home; and (3) Poison Control Centers in appropriate circumstances can direct consumers to an emergency provider, inform hospital personnel of a patient's imminent arrival, and provide hospital staff with critical information. One comment indicated that Poison Control Centers now serve the entire U.S. population, 24 hours a day, 7 days a week, providing immediate free advice to consumers and health professionals.

The agency agrees that Poison Control Centers are a valuable resource in the event of an accidental overdose or ingestion of an OTC drug product. Accordingly, the agency is retaining, and adding where needed, the reference to Poison Control Centers in revised § 330.1(g), 21 CFR 369.9, 21 CFR 369.20, §§ 369.21, and 201.314(a) and (g)(1).

6. Directions (§ 201.66(c)(6))

Section 201.66(c)(6) requires the heading ''Directions'' followed by the applicable directions for use.

15. One comment suggested that this heading read ''Follow these directions,'' to give consumers a stronger cue. The agency believes that the heading ''Directions'' is an implicit instruction to not only read the directions for use, but also to follow the directions. Accordingly, the agency prefers the more concise heading.

7. Other Information (§ 201.66(c)(7))

Section 201.66(c)(7) requires the heading ''Other information,'' when appropriate, followed by information that does not fall within any of the other categories in § 201.66(c), but which is required by or is made optional under an applicable OTC drug monograph,

other OTC drug regulation, or an approved drug application.

16. One comment asked whether information regarding proper storage of an OTC drug product must appear under this heading. The agency recognizes that there are space constraints for placement of information on OTC drug product labeling. For products that include United States Pharmacopeia (USP) or manufacturer's storage information in their labeling, this information may be placed under the ''Other information'' heading or outside the ''Drug Facts'' labeling. However, if an OTC drug monograph contains storage requirements (e.g., wart remover drug products in 21 CFR 358.150(c)(3) and corn and callus remover drug products in 21 CFR 358.550(c)(3)), then that information must be included in the ''Drug Facts'' labeling under this heading.

17. Several comments suggested that other required information for OTC drug products (such as the identification of certain inactive ingredients and the required tamper-resistant packaging statement) appear below the ''Other information'' heading. The agency is requiring inactive ingredients to be listed in a separate section. However, required information about certain ingredients (e.g., the sodium content) will appear as the first required statement in the ''Other information'' section. The required tamper-resistant labeling statement (now referred to as ''tamper-evident'' labeling (see 63 FR 59463, November 4, 1998) must be prominently placed to alert consumers about the product's tamper-evident features (see (21 CFR 211.132(c)). The agency will continue to allow flexibility as to where this statement appears in labeling and is not requiring that it be included within the ''Drug Facts'' area. However, if the statement is included in the ''Drug Facts'' area, it should be placed under ''Other information.''

18. The agency also received comments asking whether a ''sell copy'' statement or other promotional information, such as a statement of approval of the American Dental Association, may appear under ''Other information.'' Although promotional copy may be important to the sale of a drug product, it is generally not necessary for the safe and effective use of the product. Therefore, this information may not appear under the ''Other information'' heading or within the ''Drug Facts'' area, but may appear elsewhere in the labeling (e.g., PDP or side or end panel) if otherwise permitted by law.

19. FDA regulations require or will require in the future that certain information about specific ingredients be included in the labeling of OTC drug products. Examples include sodium content (21 CFR 201.64), proposed calcium content (§ 201.72 (21 CFR 201.72)), proposed magnesium content (§ 201.71), proposed potassium content (§ 201.72), and phenylalanine/aspartame content (21 CFR 201.21(b)). The agency did not include a separate heading for such dietary information in the proposed rule. However, the agency requested comment on the appropriate placement of this information. Several comments suggested that a separate heading would help ensure appropriate product selection and reduce health risks associated with certain nutrients. Other comments disagreed with the need for such a heading, arguing that this information can be placed in the ''Other information'' section.

The agency has determined that this information can appropriately appear after the heading ''Other information.'' This information is significant for individuals who monitor their intake of certain nutrients, including persons with hypertension and renal insufficiency, and for persons who want to increase their intake of certain nutrients (e.g., calcium). The agency is requiring this important information to be the first statement under ''Other information'' to draw attention to it. The information will appear as follows: ''each (insert appropriate dosage unit) contains:'' [in bold type] (insert name(s) of ingredient(s) and the quantity of each ingredient), (e.g., sodium 50 mg). The phenylalanine/aspartame content, if applicable, should appear as the next item of information. Additional information that is authorized to appear under this heading shall appear as the next item(s) of information. There is no required order for this subsequent information.

8. Inactive Ingredients (§ 201.66(c)(8))

Section 201.66(c)(8) requires the heading ''Inactive ingredients,'' followed by a listing of the inactive ingredients. If the product is an OTC drug product that is not also a cosmetic, then the established name of each inactive ingredient (any ingredient that is not an active ingredient as defined in § 201.66(b)(2)) shall be listed in alphabetical order. If the product is both a drug and a cosmetic, then the inactive ingredients would be listed in accordance with § 701.3 (21 CFR 701.3). However, because § 701.3 includes format requirements that may not be consistent with this final rule, the agency has enumerated the paragraphs within § 701.3 that would apply to the listing of ingredients in OTC drug products that are also cosmetics. Manufacturers may follow § 701.3(a), which generally requires the listing of ingredients in descending order of predominance, or § 701.3(f), which allows ingredients to be grouped in certain categories. The provisions in § 701.3 in paragraphs (e), (g), (h), (l), (m), (n), and (o) and 21 CFR 720.8, may also apply, as appropriate. The names of cosmetic ingredients are to be determined in the manner described in § 701.3(c).

This final rule incorporates the recent amendment to section 502(e) of the act under section 412 of FDAMA. Section 502(e)(iii) of the act, as amended, authorizes the Secretary to require the listing of the established name of each inactive ingredient in alphabetical order on the outside container of the retail package and, if determined to be appropriate by the Secretary, on the immediate container as well, as prescribed in regulations issued by the Secretary. Further, the amendment to section 502(e) of the act provides that if the drug product is also a cosmetic, then the inactive ingredients need not be listed in alphabetical order.

In a guidance document entitled ''National Uniformity for Nonprescription Drugs—Ingredient Listing for OTC Drugs'' (April 1998), the agency stated that it would consider whether to provide an additional opportunity for comment before finalizing provisions implementing new section 502(e)(1)(iii) of the act. Because the final rule essentially codifies the provisions of the statute, and because the final rule requires the listing of inactive ingredients in the same location as that described in the proposal, an additional opportunity to comment is not needed at this time. However, the agency recognizes the possibility that more detailed regulations or guidance on the listing of inactive ingredients may prove necessary. The agency also intends to consider whether to consolidate, to the extent permitted under the act, the requirements for listing inactive ingredients in OTC drug products with the requirements for OTC drug products that are also marketed as cosmetics. Either or both of those initiatives, if they resulted in rulemaking, would provide further opportunities for public comment.

Finally, the agency is not requiring at this time the listing of inactive ingredients on immediate containers when the product is marketed with an outside retail package that includes the required list of inactive ingredients.

9. Questions or Comments? (§ 201.66(c)(9))

Section 201.66(c)(9) identifies where manufacturers may include a telephone number for consumers. The telephone number would appear after the header ''Questions?'' (or ''Questions or comments''), is in a minimum 6-point bold type (but preferably larger), and does not need to be a toll-free number. It is recommended that the days of the week and the times when someone is available to respond to questions also be included. A graphic of a telephone or telephone receiver may appear before the heading.

20. Several comments urged the agency to allot space for the manufacturer's toll-free telephone number in bold Helvetica type. At least one comment also requested the agency to require a telephone number in clear braille over-print, to assist those with impaired eyesight in obtaining usable labeling.

Many OTC drug products already include a section entitled ''Questions or Comments?'' and provide a telephone number. The agency considers this information very beneficial because it provides a place to report concerns after product use and a source to contact when the product is not purchased in a pharmacy. A telephone number also provides a contact for the elderly or visually impaired who may not be able to read the product's labeling, and for individuals who do not use English as a primary language.

The agency has allotted space for a telephone number within the ''Drug Facts'' area. While this labeling is not required, the agency strongly encourages all manufacturers, distributors, and packers to include a telephone number. The agency also encourages the use of a point size greater than 6 to display the information, to help those unable to read 6-point type. Further, the telephone number, if shown, must appear in bold type. As requested by the comments, a Helvetica type style may be used. The agency recommends that the days of the week and the time of the day when a person is available to respond to questions (e.g., Monday to Friday, 9 a.m. to 5 p.m.) also be included. Braille labeling is discussed in comment 43 of this document.

D. Format Requirements (§ 201.66(d))

Section 201.66(d) prescribes the required format for presenting the title, headings, subheadings, and information set forth in § 201.66(c)(1) through (c)(9).

Although the comments on balance strongly support the conclusion that a standardized presentation of information will benefit consumers and health professionals, several comments raised concerns regarding specific features of the format. These concerns included the need to: (1) Further improve readability; (2) maintain internal consistency with respect to periods, spacing, and other type setting features; (3) increase usable labeling space without decreasing readability; (4) provide flexibility to accommodate required information on small packages; and (5) minimize the potential for consumer confusion.

1. Alignment and Punctuation of Headings (§ 201.66(d)(1))

Section 201.66(d)(1) requires that the first letter of each word of the title in § 201.66(c)(1) appear in uppercase. Section 201.66(d)(1) also requires that only the first letter of the first word of each heading and subheading set forth in paragraphs (c)(2) through (c)(9) appear in upper case, and that the title, headings, and subheadings set forth in paragraphs (c)(1), (c)(2), and (c)(4) through (c)(9) must be left justified.

21. Several comments recommended the use of upper case letters only for the first letter of the first word in each heading and subheading to be consistent with conventional rules of graphics and labeling design. The agency agrees that limiting the use of upper case letters to the first word in the phrases in § 201.66(c)(2) through (c)(9) will enhance readability. The agency has incorporated this recommendation into the final rule. The length of the title, however, is sufficiently short to allow the first letter of both words to appear in uppercase without compromising readability. However, when the title appears on additional panels, the term ''(continued)'' will appear in lowercase letters.

22. Several comments recommended that all headings be left justified, rather than centered, to enhance readability. The comments contended that information that is centered may be missed or overlooked, particularly when most of the information presented is left justified. In general, the agency agrees. However, to preserve the association of each active ingredient with its purpose, the agency has retained in the final rule the requirement that the heading ''Active ingredients'' appear immediately adjacent and to the left of the heading ''Purpose(s)'' (§ 201.66(d)(6)).

2. Type Size (§ 201.66(d)(2))

Section 201.66(d)(2) requires that the letter height or type size for the title ''Drug Facts'' must appear in a type size greater than the largest type size used within the ''Drug Facts'' area. The type size for the title ''Drug Facts (continued)'' must appear in no smaller than 8-point type. The headings in paragraphs (c)(2) through (c)(9) must appear in 8-point or greater type, or in a type size that is at least 2-point sizes greater than the text, whichever type size is larger. Thus, if the required information is presented in 7-point type, the headings must appear in at least 9-point type. This will ensure that the headings, which serve as important visual cues, stand out from the balance of the text, while preserving flexibility for manufacturers to use larger type sizes to enhance readability. The subheadings and all of the information described in § 201.66(c)(2) through (c)(9) must appear in at least 6-point type.

23. Many comments, particularly from consumers, urged the agency to adopt the 6-point minimum type size for all required OTC labeling, except for the manufacturer's name and address. Some comments argued that anything less than 6-point type is not readable, especially for elderly consumers. Other comments contended that a 6-point minimum should be required because, if industry is allowed to use anything less than 6-point, smaller type size will become the standard. A study (Ref. 7) was submitted demonstrating that many OTC drug products did not conform with the Nonprescription Drug Manufacturers Association (NDMA) Readability Guidelines (Ref. 10) recommended for use by the industry for OTC drug products.

Manufacturers and several trade associations argued that the 6-point minimum should be optional, to allow flexibility in fitting all of the required information into the proposed format. Manufacturers urged that a 6- point type be used where feasible, but that smaller types (down to 4.5 point) be permitted when necessary. At least one comment claimed that if 6-point type is required, the OTC labeling information would not fit on nearly 33 percent of the branded products and 95 percent of generic products. Data were not submitted to support these figures. The comments also noted that the agency has allowed 4.5-point type for dietary supplements in certain situations.

Upon careful review of the comments and supportive studies and the rationale set forth in the proposed rule (see 62 FR 9024 at 9027), the agency has determined that the type size for required OTC drug product labeling information must be no smaller than 6-point, under the conditions set forth in this final rule, including format

exceptions for small packages as defined in this final rule.

The proposed rule summarized literature studies that demonstrated how important type size is in evaluating readability, as well as the difficulty consumers have in reading OTC drug product labeling because of small type (see 62 FR 9024 at 9027 to 9029). For example, a survey of consumers' ability to read OTC drug product labeling printed with the minimum type sizes recommended by NDMA's Readability Guidelines demonstrated that a significant portion of the adult population over 20 years of age is not able to read OTC drug product labeling with 4.5-point minimum type size. Further, only 48 percent of the public who currently purchase OTC drug products are able to read labels with the 4.5-point minimum type size. People over 51 years of age have the most trouble reading labels with 4.5-point type size, with only 32 percent able to read them, and only 63 percent of people under age 51 were able to read the existing (or tested) labels (62 FR 9024 at 9029).

Another study evaluated the ability of persons over 60 years of age to read OTC drug product labeling (Ref. 11). The study found a significant portion of this population cannot adequately read the print on certain existing OTC drug products due to small type size (vertical height) and horizontal letter compression (type style). The study concluded that to maximally enhance readability for this target population, OTC drug information should be presented in a minimum vertical type size of 6.7-point and a letter compression of no more than 39 characters per inch. Recognizing the space constraints in existing labeling, the agency chose to require a minimum type size of 6-point and type styles which ensure letter compression of no more than 39 characters per inch.

Finally, the agency acknowledges that it has allowed 4.5-minimum type size under certain conditions in dietary supplement labeling for small packages (see § 101.36(i)(2) (21 CFR 101.36(i)(2)). In these instances, however, much of the required labeling consists of numerical information regarding the content of the product. With limited exception, this information may be presented in a well-defined tabular format with ample white space to enhance readability. OTC drug product labeling, on the other hand, consists largely of running text, including descriptive information essential to the safe and effective use of the product. This information often occupies one or more full panels of the product's packaging. It also tends to vary considerably from product to product, and is no less important on small packages than it is on larger packages. As a result, OTC drug product labeling places particularly significant demands on the reader. The agency therefore believes that while 4.5 point type may be appropriate in exceptional cases for nutritional information on a dietary supplement product, it is not an appropriate minimum type size for OTC drug products.

The agency recognizes the delicate balance between: (1) The need for the required information to fit within customary labeling and packaging constraints, and (2) the need to ensure that the required information is prominent and readable under customary conditions of purchase and use. The agency believes it has selected type sizes and styles that are consistent with the need for readable OTC drug product labeling by a majority of OTC drug consumers, while at the same time taking into account the manner in which OTC products are marketed and the economic impact posed by setting these minimum requirements (see section VIII of this document).

24. Some comments suggested a sliding scale for type size based on package size, similar to the requirements for dietary supplements and food labeling (§§ 101.9(j)(13) and 101.36(i)(2)). The agency generally supports the approach of requiring larger type sizes and more generous formatting for products marketed in progressively larger packages. There is, however, less of need to develop such an approach for OTC drug products than for food products because the range of package sizes for OTC drug products is much smaller than the range for food packages. Therefore, the agency has focused in this rulemaking on developing minimum requirements suitable for typical OTC drug products. Nevertheless, the agency encourages drug manufacturers to enlarge point size wherever the package may accommodate larger labeling text. To that end, the agency has specified in § 201.66(d)(2) the relative increase in point size for the title and headings when a larger type size is used for the required text.

3. Font, Leading, Kerning, Contrast, and Highlighting (§ 201.66(d)(3))

Section 201.66(d)(3) contains font, leading, kerning, contrast, and highlighting requirements. The agency has determined that at least 0.5-point leading (i.e., the space between two lines of text) is needed to ensure readability. While the proposal would have limited type style to Helvetica, the final rule will allow any single, clear, easy-to-read, type style. The agency notes that san serif type styles have been adopted by at least one trade association as the industry standard. The agency believes that san serif types styles are the most likely to be considered clear and easy-to-read. The agency also is requiring the title ''Drug Facts'' and the ''Drug Facts'' part of the ''Drug Facts (continued)'' title to appear in bold italic print to draw even more attention to the required information panel and, thereby, contribute to the goal of ensuring that consumers are appropriately signaled to read and use the information which follows. The agency is requiring the type to be all black or one dark color, printed on a white or other light, neutral color, contrasting background.

25. Several comments requested that the agency allow the use of any sans serif type style in OTC drug product labeling.

The agency is allowing any single, clear, easy-to-read, type style. Because font styles vary in their stroke weight characteristics (i.e., the thickness of the character of each letter is variable). Helvetica and Univers font styles in particular have consistent and uniform stroke weight characteristics and are both commonly available. The agency therefore recommends the use of either one of these font styles.

26. Several comments requested that only the format layout should be required and not the graphical features (i.e., type size, leading, kerning, and highlighting). If graphical features are required, the comments requested reduced type size and leading.

Based on the discussion in the proposed rule (62 FR 9024 at 9036), the agency has determined that both format layout and graphical features are necessary to ensure that labeling information is conveyed in a manner that enables the consumer to readily notice and comprehend such information. The agency has revised the leading requirement from the proposed 1-point leading to 0.5-point leading in this final rule.

4. Bullets (§ 201.66(d)(4))

Section 201.66(d)(4) specifies the style and format for using bullet points to introduce and highlight statements of information. The bullet style is limited to solid squares or solid circles of 5-point type size and must be presented in the same shape and color throughout the labeling. The use of a solid circle or square will avoid selection of an icon that may have an independent meaning, such as an octagon (stop) or inverted

triangle (caution). This format provides a valuable visual cue for introducing each required ''chunk'' of information, without unnecessarily distracting or confusing the reader. The bullets and bulleted statements under each heading or subheading must be vertically aligned, to ensure visual separation and adequate white space between discrete information chunks. This section also establishes standards for presenting more than one bulleted statement in the same horizontal line of text and for the vertical alignment of such additional bulleted statements.

27. To increase usable labeling space, several comments requested that the agency allow more than one bulleted labeling statement per line and not require that bulleted phrases be separated by at least two square ''ems'' (two squares of the size of the letter ''M''). The agency agrees that allowing more than one bulleted statement per line is an effective way to optimize labeling space. The agency has incorporated this into the final rule. However, if more than one bulleted statement appears on the same horizontal line, each statement must be separated by at least two square ems.

5. Multiple Panels (§ 201.66(d)(5))

The proposed rule would have required that all of the information presented under the ''Warnings'' heading appear in one continuous space, on one panel. As described in the following paragraphs, § 201.66(d)(5) of the final rule provides increased flexibility with respect to the presentation of the required labeling information on more than one panel of the retail package.

28. Several comments requested that the agency allow the warnings section to appear on more than one panel if: (1) Text or a visual graphic such as an arrow leads the consumer to the continuation onto the next adjacent panel, (2) the adjacent panel has an appropriate heading, and (3) there is no intervening copy or symbols. One comment noted that the Universal Product Code (UPC) symbol should not be allowed to interrupt the flow of information in the required OTC drug product labeling.

The agency agrees with these comments. Section 201.66(d)(5) of this final rule provides that the headings, subheadings, and information required under § 201.66(c), including the warnings section, may appear on more than one panel. However, appropriate visual cues must be provided, so that the flow of information is retained. The title ''Drug Facts (continued)'' must appear on each subsequent panel with a graphic such as an arrow, directing the consumer to the continuation of the information on the next panel. The continuation of the required content and format onto multiple panels must retain the required order and flow of headings, subheadings, and information. The UPC symbol may appear on the same panel as some of the information, but must be outside the box or enclosed. Section 201.66(d)(7) provides that graphical images, such as the UPC symbol, and information not set forth in paragraphs (c)(1) through (c)(9) and (d)(1) through (d)(10), may not appear in or otherwise interrupt the content and format required by these parts of the final regulation.

6. Active Ingredient, Purpose, and Warning Headings (§ 201.66(d)(6))

Section 201.66(d)(6) establishes the required format for listing the established name, the quantity or proportion, and the ''purpose'' of each active ingredient. This section also provides that no other text is permitted to appear on the same line as the ''Warning'' or ''Warnings'' heading.

29. Several comments recommended that the agency allow products containing more than one active ingredient with the same purpose to list the purpose only once, adjacent to the listing of the last active ingredient. The agency agrees. However, the presentation must allow the reader to readily associate each active ingredient with its purpose. The agency has incorporated this recommendation into the final rule.

7. Graphical Images and Interruptions (§ 201.66(d)(7))

Section 201.66(d)(7) requires that graphical images, such as the UPC symbol, and any information that is not set forth under § 201.66(c), must not interrupt the required information panel or panels. The UPC symbol may appear on the same panel as required information but must be outside the box or enclosure.

8. Required Lines (§ 201.66(d)(8))

Section 201.66(d)(8) sets forth the placement and style of lines that define the title, headings, subheadings, and information described in § 201.66(c)(1) through (c)(9). The proposed rule requires a horizontal line to separate the information under each major heading (62 FR 9024 at 9036 and 9051). In this final rule, the agency is including more specific requirements for the use of these hairlines and is requiring a barline to set off the ''Drug Facts'' labeling from other information that appears in the labeling.

Under § 201.66(d)(8), a barline must be used to form a box or similar enclosure around the information described in § 201.66(c). Example 7 of the sample labeling in the proposed rule (62 FR 9024 at 9060) depicted the required information surrounded by a hairline forming a box. Also under § 201.66(d)(8), a horizontal hairline extending within two spaces on either side of the ''Drug Facts'' box or similar enclosure must immediately follow the title set forth in § 201.66(c)(1). A distinctive horizontal barline extending to each end of the ''Drug Facts'' box or similar enclosure must provide separation between each of the headings listed in § 201.66(c)(2) through (c)(9). And, a horizontal hairline extending within two spaces on either side of the ''Drug Facts'' box or similar enclosure must immediately precede the subheadings set forth in § 201.66(c)(5), except the subheadings in § 201.66(c)(5)(ii)(A) through (c)(5)(ii)(G).

The placement and style of barlines and hairlines set forth in § 201.66(d)(8) will highlight the information, making it more prominent and easier to read and process. Section 330.1(c)(2) previously provided for the use of a boxed area, in conjunction with titles such as ''FDA Approved Uses'' and ''FDA Approved Information,'' to set off this information from other OTC labeling information. The agency has used the box technique to highlight information in several other notable instances (see, e.g., § 101.9(d)(1)(i)).

9. Directions (§ 201.66(d)(9))

Section 201.66(d)(9) adds the requirement that dosage directions, when provided for three or more age groups or populations, must be presented in a table format. The agency displayed this labeling technique in example 2, 7, and 9 of the proposed rule (62 FR 9024 at 9055, 9060, and 9062 and in the sample cough-cold product used in Study B.

30. Several comments requested that the agency allow flexibility in the arrangement of information under ''Direction(s)'' and not mandate a table format. One comment added that other formats, e.g., running text, can adequately convey the information while maximizing text in a minimal amount of space.

Study A confirmed that consumers are less likely to make a dosing error when dosing information for multiple populations is separated within an easy-to-read table as compared to such information appearing in a paragraph format. Tables are now widely used in the labeling of many OTC drug products, including those marketed

under NDA's and ANDA's. The agency therefore has incorporated into this final rule a requirement that a table be used when dosing information is complex, as when separate dosing instructions are presented for three or more age groups. A text format may be used when there are less than three dosage directions.

10. Small Packages (§ 201.66(d)(10))

Section 201.66(d)(10) establishes a modified labeling format for packages that cannot meet the format requirements of paragraphs (d)(1) through (d)(9).

31. Several comments urged the agency to adopt a broad, blanket small package exemption from the proposed content and format requirements. The comments described small packages as those products that are marketed in unit doses, convenience sizes, samples, minimal net content packages, analgesic products with less than 6 square inches of usable labeling space, uniquely shaped containers (e.g., envelope packaging, which has a front and back panel only), tubes, roll packs commonly used for antacids, some ophthalmic products, a number of drug-cosmetic products, and bottles without an outer carton.

Many comments suggested graphical flexibility to accommodate products marketed in small packages, such as: (1) Use of more than one panel, (2) use of sans serif fonts or more than one font, (3) reduced type size (to 4.5-point), (4) reduced or no leading, (5) interlined spacing such that one line's ascenders do not touch the preceding line's descenders, (6) eliminate hairlines and required bullet spacing, and (7) consolidate warning information. One comment suggested that graduated type size requirements could be adopted depending on the available label space and cited the dietary supplement labeling provisions in § 101.36(c)(6) (amended and recodified at § 101.36(i), effective March 23, 1999 (62 FR 49826, September 23, 1997)). Another comment pointed out that the dietary supplement labeling provisions allow a minimum 4.5-point type size.

Some comments contended that relying on a subjective standard to support an exemption would be inefficient. These comments recommended that a small package be defined as any outer package: (1) Where the total surface area available to bear labeling is less than 12 square inches (including the PDP); or (2) where more than 60 percent of the total surface area available for labeling on the back and side panels must be used to satisfy the ''content requirements'' in proposed § 201.66(c); or (3) that is a trial size package, packet, or single use unit. Some comments proposed that any drug or drug-cosmetic product that meets this definition be exempt from the new format and content requirements, but should still bear all required labeling. Some comments stated that a performance standard, as described in the proposed rule (62 FR 9024 at 9036), has not been established or validated and would be impractical to use for small packages at this time.

The agency agrees that some manufacturers may have difficulty providing important drug information, which is prominent and easy to read, on packages that are irregular (i.e., bottle labels) or small (i.e., unit does). However, the agency also considers the required OTC drug labeling information essential for the safe and effective use of OTC drug products, irrespective of the size or the shape of the package.

Because readability is especially dependent on vertical letter height and letter compression, the agency disagrees that less than 6-point type or letter compression allowing more than 39 characters per inch should be permitted (Ref. 11), even on ''small packages.'' As discussed in response to comment 23 in section IV.D of this document, the agency considers 6.0 type the minimum allowable for OTC drug product labeling.

The agency, however, is including in § 201.66(d)(10) of this final rule several modifications that may be used with packages that are too small to meet the format requirements of paragraphs (d)(1) through (d)(9). Under § 201.66(d)(10), headings may be presented in a minimum 7-point or greater type size. The leading may be adjusted so that the ascenders and descenders of the letters do not touch, rather than the 0.5-point leading required under § 201.66(d)(3). Also, bulleted statements may continue to the next line of text and need not be vertically aligned. Finally, the box or similar enclosure required in § 201.66(d)(8) may be omitted if the headings, subheadings, and information in § 201.66(c)(1) through (c)(9) are set off from the rest of the label by color contrast.

As suggested by the comments, a product will be considered ''small,'' and will be permitted to apply these modifications, if more than 60 percent of the total surface area available to bear labeling on the entire outside container or wrapper, or the immediate container label if there is no outside container or wrapper, would be needed to present FDA required labeling. This consists of the labeling required by § 201.66(c)(1) through (c)(9), in accordance with the minimum specifications in § 201.66(d)(1) through (d)(9) and any other FDA required information for drug products and, as appropriate, cosmetic products, other than information required to appear on a principle display panel. This formula is consistent with the idea that 40 percent of available labeling space is generally reserved for the UPC symbol and PDP (see, e.g., 21 CFR 101.1 and § 201.60 (21 CFR 201.60)).

In determining whether more than 60 percent of the available surface area is needed, the indications listed under the ''Use(s)'' heading must be limited to the minimum required uses allowed under the applicable monograph. Also, for purposes of this rule, the ''total surface area available to bear labeling'' does not include the flanges at the tops and bottoms of cans and the shoulders and necks of bottles and jars. All other surface areas are considered to be ''available to bear labeling.''

32. Several comments stated that the format under the proposed rule would require manufacturers to increase the package or container size of a significant number of OTC drug products. NDMA, for example, reported that a survey of its members showed 33 percent of branded products and 95 percent of private label products could not comply with the proposed format without making some change in package or container size. Some comments also opposed the mandatory use of alternative packaging designs, such as extending a single side panel of a package to increase labeling space, as had been suggested by the agency in the proposed rule (62 FR 9024 at 9036). According to these comments, the cost of adding such packaging features, and the additional environmental waste associated with increasing package size or configuration, outweighs the need to set a minimum 6.0 type size and other minimum format requirements. Several comments made general reference to state ''slack fill'' laws, which prohibit the use of oversized containers to mislead consumers.

Other comments, however, encouraged the use of alternative packaging to ensure that important information is presented in a readable type size with user-friendly visual cues. They emphasized that consumers need the information, and need to be able to read and understand the information, for proper self-selection and self-medication, and that these concerns support the required use of alternative packaging to increase available labeling space.

As discussed in section VIII of this document, the comments that oppose the required use of alternative packaging

design greatly overestimated the number of products that would not be able to accommodate the proposed format within the confines of current packaging. In addition, the modified format authorized under § 201.66(d)(10) of the final rule is expected to enable many small package products to comply without increasing container or package size.

For those remaining products that are unable to accommodate the modified, small package format, a number of design techniques are available to increase labeling space. As suggested in the proposed rule, labeling space can be increased by, for example, extending a single side panel or widening the label affixed to a bottled drug product (62 FR 9024 at 9036). In a survey described in section VIII of this document, the agency found that many products are now marketed with extended panels, peel back or fold out labels, or are otherwise mounted on cardboard cards or placards. These alternative packaging techniques often increase labeling space for promoting the sale of the product and could also be used to accommodate FDA required information. The agency likewise expects that any packaging changes needed to conform to this rule will be sufficiently minimal, and can be done in a manner, as to not render the product misleading under a ''slack fill'' law or similar provision (see, e.g., section 502(i)(1) of the act).

Thus, products that are unable to meet the labeling format described in § 201.66(d)(1) through (d)(9), or the modified format authorized under § 201.66(d)(10), will be expected to be reconfigured to meet the format requirements of this rule. The agency will not routinely grant exemptions or deferrals under § 201.66(e) for products that claim to be too small to meet the requirements of this rule.

Finally, the agency is not requiring manufacturers to increase the size of immediate containers (for those products that are marketed with outside retail packages) in order for the required format to be applied to the immediate container (see 62 FR 9024 at 9037). As stated in response to comment 3 in section IV.C of this document, for products that are sold with an outer package, the agency is encouraging, but not requiring, the use of the modified, small package format in § 201.66(d)(10) on the immediate container.

E. Exemptions and Deferrals (§ 201.66(e))

Proposed § 201.66(e) provided that the required labeling information must be the first information that appears on the back or side panel of the outside container or wrapper of the retail package (or the immediate container label if there is no outside container or wrapper) of all marketed OTC drug products. As explained in the following paragraphs, the agency has eliminated this requirement to give manufacturers more flexibility. In addition, the agency has codified proposed § 201.66(f), Exemptions and deferrals, as § 201.66(e) and has made several changes to make the exemption process less burdensome on manufacturers and on the agency.

33. Several comments recommended that the agency allow the inclusion of a brand name and product attributes anywhere on the information panel as long as they do not interrupt the flow of the required information and as long as the labeling is in compliance with the type size requirements. Several comments requested that the product brand name be the first text allowed on the information panel and that the equivalent of three lines of type be allocated at the top of the panel for a brand name and product attributes such as: (1) Information about dosage form, flavor, the absence of certain ingredients, directions for opening the package, and reference to the importance and benefits of proper use; (2) references to alternative products that are available; and (3) information from organizations endorsing the product. Other comments raised concerns about whether adequate space would be allowed for guarantee statements, signage, and sell copy. Another comment suggested that the space for a brand name and product attributes should be equivalent to the greater of either: (1) Three lines of the minimum size copy across the width of the information panel; or (2) 10 percent of the main information panel, at the option of the manufacturer. The comments maintained that this information is important to consumers for comparative purposes and for identification of products with desired features.

The agency has determined that the required OTC drug product labeling information need not appear as the first information on the back or side panel, provided there is adequate space on the outside container or wrapper for the labeling to conform with § 201.66(c)(1) through (c)(9) and § 201.66(d)(1) through (d)(10). Accordingly, the agency is not including proposed § 201.66(e) in this final monograph. Thus, a brand name and product attributes may appear anywhere on the labeling outside of the boxed area.

34. A number of comments suggested that FDA establish an exemption process other than a citizen petition. The comments contended that the petition process is too slow and burdensome for both industry and the agency, and would cause marketing delays. Some comments suggested a simple notification process when a company is unable to comply with the final rule. The company would notify the agency, a certain time would be allowed for the agency to respond with any objections, and, if no objections were provided, marketing could then proceed.

Section 201.66(e) in this final rule provides that FDA, on its own initiative, or in response to a written request from any manufacturer, packer, or distributor, may exempt or defer, based on the particular circumstances presented, one or more specific requirements set forth in § 201.66(a) through (d), on the basis that the requirement is inapplicable, impracticable, or would be contrary to public health or safety.

The agency agrees that the exemption process need not require a citizen petition. However, the process should be a matter of public record and requests for exemptions must be granted by the agency prior to marketing. Requests for exemptions must be submitted in three copies in the form of an ''Application for Exemption'' to the agency. The requests shall be clearly identified on the envelope as a ''Request for Exemption from 21 CFR 201.66 (OTC Labeling Format)'' and with Docket No. 98N–0337. A separate request must be submitted for each OTC drug product. In addition to the three copies of the exemption request submitted to the agency, manufacturers of a product marketed under an approved drug application must also submit a single copy of the exemption request to their application. Decisions on exemptions and deferrals will be maintained in a permanent file in this docket for public review.

The request for exemption or deferral must: (1) Document why a particular requirement is inapplicable, impracticable, or would be contrary to public health or safety, and (2) include a representation of the proposed label and labeling, including outserts, panel extensions, or other graphical or packaging intended to be used with the product.

35. In the proposed rule, the agency asked for comment on whether there are particular types of products or packages that should be granted a regulatory exemption (62 FR 9024 at 9038). At least one comment, from a trade association, requested that ''drug-cosmetic products,'' and particularly those that do not have a dosage limitation (e.g., antidandruff shampoos, anticaries

toothpastes, antiperspirants, and sunscreens), be exempted from the new labeling requirements. The comment argued that these products do not raise serious adverse event concerns, are not used to treat serious health problems, do not raise serious misuse concerns, do not have the potential for significant new therapeutic uses in the future, and are limited in the space available for other information concerning product attribute labeling. Several comments contended that some drug-cosmetic products are used primarily for their cosmetic effects, and one comment argued that most of the required information on these products consists of ''common-sense'' statements and, therefore, do not need to be subject to this rule.

One comment also argued that drug-cosmetic products must include more mandatory labeling information than other OTC drug products, leaving even less space on drug-cosmetic products for the required format. In particular, the comment stated that drug-cosmetic products, unlike other products, must include a full list of all ingredients (see § 701.3). According to the comment, the proposed format would force this information to be listed on more than one panel, making it difficult for consumers (particularly those who may be allergic to certain ingredients) to find important ingredient information. This comment, however, has largely been superseded by the recent amendment to section 502(e) of the act, which authorizes the agency to require that all OTC drug products bear a full list of ingredients. The final format includes a prominent location for the listing of this information on all OTC drug products, including those that may also be intended for cosmetic uses.

The agency also received comments questioning whether the factual record supports the need to standardize the labeling format for drug-cosmetic products, especially those without a specified dosage limitation. One comment noted that the agency failed to include drug-cosmetic products in its consumer research studies, and that the agency lacks a factual basis for applying this rule to these products.

Finally, several comments provided additional reasons why sunscreens, in particular, should be exempted: (1) The names of sunscreen active ingredients have little meaning to consumers; and (2) the prominent display of words such as ''Active ingredients,'' ''Uses,'' and ''Warnings'' may discourage the use of traditional cosmetic products containing a sunscreen or cause manufacturers to leave out the sunscreen ingredient.

The agency disagrees and finds no basis for including a broad exemption because a product is marketed both as a drug and a cosmetic, because a product does not require a precise dosage limitation, or because the labeling of the product includes ''common-sense'' statements. When therapeutic claims are made for a product, the drug provisions of the act apply to ensure the safety and effectiveness of the drug ingredients, whether or not these products may also be used for other purposes (see sections 201(g)(1) and (p) (21 U.S.C. 321(g)(1) and (p)), 502, and 505 of the act). The agency also does not agree that it lacks a sufficient factual basis for requiring the new format and content requirements on all OTC drug products.

The agency does not believe that consumers should be denied the benefits of the new labeling requirements simply because a product may have both drug and cosmetic attributes. Moreover, under the approach suggested by the comment, a manufacturer who markets a standard sunscreen product for sunscreen (i.e., ''drug'') uses and for moisturizing (i.e., ''cosmetic'') uses, would not be required to follow the new labeling requirements, while a manufacturer whose product is marketed solely as a sunscreen would be required to follow those requirements. Both products, nevertheless, are regarded as drug products and share the intended use of sunburn prevention. The agency is concerned that consumers may be unneccessarily confused if the rule would allow these products to bear markedly different labeling.

The agency also disagrees with the comment that products without dosage limitations do not raise safety issues and, therefore, the agency lacks a rational basis for applying the new labeling requirements to such products. While the agency takes steps to ensure that all OTC drug products are safe for their intended uses, adverse reactions do occur in the categories of products for which a blanket exemption has been requested. For example, certain sunscreen ingredients have the potential to cause photo allergenicity; certain antidandruff ingredients may promote sunburn or cause even more serious events if used for prolonged applications; and fluoride-containing preparations may contribute to fluorosis or may cause acute symptoms in overdose ingestions. Thus, even products that do not require discrete dosage limitations contain ingredients that raise safety risks which the labeling must convey to the consumer.

The agency also disagrees with the suggestion that the required labeling in such products consists of nothing more than ''general common-sense limitations'' such as ''if condition persists, consult a health professional'' or ''if a rash develops, stop use.'' For example, a number of acne medications (which are marketed for both drug and cosmetic uses) contain important warnings for persons who are sensitive to or have a known allergy to salicylic acid. Dandruff products that contain coal tar likewise must bear important drug-drug and sunburn warnings (see 21 CFR 358.750). In any case, the agency does not accept the argument that ''common-sense'' precautions need not be prominent and readable. However, the agency will continue to consider whether required labeling for these products can be simplified and condensed even more.

The agency has an ample factual record, discussed elsewhere in this document and in the proposed rule, to support the conclusion that current labeling conventions are inadequate. The act requires readable and understandable labeling, irrespective of a specific showing of harm. The agency endeavors to require the least amount of information possible to assure proper self-selection and use. Nevertheless, the information the agency does require under the act must be prominently and conspicuously displayed (section 502(c) of the act) and must be readable and understandable to ensure that all material facts are provided to consumers (sections 201(n) and 502(a) of the act). Moreover, improved labeling is needed not only to address potential safety issues, but also to ensure selection of the most appropriate product and use of that product in an effective manner.

With respect to whether sunscreen ingredient names have little meaning to consumers, the same argument can currently be made for many OTC drug active ingredients. The new format requires prominent listing of the active ingredients for all products, together with the purpose of each active ingredient. The agency believes that this element of the new format will improve consumer understanding of the names and purposes of active drug ingredients, including those typically used in sunscreens. This will assist the consumer and pharmacist in identifying changes in formulation (and purpose) of many combination OTC drug products so that medication errors can be avoided and consumers can appropriately self-select an OTC drug product for their condition(s).

The agency also emphasizes that with drug-cosmetic products, self-selection is

very important because consumers often must choose between a cosmetic or a drug-cosmetic product. A consumer who has dandruff should select an antidandruff-conditioner shampoo rather than a conditioner shampoo; a consumer who wishes to prevent sunburn should select a sunscreen-moisturizer rather than a moisturizer; a consumer who perspires heavily should select an antiperspirant-deodorant rather than a deodorant; a consumer who needs to prevent caries should select a fluoride toothpaste rather than a nonfluoride toothpaste. This final rule provides a format for presenting information that will allow consumers to readily distinguish among seemingly similar products and to readily access important drug information.

The agency agrees that there may be limited instances in which a labeling requirement may discourage manufacturers from marketing certain products for a drug use (e.g., lipsticks containing sunscreens or lip balms containing skin protectant ingredients). These products, when they contain an ingredient intended to provide a therapeutic effect, do provide significant public health benefits to consumers.

When developing drug labeling, the agency considers the risks and benefits of the drug, the intended use, and the need to communicate limitations or restrictions about the use of the product to the target population. The quantity and complexity of information which must be communicated to ensure appropriate product selection, convey the effectiveness of the drug, communicate risks, and provide complete directions for use, varies with the drug ingredient, the target population, the disease or symptoms the product is intended to treat or prevent, and related information about the conditions which must be provided for the safe and effective use of the drug.

In some cases (e.g., lipsticks or lip balms containing sunscreen), minimal information is needed for the safe and effective use of the product. Such products may typically be packaged in small amounts, have a high therapeutic index, carry extremely low risk in actual consumer use situations, provide a favorable public health benefit, require no specified dosage limitation, and require few specific warnings and no general warnings (e.g., pregnancy or overdose warnings). The agency will identify products with these characteristics and will consider appropriate exemptions in their respective monographs and drug marketing applications to the extent possible. In addition, under new § 201.66(e), FDA, on its own initiative, or in response to a written request from any manufacturer, packer, or distributer, may exempt or defer one or more specific requirements set forth in § 201.66 (a) through (d).

36. One comment noted that OTC drug product labeling varies among different countries, particularly for products that are considered drug-cosmetics in the United States but are regulated as cosmetics in other countries. The comment contended that these variations make it difficult to label products intended to be sold in more than one country. The comment pointed out that FDA is increasingly focused on international harmonization as a matter of policy. However, requiring products to meet the new OTC labeling content and format requirements represents a barrier to trade and harmonization. Another comment requested that FDA exempt OTC drug products intended for export from the new labeling requirements.

The agency disagrees with these comments. As discussed, sound public policy and the dictates of the act require that drug-cosmetic products present readable, understandable, prominent, and conspicuous drug labeling. With respect to export issues, section 802 of the act (21 U.S.C. 382) sets forth those instances in which exported drug products are not required to be labeled in accordance with the requirements for domestic marketing. The agency notes that an OTC drug product exported in accordance with section 802 of the act would not be required to meet labeling requirements for domestic marketing (such as the requirements imposed by this rule), except to the extent that the import country itself has adopted U.S. requirements (see section 802(b)(1) and (f) of the act).

F. Interchangeable and Connecting Terms (§§ 201.66(f) and 330.1(i) and (j))

Section 201.66(f) permits specific terms codified in § 330.1(i) (''interchangeable terms'') to be used interchangeably in the labeling of OTC drug products, provided such use does not alter the meaning of labeling established in an applicable OTC drug monograph or regulation. Section 201.66(f) also permits the terms listed in § 330.1(j) (''connecting terms'') to be deleted from the labeling of OTC drug products, provided again that such deletion does not alter the meaning of established labeling. However, the title, headings, and subheadings listed in § 201.66(c)(1) through (c)(9) cannot be changed through the use of interchangeable or connecting terms.

Proposed § 330.1(i) has been modified in the final rule to include 43 additional interchangeable terms. In addition, two of the proposed terms were combined and seven others were modified slightly in this final rule. (See § 330.1(i)(12), (i)(16), (i)(48), (i)(49), (i)(52), (i)(54), (i)(68), (i)(69), and (i)(72).)

Although the agency specifically sought recommendations on additional connecting terms that should be added to the list (62 FR 9024 at 9039), no terms were submitted. Proposed § 330.1(k) has been redesignated as § 330.1(j) in this final rule and modified to include seven additional connecting terms based on further analysis of OTC drug monograph labeling. The agency recognizes that there may be other connecting terms that can be deleted and that will help required statements and clauses fit into the new format. The agency encourages manufacturers, packers, and distributors to submit these terms to the agency as soon as possible so this list can be further amended before the implementation dates for this final rule.

37. One comment requested that an interchangeable term be added to accommodate products intended for use only in children under 12 years of age, because the information should be directed to the child's guardian or care giver.

The agency agrees that for products intended for use only in children under 12 years of age the information should be directed to a care giver, rather than to the child. Accordingly, for such products, the term ''the child'' may be interchanged with ''you'' or the term ''the child's'' may be interchanged with ''your.''

G. Liable to Regulatory Action (§ 201.66(g))

Section 201.66(g) states that an OTC drug product that is not in compliance with the format and content requirements is subject to regulatory action. The wording in § 201.66(g) of the final rule is changed slightly from the proposal, but the meaning remains the same.

H. Flexibility for Uses (§ 330.1(c)(2))

Section 330.1(c)(2) retains flexibility of labeling for the OTC drug product's ''Uses'' section by allowing alternative truthful and nonmisleading statements describing those indications for use that have been established in an applicable OTC drug monograph. The agency, however, is shortening and simplifying the previous labeling requirements in § 330.1(c)(2). This reflects the decision to require the title ''Drug Facts'' and the boxed or similar enclosure format for all OTC drug products, in place of the ''Approved Uses'' or ''Approved Indications'' title and format. The

agency is consolidating into a new § 330.1(c)(2) the ''exact language'' requirement currently in § 330.1(c)(2)(vi) for language (other than indications) established and identified by quotation marks in an applicable OTC drug monograph or by regulation (e.g., § 201.63), except as provided in § 330.1(i) and (j). A number of comments expressed their support for the existing flexibility policy, which is being retained in this final rule.

I. Miscellaneous Comments

38. Several comments requested that OTC drug product labeling include information on: (1) When to take the drug, e.g., morning or night, before or after meals; (2) whether the drug can be taken with liquids; (3) whether analgesics or antibiotics interfere with effectiveness; and (4) a warning to the elderly that a smaller dosage may be needed. The comments argued that these facts should be in the labeling because many consumers may not ask, and some health professionals do not provide, this information.

The agency notes that this information is currently included in OTC drug product labeling when the information is known and when it is considered to be necessary for the safe and effective use of the product. For example, labeling for an OTC drug product containing naproxen sodium includes information on how to reduce the dosage for the elderly. The labeling for acid reducer products indicates how the drug should be taken in relation to foods or beverages. In addition, the warnings section for OTC analgesic products must indicate when particular drinks (e.g., alcohol) or substances (e.g., caffeine) should be avoided while taking these products.

39. Several comments recommended that OTC drug product labeling should state how long a drug remains in the body.

The agency believes that information about how long a drug remains in the body is important. However, it is difficult to state the actual time that a drug remains in the body in terms meaningful to consumers because of the variability of metabolism in individuals and because the time may vary depending on whether the drug is taken with or without food. Instead, when known and when relevant, the agency requires labeling that tells consumers when to redose, the maximum number of doses to take per day, and which drugs or foods to avoid to obtain maximum effectiveness and safety in the use of their OTC drug products.

40. Several manufacturers requested that FDA allow voluntary warnings to appear under the appropriate headings to further protect consumers from possible misuse of the product. Otherwise, placement of such information outside of the headings could create the impression that these warnings are less or more important than the required warnings.

The agency encourages manufacturers to discuss with the agency the addition of voluntary warnings to OTC drug products. As a general matter, FDA agrees that consumers may be confused if an appropriate warning were placed outside of the Drug Facts area. Thus, the agency expects such warnings to appear under the ''Warnings'' heading, preceded by an appropriate subheading.

41. In the proposed rule, the agency invited comment on whether current regulations should be revised to require expiration dating to appear in a specific location with specific legibility requirements on both the outer and immediate container packaging, especially for products marketed in tubes (62 FR 9024 at 9035 to 9036) as requested by a citizen petition (Ref. 12).

The agency evaluated the petition and concluded in a letter dated April 22, 1997 (Ref. 13) that the expiration date should be readily seen under usual and customary circumstances but did not require that it be placed in a specific location in the labeling. Comments to the proposed rule provided no new information for the agency to revise this conclusion.

42. Several comments were uncertain about whether the proposed rule would affect the PDP. This final rule does not affect the PDP requirements set forth in § 201.60, and 21 CFR 201.61 and 201.62.

43. Several comments requested that products with multilingual or braille labeling be exempted from the requirements of the final rule because space is not available on these labels to follow the requirements.

Current regulations (21 CFR 201.15) set forth the requirements for using foreign languages in labels and labeling. (Although analogous to multilingual labeling, braille is not specifically addressed in current regulations.) The regulations provide that ''No exemption depending on insufficiency of label space, as prescribed in regulations promulgated under section 502(b) or (e) of the act, shall apply if such insufficiency is caused by: * * * The use of label space for any representation in a foreign language.'' When multilingual or braille labeling is used, the agency considers it important that all labeling on the package be readable and understandable because it is not known which language the purchaser will use. Therefore, the agency will not categorically exempt multilingual or braille labeling from the new format.

44. Several comments recommended that the agency continue to permit voluntary use of symbols or pictograms in addition to required warning language. Some stated that symbols and pictograms may confuse consumers because they may have different meanings for different people. One comment recommended that if pictograms are used, USP pictograms should be adopted.

The use of symbols and pictograms will remain voluntary, provided their use is not a substitute for required OTC drug product labeling. In addition, a symbol or pictogram that directs attention away from required information, or one that is ambiguous or can be misunderstood by consumers, may render the product misbranded. The agency is allowing voluntary use of a telephone or telephone receiver in § 201.66(c)(9).

45. One comment recommended field testing new OTC drug labels to: (1) Assist in the development of criteria that define good OTC drug labeling; and (2) confirm, with representative consumer groups, that the new labels are readable, understandable, and cause the desired drug use behavior.

The agency agrees. Over the past several years, the agency has approved OTC drug product labeling, similar to the format required in this final rule, for new drugs that have moved from prescription to OTC marketing status. This labeling often is field tested by manufacturers under OTC usage conditions, and is presented to the agency in supplemental ''switch'' applications. The agency has incorporated in this rule content and format elements that have emerged through that process. Studies A and B (see section III.A and B of this document) also involved field testing which led to refinements of earlier labeling prototypes.

J. Reporting Requirements

Products that are marketed under an OTC drug monograph are not required to submit labeling to the agency for preapproval. However, if manufacturers have questions about how to implement the new requirements, they are encouraged to seek FDA guidance from the Division of OTC Drug Products.

Labeling changes to an OTC drug product marketed under a NDA or ANDA must be made in accordance with § 314.70 (21 CFR 314.70). Manufacturers of these products are also encouraged to seek agency guidance.

46. The agency specifically requested comment on whether labeling changes

required by the rule, for products marketed under approved applications, should be made under § 314.70(b), (c), or (d), and whether these changes should require agency preapproval (62 FR 9024 at 9042).

Several comments stated that the changes should be considered ''editorial'' or ''minor.'' The comments contended that the rulemaking itself takes the place of approving product-specific supplements, and that the filing of a supplement would impose an unnecessary burden. One comment favored preapproval supplements as the appropriate mechanism, because close collaboration between the agency and drug sponsors will be needed to ensure that final OTC drug product labeling meets the requirements of the new rule. Another comment argued that the appropriate process under § 314.70 would vary from product to product depending upon the nature and extent of the changes needed.

The agency agrees that it should not single out one process because the nature and extent of the changes needed to conform to the new format and content labeling requirements will vary depending on the product class and uses. The agency expects, however, that the majority of the changes required by this final rule can be submitted under § 314.70(d)(3). Section 314.70(d)(3) would cover any labeling changes that precisely follow § 201.66(c) and (d) and that require editorial changes specified in § 330.1(i) or (j). All other labeling changes would be submitted under § 314.70(b)(3) or (c)(2), as appropriate. However, most changes to required content beyond those specified in § 330.1(i) or (j) are expected to require preapproval under § 314.70(b).

K. Implementation Plan

47. Several comments urged that the time allowed for implementation of a final regulation on OTC drug labeling be extended to 3 years, with one comment urging an extension to 4 years. The comments argued that the number of product lines and stock keeping units (SKU's) involved creates a tremendous workload, especially in the case of private label manufacturers who may have to change hundreds of labels and must obtain approval of changes from their clients. One comment presented data intended to show that incremental costs to comply with a final rule in 2 years would be $140 million but would drop by half to only $70 million for a 3-year implementation date. No cost data were presented for a 4-year implementation date.

The final implementation plan, set forth in section V of this document, generally retains a 2-year implementation period for currently marketed products that are the subject of final monographs or approved drug applications. An additional year is allowed for low volume products. The economic basis for retaining this implementation plan is discussed in section VIII of this document. In addition, an outside date of 6 years from the effective date of this rule, or the next major labeling revision (whether required or voluntary) after the rule has been in effect for 2 years, whichever comes first, is set for all marketed OTC drug products (except those marketed under final monographs or approved drug applications) to comply with the new format and content requirements.

The plan is intended to minimize the economic burden on the industry while providing consumers with the benefit of more readable and understandable OTC drug product labeling at the earliest feasible date. As discussed in section VIII of this document, this implementation plan provides manufacturers with sufficient time to design and print new labeling and to deplete existing stock. Products that do not comply with the format and content requirements in this final rule on or after the applicable implementation date may be considered for regulatory action. The agency will review and, as needed, initiate steps to revise existing statements of enforcement policy to be consistent with this final rule document.

L. Preemption

In the proposed rule, the agency tentatively concluded that State and local laws that would establish different or additional format or content requirements than those in the proposed rule should be preempted (62 FR 9024 at 9041 to 9042). The agency is not finalizing the proposed preemptions sections (proposed § 201.66(h) and (i) as a result of a recent amendment to the act under FDAMA.

48. The agency received a significant number of comments supporting the proposed preemptive effect of the labeling requirements. Several comments suggested that the agency extend the scope of the preemption and preempt State requirements on safety and efficacy, dosage form, and packaging.

Subsequent to the issuance of the proposed rule, Congress enacted section 412(a) of FDAMA, which added to the act section 751 (21 U.S.C. 379r), titled ''National Uniformity for Nonprescription Drugs.'' Section 751(a) of the act provides that no State or political subdivision of a State may establish or continue in effect any ''requirement'' that relates to a nonprescription drug that is ''different from or in addition to, or that is otherwise not identical with'' a requirement under the act. A ''requirement'' that relates to a nonprescription drug is defined in section 751(c)(2) of the act as ''any requirement relating to public information or any other form of public communication relating to a warning of any kind for a drug.'' Similar to the preemption provision in the proposed rule, section 751(b) of the act establishes a process by which a State or political subdivision may seek an exemption from the preemptive effect of section 751(a) of the act.

Section 751 of the act also addresses the two issues on which FDA had specifically requested comment, i.e., the preemptive effect of the proposed OTC drug product labeling requirements on product liability lawsuits and the preemptive effect of the proposed labeling requirements on State initiatives such as California Proposition 65. On the issue of product liability suits, section 751(e) of the act states that ''[n]othing in [section 751] shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State.'' On the issue of whether the proposed labeling requirements preempt State initiatives, section 751(d)(2) of the act specifically provides that the national uniformity requirements in section 751 ''shall not apply to a State requirement adopted by a State public initiative or referendum enacted prior to September 1, 1997.''

This amendment to the act supersedes the agency's proposed regulation preempting State and local labeling requirements. The agency, therefore, has removed the preemption provision from this final rule and will, at this time, rely on the terms of the statute in addressing preemption issues.

M. Comments on Studies A and B

49. Two comments stated that it is generally accepted by industry and by experts in label readability that a format that includes a standard order of information, standard headings, bullet points, and interchangeable terms is superior to the ''old'' format. However, the comments maintained that the results of Studies A and B should be given little or no weight in FDA's deliberations because these studies covered only a small segment of all label readability issues.

The agency agrees that a number of format variables can affect readability,

and that Studies A and B did not evaluate all format variables that affect readability. The agency has been mindful of the limitations of these studies in its deliberations. Indeed, all of the significant conclusions in this proceeding have been informed by data gathered from a variety of sources. In addition to the two studies, the agency has considered and relied upon information provided by comments, information gathered from the leading literature on label design, graphics, and readability, and information drawn from the agency's own expertise in drug labeling.

50. The comments requested that the agency provide an extension to the comment period for Studies A and B. The comments also requested that the agency provide its analyses of the studies for public comment.

The agency provided two 45-day comment periods for these studies (see section I of this document). In order to facilitate public comment, the agency also made available in electronic format all of the data collected for these studies, including full tabulations of the data organized along key variables. The agency's summary analyses for these studies are contained in this document and an expanded review will be placed on file in the Dockets Management Branch (Ref. 14).

In light of the opportunities for comment already provided on the design and outcome of the studies, and the extent to which the agency in the end relied on the studies, the agency disagrees that there is a need for one more opportunity for comment.

51. One comment stated that the data from Study A are irrelevant to whether the proposed new OTC labeling is necessary for ''drug-cosmetic products,'' because no such product was evaluated in the study. The comment contended that consumer research concerning OTC analgesic and cough-cold drug products is not relevant to drug-cosmetic products. The comment urged the agency to undertake consumer research relevant to drug-cosmetic labeling, taking into account the differences between OTC drug products and OTC drug-cosmetic products.

For several recent prescription-to-OTC switches of drug-cosmetic products, the agency has observed labeling comprehension results similar to that seen in Study A. The results of several of these studies have been presented and discussed at open public advisory committee meetings (e.g., Rogaine). Given this experience, the agency believes that the findings from Study A can be applied to all OTC drug products, including those marketed as drug-cosmetics.

Study A evaluated the influence of label format, comparing the existing style formats to the proposed new format. This comparison demonstrated that the new format takes less time to read and helps people make better product use decisions. This comparison also found that consumers preferred the new format to the existing format. The agency believes that these findings would not differ if the product were marketed as a drug-cosmetic because the drug information would appear in the ''Drug Facts'' labeling format (see also comment 35 section IV.E of this document).

Study A also evaluated how the amount of information affected the time it takes to find information needed to answer specific questions. This was done by examining two drug types, a three-ingredient cough-cold product and a single-ingredient analgesic. The study demonstrated that the greater the amount of information, the longer it takes to find relevant information in the labeling. Again, although a drug-cosmetic was not evaluated in Study A, there is no reason to expect the results to be different if the product were a multi-ingredient drug-cosmetic versus a single ingredient drug-cosmetic.

Finally, Study A evaluated the influence of highlighting, or graphic design emphasis, on communication of important OTC drug product labeling information. The results showed that more, compared to less, highlighting helped participants make correct product use decisions when there is a large amount of information in the labeling. Labeling with more highlighting was also considered more useful. The agency considers the use of highlighting equally applicable to drug-cosmetic products that contain a large amount of information in the labeling.

52. One comment maintained that Study B is flawed in design and rationale because of its complexity and its intention to use consumer preferences as indicators of important labeling elements. The comment stated that the order of information should not be determined by consumer preference.

The agency carefully designed the protocol for Study B and solicited public comment on the design prior to initiating the study. The agency agrees, however, that consumer preference should not be the sole determinant of labeling design or information (Ref. 15). Thus, the final order and placement of label information in this rule is intended to follow a logical decisionmaking process that assists the consumer in the appropriate selection and use of OTC drug products.

However, Study B clearly indicated that the presence of a title for OTC labeling information was the most important factor in determining preference rankings. Consumers are the ultimate users of the OTC drug product labeling. They stated that they preferred the title because it drew their attention to the required information and made the required information appear more credible. The agency considers such unequivocal consumer input very important and useful in the design of OTC drug product labeling format.

53. One comment stated that because inactive ingredients were not included in Study B and because the terms for the active ingredients were not authentic, there was no way to determine whether these omissions or fabrications would have any impact on consumer label preference.

The agency used fabricated names for the active ingredients to reduce the influence of preconceived knowledge about specific OTC drug products. Because new drug ingredients are novel to consumers when these products first enter the marketplace, use of novel names for active ingredients would simulate this condition. The agency has no reason to believe that not including inactive ingredients or using fabricated names for the active ingredients influenced consumer preference in Study B.

V. Final Implementation Plan

The applicable implementation dates vary according to the regulatory status of the product. Any product that does not comply with this final rule as of the applicable implementation date may be considered for regulatory action. The agency will review and, as needed, initiate steps to revise existing statements of enforcement policy to ensure consistency with this implementation plan.

A. Products in the OTC Drug Review

Products marketed under final OTC drug monographs must comply with this rule as of April 16, 2001. Products for which a final monograph becomes effective on or after April 16, 1999, must comply with this rule as of: (1) The applicable implementation date for that final monograph, (2) the next major revision to any part of the label or labeling after April 16, 2001, or (3) April 18, 2005, whichever occurs first.

Combination drug products in which all of the active ingredients are the subject of a final monograph or monographs must comply with this rule as of April 16, 2001. Combination

products in which one or more active ingredients are the subject of a final monograph, and one or more ingredients are still under review as of the effective date of this rule, must comply with this rule as of the implementation date for the last applicable final monograph for the combination, or as of April 16, 2001, whichever is earlier. Combination products in which none of the active ingredients is the subject of a final monograph or monographs as of the effective date of this rule, must comply with this rule as of: (1) The implementation date of the last applicable final monograph for the combination, (2) the next major revision to any part of the label or labeling after April 16, 2001, or (3) April 18, 2005, whichever comes first.

B. Products Marketed under NDA's and ANDA's

Products that are the subject of an approved drug application (NDA or ANDA) before April 16, 1999, must comply with this rule as of April 16, 2001. Products that become the subject of an approved marketing application (NDA or ANDA) on or after April 16, 1999, must immediately comply with this rule.

C. Additional Provisions

Any OTC drug product not described in section V.A. and B of this document must comply with this rule as of: (1) The next major revision to any part of the label or labeling after April 16, 2001, or (2) April 18, 2005, whichever occurs first.

Products (including combinations) marketed under a final OTC drug monograph or monographs, or under an approved drug application (NDA or ANDA), with annual sales of less than $25,000, must comply with this rule as of April 16, 2002. This is intended to provide marketed products with a low level of distribution an additional year to come into compliance with this final rule.

Finally, irrespective of the regulatory status of the product, the agency strongly encourages all manufacturers, distributors, and packers of OTC drug products to voluntarily implement the new content and format requirements as soon as possible, particularly when existing labeling is exhausted and relabeling would occur in the normal course of business. The agency also encourages sponsors of products marketed under NDA's and ANDA's to submit any required labeling supplements as soon as possible, to ensure timely review.

Provided below is a chart that summarizes the time periods within which the various categories of marketed OTC drug products must be in compliance with this final rule. Unless otherwise stated, all time periods begin on the effective date of this final rule.

TABLE 1.—IMPLEMENTATION CHARTS

Products	Time Periods
Single entity and combination products subject to drug marketing applications approved before April 16, 1999.	Within 2 years (or within 3 years if annual sales of the product are less than $25,000).
Single entity and combination products subject to drug marketing applications approved on or after April 16, 1999.	Immediately upon approval of the application.
Single entity products subject to an OTC drug monograph finalized before April 16, 1999.	Within 2 years (or within 3 years if annual sales of the product are less than $25,000).
Single entity products subject to an OTC drug monograph finalized on or after April 16, 1999.	Within the period specified in the final monograph. However, if a monograph has not been finalized as of April 16, 2001, then the product must comply as of the first major labeling revision after April 16, 2001 or within 6 years, whichever occurs first.
Combination products subject to an OTC drug monograph or monographs in which all applicable monographs were finalized before April 16, 1999.	Within 2 years (or within 3 years if annual sales of the product are less than $25,000).
Combination products subject to an OTC drug monograph or monographs in which at least one applicable monograph was finalized before April 16, 1999 and at least one applicable monograph was finalized on or after April 16, 1999.	Within the period specified in the last applicable monograph to be finalized, or within 2 years (or 3 years if annual sales of the product are less than $25,000), whichever occurs first.
Combination products subject to an OTC drug monograph or monographs in which all applicable monographs are finalized on or after April 16, 1999.	Within the period specified in the last applicable monograph to be finalized. However, if the last monograph is not finalized as of April 16, 2001, then the product must comply as of the first major labeling revision after April 16, 2001 or within 6 years, whichever occurs first.
All other single entity and combination OTC drug products (e.g., products in the OTC Drug Review that are not yet the subject of proposed OTC drug monographs).	If a monograph has not been finalized as of April 16, 2001, then the product must comply as of the first major labeling revision after April 16, 2001 or within 6 years, whichever occurs first.

VI. The Paperwork Reduction Act of 1995

This final rule contains information collections that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection provisions are shown below with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing instructions, gathering and maintaining the data needed, and completing and reviewing the collection of information.

With respect to this collection of information, FDA invited comments on: (1) Whether the proposed collection of information is necessary for proper performance of FDA's functions, including whether the information will

have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology. FDA received no comments concerning the proposed burden estimates of this rulemaking under the Paperwork Reduction Act of 1995 (62 FR 9024 at 9044).

Regarding OMB's concerns about various label formats informing consumers about purchasing and using OTC drug products in a manner that will improve their health, FDA discussed this subject in the February 27, 1997 (62 FR 9024 at 9031) proposal. The agency points out that the required label format (i.e., the order for the placement of information) is modeled after the decisionmaking process consumers would be expected to follow, and should follow, when selecting and using OTC drug products. This new required labeling format should help consumers to more efficiently and better use OTC drug products.

OMB, in its notice of action did state that it wished to allow the industry and the public to consider the notice of proposed rulemaking, specifically its concerns about the utility of various label formats to inform consumers about purchasing and using OTC drug products in a manner that will improve their health. FDA has met with the industry on numerous occasions over the past 4 years to discuss various aspects of the new labeling formats and believes that the industry and public sector has had ample opportunity to express their views and be aware of the reporting burdens established by this final rule. Throughout the preamble, the agency has addressed numerous comments received concerning information collection. The agency adds that many manufacturers of OTC drug products have begun on their own initiative implementing the labeling format provided in this rule as part of their routine labeling redesign practice.

Title: Over-the-Counter Human Drugs; Final Rule for Labeling Requirements.

Description: FDA is amending its regulations governing labeling requirements for human drug products to establish a standardized format and standardized content requirements for the labeling of all marketed OTC drug products. The rule requires that the outside container or wrapper of the retail package (or the immediate container label if there is no outside container or wrapper) of all OTC drug products include uniform headings and subheadings, presented in a standardized order, with minimum standards for type size and other graphical features. FDA is issuing these requirements because it has determined that the design and format of labeling information varies considerably among OTC drug products and consumers may have difficulty reading and understanding the information presented on OTC drug product labeling. The rule is intended to enable consumers to better read and understand OTC drug product labeling and to apply this information to the safe and effective use of OTC drug products.

FDA's legal authority to modify and simplify the manner in which certain information is presented in OTC drug product labeling derives from sections 201, 502, 503, 505, and 701 of the act. Regulating the order, appearance, and format of OTC drug product labeling is consistent with FDA's authority to ensure that drug labeling conveys all material information to the consumer (sections 201(n) and 502(a) of the act), and that labeling communicates this information in a manner that is ''likely to be read and understood by the ordinary individual under customary conditions of purchase and use'' (section 502(c) of the act).

FDA concludes that the labeling statements required under this rule are not subject to review by the OMB because they are ''originally supplied by the Federal government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)) and therefore do not constitute a ''collection of information'' under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq*.).

Section 201.66 requires all OTC manufacturers to format labeling as set forth in subsections (c) and (d). FDA has learned from the industry that OTC manufacturers routinely redesign the labeling of OTC products as part of their usual and customary business practice. This rule provides varied timeframes for implementing the OTC labeling requirements. Therefore, the majority of respondents will be able to format OTC labeling in accordance with § 201.66 as part of their routine redesign practice, creating no additional paperwork or economic burden. However, of the 39,310 SKU's currently marketed under a final monograph, FDA has determined that approximately 32 percent, or 12,573 products, may necessitate labeling format changes sooner than provided under their usual and customary practice of label redesign. FDA has estimated that of the 400 respondents who produce OTC products, including the 12,573 products described above, each may be required to respond approximately 31.4 times to this rule outside of their usual and customary practice. Each response is estimated to take, on the average, 4 hours, for a total of 50,292 hours per year. This burden is expected to be a one-time burden.

Although the usual and customary practice of label redesign will minimize the burden for the remainig 68 percent of SKU's currently marketed, or 26,737 products, additional time may be necessary for each company to make the format changes under this rule. FDA has estimated that of the 400 respondents who produce OTC products, each may be required to respond approximately 66.8 times to bring the 26,737 products into compliance with this rule. FDA estimates that for this group, each response will take an average of 2.5 hours for a total of 66,842 hours. This is expected to be a one time burden. The chart reflects this group on the second line.

Section 201.66(c) and (d) will also trigger the requirement that OTC manufacturers with approved or pending new drug applications (NDA's) and abbreviated new drug applications (ANDA's) must submit to FDA supplements and amendments regarding labeling changes under 21 CFR 314.60(a), § 314.70, 21 CFR 314.96(a), and 21 CFR 314.97. In the proposed rule, the agency attributed this paperwork burden to these specific NDA and ANDA regulations. For the final rule, the agency has redesignated the burden under § 201.66(c) and (d). Based on its records and experience, FDA estimates that approximately 61 respondents hold applications (41 NDA holders and 20 ANDA holders) for which supplements and amendments will be required. FDA expects that approximately 522 submissions (350 to NDA's and 172 to ANDA's) will be required regarding labeling changes under § 201.66(c) and (d), which averages to 8.5 submissions per respondent. Based on information and experience, FDA further estimates that each submission will take an average of 2 hours to prepare, for a total of 1,040 hours annually. This burden is also expected to be a one-time burden.

Under § 201.66(e), respondents subject to this rule will be required to submit requests in writing for exemptions and deferrals from the specific requirements of § 201.66. Based on its experience with exemption and deferral requests under similar provisions, FDA estimates that

approximately 16 percent of the total number of respondents, or 25 manufacturers, packers, or distributors, could be expected to submit such requests on the average of one time per year. Such requests may take an average 24 hours each for a total of 2,400 hours annually.

The agency estimates that approximately 59,329 SKU's are moving towards publication of a final monograph. The burden associated with label reformatting for these products is not included below. The burden below will be adjusted after these products become final.

TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
201.66[2]	400	31.43	12,573	4	50,292
201.66	400	66.8	26,737	2.5	66,842
201.66(c) and (d)[2]	61	8.5	522	2	1,044
201.66(e)	25	4	100	24	2,400
Total					120,578

[1] There are no capital costs or operation and maintenance costs associated with this collection of information.
[2] One-time burden.

VII. Environmental Impact

The agency has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VIII. Analysis of Impacts

A. Background and Summary

FDA has examined the impacts of the final rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act (2 U.S.C. 1501 *et seq.*). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Under the Regulatory Flexibility Act, if a rule has a significant impact on a substantial number of small entities, an agency must analyze regulatory options that would minimize any significant impact of the rule on small entities. Title II of the Unfunded Mandates Reform Act requires that agencies prepare a written assessment and economic analysis before proposing any rule that may result in an expenditure in any 1 year by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million (adjusted annually for inflation).

The agency believes that this final rule is consistent with the principles set out in the Executive Order and in these two statutes. The final rule is a significant regulatory action as defined by the Executive Order due to the novel policy issues it raises. It is also an economically significant regulatory action because of its substantial benefits. With respect to the Regulatory Flexibility Act, the following analysis constitutes the agency's Final Regulatory Flexibility Analysis. Because the rule does not impose any mandates on State, local, or tribal governments, or the private sector, that will result in an expenditure in any 1 year of $100 million or more, FDA is not required to perform a cost-benefit analysis according to the Unfunded Mandates Reform Act.

The standardized format and easier-to-read labels established by this rule will have a positive effect on the nation's public health by enhancing the ability of consumers to find, read, and understand important safety and use information. The expected benefits of the rule will include: (1) Improved drug effectiveness for labeled indications, (2) reduced adverse drug reactions, and (3) more efficient consumer search activities. The health benefits that will result from improved drug effectiveness could not be quantified, but FDA believes that they are substantial. With respect to the anticipated reduction in adverse drug events, the agency finds that if the rule prevents just 5 percent of the hospitalizations associated with the unintended consequences of self-medication, the economic savings could be $39 million annually in direct benefits and $52 million annually from indirect benefits. In addition, by reducing consumer search time, the uniform format could lead to consumer time savings valued at from $19 million to $38 million per year. The total benefits of this rule range from $110.5 million to $129.6 million per year.

The costs of the product redesign and relabeling imposed by this rule will be incurred by the manufacturers of OTC drug products. FDA estimates that the required labeling redesign will cost about $19.4 million. In addition, the minimum print size and other format changes will require a small percentage of products (estimated at 6.4 percent) to increase the size of their label and/or package. These size-related adjustments will add about $38 million in one-time costs and $11.5 million in annually recurring costs. Overall, therefore, the agency estimates that the one-time costs of this rule will amount to about $58 million and the annual recurring costs about $11.5 million.

B. Benefits of Regulation

The purpose of this final rule is to establish a standardized format for the labeling of all OTC drug products so that the labeling will be easier to read and understand, and will provide consistent information in like situations. Thus, the final rule will enhance the safe and effective use of OTC drug products by improving the ability of consumers to find, read, and understand important safety and use information. As discussed in section III.A of this document, the agency conducted a study (Study A) to examine the influence on comprehension of the new versus the previously used OTC labeling format. That study supports the conclusion that the new format will take less time to read and will help consumers make a greater number of correct product use decisions when such decisions require a simple search for information in the product labeling. The study found that individuals like a format with strong visual cues and consider information easier to use when presented in easy to read ''chunks.'' Especially when attention is divided, individuals felt more confident in their ability to use such a format.

Both the variability and the presentation of existing OTC drug product labeling make it difficult for consumers to select the most appropriate OTC drug product and to use the product safely and effectively. For consumers to gain the greatest benefit from these products, relevant information must be easy to find, readable, readily understood, noted, and acted upon. Despite the critical importance of safety and use information, OTC drug product labeling is often printed in small type with a crowded layout and minimal white space. Although the OTC drug industry has developed voluntary labeling standards encouraging a minimum 6-point type size, many OTC drug product labels fail to meet this standard. Moreover, the placement of the information varies, making it harder for consumers to find and compare similar information on competing products.

The revised labeling will produce at least three important benefits: (1) The new label will enhance the therapeutic value of OTC drug products by helping consumers select appropriate products and adhere to proper dosage regimens; (2) consumers will find it easier to avoid ingredients or products that in some circumstances cause adverse events such as allergic reactions, adverse drug interactions, or other unintended outcomes, ranging from minor discomfort to hospitalization; and (3) consumers will increase the economic efficiency of their OTC drug purchases by more quickly locating and identifying key elements of product information, such as appropriate ingredients, uses, and warnings.

1. Improved Product Selection and Use

The number of consumers relying on self-diagnosis and self-treatment has increased rapidly over the past decade, due in part to the rising cost of health care and the increasing number of drug products switched from prescription to OTC status. Consumers, however, are faced with a growing number of choices for purchase decisions and often find it difficult to determine the product that is best for their particular condition. The absence of uniform and easily readable product information complicates product comparisons and can result in less than optimal health outcomes. Moreover, even informed product selections can produce disappointing results if directions for use are misread. Inappropriate product selections or illegible dosage directions can postpone relief from aches or pains, or permit other discomforts to persist longer than necessary. Study A suggests that the standardized labeling format will reduce such incorrect product use decisions. Although FDA cannot quantify the value of the health improvements that would result, the agency is confident that the more informed OTC drug selection and use produced by this rule will increase consumer satisfaction and, at times, reduce health care costs for additional or supplemental medications, doctor visits, and hospitalizations.

2. Savings From Reduced Adverse Drug Reactions

Although adverse events associated with some OTC drug products are not systematically tracked and recorded, substantial documentation does exist for the more serious events. Numerous studies in the literature have documented drug-related hospitalizations (60 FR 44182 at 44232, August 24, 1995). One comprehensive review of 36 articles focused specifically on adverse drug reactions (ADR's) as the primary cause of hospitalization. This study counted the number of events attributed to the unintended consequences of drug therapy, excluding admissions due to overdose, intentional poisoning, attempted suicides, drug abuse or intoxication, and found that the percentage of hospitalizations due to ADR's ranged from 0.2 to 22 percent, with a mean of 5.5 percent (Ref. 16). Of those studies that distinguished between prescription and OTC drugs, the reported OTC share ranged from between 4 (Ref. 17) and 18 percent (Refs. 18 and 19). Thus, FDA estimates that unintended OTC drug-related hospitalizations may account for about 0.55 percent (5.5 percent x 10 percent), or 170,500 of the nation's 31 million annual hospital admissions. Investigators have determined that between 48 and 55 percent of all hospital admissions related to adverse reactions are preventable (60 FR 44182 at 44232). (A recent study of in-hospital adverse drug reactions also found that almost 50 percent were preventable.) (Ref. 20). Consequently, on the assumption that 50 percent of the hospitalizations attributable to OTC drug adverse reactions are preventable and that the cost of an average hospital stay is $9,191 (Ref. 21), FDA finds that $784 million (170,500 x 50 percent x $9,191) is spent annually on hospitalizations due to potentially avoidable OTC drug ADR's.

The realized benefits of the rule will depend on the degree to which consumers are better able to read and understand OTC drug product labeling and to act on that information to make choices that would reduce drug side effects, drug interactions, allergic reactions, and other unintended consequences of self-medicating. If the improved labeling format and larger print size contributed to the avoidance of only 5 percent of these hospitalizations, the economic savings would amount to $39 million annually.

The indirect benefits from reduced drug-related illnesses include avoided costs due to lost work time or reduced productivity. Roughly 58 percent of adverse drug reaction admissions were for patients aged 20 to 59. The remaining 42 percent of admissions were for patients under 20 years (<10 percent) and over 59 years old (Refs. 17, 18, and 22). To calculate productivity losses, the agency assumed 56 hours per admission for the patients aged 20 to 59 years (40 hours of lost work per hospitalization plus 16 additional hours for recovery and followup doctor visits) and 14 hours for the remaining group (to account for lost volunteer time or for time away from work for the care givers of dependent patients). Using the average hourly production workers earnings plus 30 percent for fringe benefits of $15.96, the estimated value of lost productivity is $44.2 million patients for aged 20 to 60 and $8 million for the remaining patients or their care givers (Ref. 23). These estimates may somewhat overstate the value of lost productivity for the 20 to 59 age group because all patients are assumed to be employed. On the other hand, indirect benefits for the remaining age groups are understated because many of these patients are in the workforce and for those who are not, data are inadequate to measure their contribution to society.

Although less severe adverse incidents have not been systematically tracked and recorded, they likely occur frequently, as over 5 billion OTC drug products are purchased annually. The crowded format and small print size found on many of these products obscures important directions and warnings that might otherwise be heeded by consumers. For example, certain OTC drug products contain warnings about not driving or operating heavy equipment when using those products. Some consumers inadvertently overdose because they are unaware that a particular ingredient was also contained in a multi-symptom product. In the case of combination products with multiple active ingredients, especially in the cough/cold category, consumers often treat symptoms that are not present, raising the likelihood of an adverse drug event. The new label format will establish a consistent order of presentation and group similar information (such as ingredients, warnings, and directions) together under relevant headings so that

it will be easier for consumers to find and read this information, thus helping to reduce the number of adverse event occurrences.

3. Savings From More Efficient Product Search

By facilitating product comparisons, easier-to-read labeling will reduce those suboptimal purchases that result from inappropriate price-quality relationships and competitive inefficiencies. For example, the uniform format will reduce consumer search and transaction costs, because all products will display information in the same order. In turn, consumers will find it easier to purchase more economical items by comparing products with similar ingredients and uses. Although FDA could not assign an economic value to this expected efficiency gain, Study A found that the time required to read the complete safety and use information in the proposed format was reduced by a statistically significant 10 seconds compared to traditional formats. The total time saved searching for specific information components, such as ingredients and their therapeutic benefits, or for conducting product comparisons, should be even greater at the point of purchase.

According to A.C. Nielsen (Nielsen), a recognized provider of market research business information and analysis, consumers purchased 5.6 billion units of OTC drug products in 1995. (This figure excludes dandruff shampoos and facial makeup and lipstick with sunscreen.) If 10 percent of these purchases represent first time or annual evaluations of purchase decisions, 0.6 billion product decisions are made annually. If consumers save only the reported 10 seconds per purchase decision, they would save 1.6 million hours annually. Using 1997 average hourly production worker earnings of $12.28, the approximate economic value of this time savings is $19.1 million per year (Ref. 23). If consumers compare two products, the additional time could double, with a value of $38 million per year.

4. Summary of Expected Benefits

In summary, FDA expects revised OTC drug product labeling to generate substantial benefits, many of which the agency could not quantify. While the majority of the costs attributed to this rule are one-time costs associated with labeling redesign and packaging reconfiguration, the benefits from improved labeling will accrue annually. Better informed product selection and use will raise the likelihood that OTC drugs will produce desired health outcomes. The standardized format and easier-to-read labeling is expected to reduce the number of ADR's associated with OTC drug products. A 5 percent decrease, for example, would reduce annual hospital costs by about $39 million and reduce annual productivity losses by $59 million. Finally, FDA expects that easier-to-read information will lead to more efficient marketing transactions, because product and price comparisons will be simpler and faster, permitting consumers to obtain comparable results in less time. The value of the reduced search time could range from $19 to $38 million annually. The total benefits of this rule range from $110 million to $129 million annually.

C. Costs of Regulation

For its analysis of the proposed rule, FDA determined that the cost of revising labeling for thousands of OTC drug products would be substantial, involving numerous levels of review and verification, in addition to extensive graphic redesign. The agency found, however, that regulatory costs would be moderated by the standard business practice of periodic redesign. Because a majority of the labeling would undergo design changes even in the absence of a new rule, FDA estimated the costs of redesign by counting only the value of the label-years that would be lost, after adjusting for the length of the traditional labeling cycle. The regulatory cost was calculated as the product of the number of SKU's, which are the individual products, packages, and sizes affected; the number of years of labeling life lost; and the value of each year of labeling life lost (see 62 FR 9024 at 9045 through 9049). As explained below, upon review of the comments, FDA has concluded that its methodology for estimating the cost of a labeling change was sound. The agency has, however, refined its earlier cost estimates, based on the comments and other supplemental information, and has added costs for increasing the size of certain packages and labeling.

1. Number of Products Affected

Once the rule is fully effective, a new OTC drug product labeling design will be required for each SKU. For its initial analysis, FDA based its estimate of the size of the affected OTC drug market on data from Nielsen. According to Nielsen, OTC drug products in 1995 accounted for $18.7 billion in sales in grocery stores, drug stores, and mass merchandise outlets. FDA allocated the products in Nielsen's inventory into review categories based on their monograph review status. This categorization indicated that almost 30,000 brand name SKU's were regulated under the OTC drug monograph review process. The breakdown of these branded SKU's by monograph review status showed: 10,910 under a final monograph (including products switched from prescription to OTC status), 8,241 scheduled to become final before this final rule, and the remaining 8,488 scheduled to become final after this final rule is published. (The latter figure was subject to greater uncertainty because of incomplete coverage of products with sunscreens in the Nielsen data base.) (See Table 3 of this document.)

TABLE 3.—NUMBER OF ESTIMATED SKU'S BY REGULATORY STATUS

	Brand name	Private	Total
Marketed under final monograph	10,910	28,400	39,310
Under review, scheduled for final monograph	8,241	21,300	29,541
Remaining	8,488	21,300	29,788
Total	27,639	71,000	98,639

Because the Nielsen data base did not break out SKU's for private label store brands, FDA estimated the number of private label SKU's using data on the number of retail chains likely to market private label brands (Ref. 24) and Nielsen data on the average number of SKU's carried by firms that relabel generic OTC drug products. The agency estimated 71,000 private label SKU's (62 FR 9024 at 9046 to 9047) and assumed the same regulatory status distribution as for branded SKU's.

While this rule will ultimately affect all OTC drug products, the implementation dates for the labeling changes will vary according to the

regulatory status of the product. For its analysis of the proposed rule, FDA assumed that products currently covered by a final OTC drug monograph or marketing application, or about 39,310 SKU's, would incur labeling design costs. A second group of up to 29,541 SKU's was thought to be potentially affected, depending on the timing of the publication of their final OTC drug monographs. The agency assumed that monographs for the remaining 29,788 SKU's would become final only after publication of the final rule. Because products marketed under this latter group of OTC drug monographs would require labeling changes regardless of the final rule, no design-related costs were assigned to this group of products. Although FDA received no comments questioning this SKU allocation, the agency has now determined that the 29,541 SKU's in the review category will not be finalized before this rule is published. As a result, only those 39,310 SKU's currently covered by final OTC drug monographs are expected to incur incremental labeling design costs.

2. Original Agency Estimate

a. *Cost of labeling redesign*. FDA's previous analysis (62 FR 9024 at 9045 to 9049) found that redesign cost estimates varied from $2,700 to $10,000 per SKU for branded products and from $500 to $1,500 per SKU for private label products. These costs included the drafting of language, art work, review, and implementation and generally included redesign of the PDP. FDA assumed that the PDP accounted for 50 percent of the cost to redesign branded product labeling and reduced the estimated redesign costs by one-half, on the presumption that the rule would not affect the PDP. To derive an average cost, the agency weighted the affected share of private label and branded SKU's at 80 and 20 percent, respectively, based on FDA's estimate of 71,000 private label SKU's and an analysis of Nielsen sales data covering the remaining 27,639 branded SKU's. Because the analysis found that a substantial proportion of the branded products were regional and/or low sales volume items, FDA assumed that the redesign costs for regional and low sales volume branded products would be similar to that for private label products. Using the midpoints of the cost ranges, and reducing the cost for branded products by 50 percent to account for the PDP adjustment, the analysis calculated an average redesign cost of $1,500 per SKU. However, as described in section VIII.E.3 of this document, based on additional information, the agency's final analysis eliminates the PDP adjustment.

b. *Methodology*. The agency's assessment of the proposed rule found that frequent labeling redesigns are recognized as a cost of doing business in the OTC drug industry. Thus, labeling that would normally be redesigned within the implementation period was assumed to incur no additional costs. To represent the distribution of typical labeling replacement intervals, the agency had estimated that the labeling for 20 percent of the affected SKU's would be redesigned at least every 2 years, 40 percent every 3 years, and 40 percent every 6 years. Both the number of OTC drug products requiring redesign and the market value of the labeling were assumed to be evenly distributed over their labeling lifetimes. That is, for labeling with a 6-year lifetime, one-sixth would be redesigned in year 1, one-sixth in year 2, and so on. FDA then measured the economic cost of the proposed labeling redesign requirement as the lost value of the remaining life-years of the existing labeling designs. For example, given a 2-year phase-in period, product labeling with a remaining 3-year lifetime would lose the value of 1 year of labeling-life.[1]

FDA found that, with a 2-year implementation period, the cost of the proposed requirements would be $19.7 million. To reduce the economic impact on small entities, the agency proposed an additional 1 year extension for OTC drug products with sales of less than $25,000 per year. Based on the Nielsen data, this extension applied to about 40 percent of OTC drug products, but only about 1 percent of OTC drug retail sales. With this added deferral, FDA estimated the cost of the proposed rule at $14.2 million.

3. Response to Comments

A number of comments from the OTC drug industry asserted that the agency understated the cost of the proposed rule. These comments stated that: (1) FDA's estimated average cost to redesign labeling was too low, (2) FDA's methodology to calculate the economic impact of the proposal was inappropriate, and (3) FDA incorrectly assumed that package and label sizes would not need to be increased. The following section addresses each of these issues while focusing primarily on the comments and alternative economic analysis submitted by NDMA. Appendix G of NDMA's comment provides a full description of its explanatory data and methodology (Ref. 25).

NDMA stated that the cost to comply with the proposed rule, assuming a 2-year implementation period, would be a minimum of $140 million, even without changes to package and label sizes. NDMA subsequently recommended the use of a net present value approach, which reduced its cost estimate to $114 million. Further, FDA had proposed an additional implementation year for SKU's with annual sales below $25,000. This adjustment reduces NDMA's cost estimate (assuming no package or label size changes) to $86 million, substantially less than the originally stated $140 million figure, but still far above FDA's estimate of $14.2 million.

a. *Cost of redesigning drug label*. NDMA agreed that FDA ''approached the very complex task of assessing the economic costs resulting from the proposed rule in a rational, data-based manner'' and that ''many of the parameters that FDA used as a basis to determine label design costs were supported by reliable market research data.'' For example, NDMA accepted FDA estimates for both the number and life cycle of the affected drug labels. Nevertheless, NDMA asserted that the agency had understated the cost of redesigning a label for the following reasons: (1) FDA's unit cost estimate was based on a small, nonrandom sample; (2) FDA was incorrect in eliminating PDP redesign from the cost of relabeling branded OTC drug products; and (3) FDA did not consider either the cost of scrapping label inventory or the administrative burden that would be incurred by firms in developing compliance strategies.

i. *Unit cost estimate (without scrap)*. NDMA reports that it developed a cost estimate by surveying 74 member firms regarding the average cost of redesigning an OTC drug product label. The survey (Ref. 25) requested information on minor and major label changes. Thirty-four firms responded, of which 31 were brand label manufacturers and 3 were private label manufacturers. The reported cost per SKU to redesign a label ranged from $500 to $420,000. Excluding three extreme outliers,

[1] Mathematically, the following formula was used to calculate the costs:

$Cost_{yx} = \Sigma j N_x A_x (1/x)$, where j = 1 to (x-y)

Total $Cost_y = Cost_{y6} + Cost_{y3} + Cost_{y2}$

where:

x = life of labeling in years (2, 3, or 6),

y = implementation period in years,

N_x = number of SKU's with labeling life of x years, and

A_x = amortized annual value of labeling with a life of x years.

(A_x is equivalent to the annuity value to pay off an initial investment, i.e., $A_x = C \times \{ I / [1 - (1/(1 + I)^x)]\}$; where C = the average weighted cost to redesign a labeling ($1,500); I = the discount rate (7%); and x = the life of a labeling in years (2, 3, or 6).)

NDMA projected an average cost (omitting scrap) of $15,154 per SKU to redesign a branded label and $1,261 for a private label. Assuming a 20/80 market split for branded and private label products, NDMA calculated a weighted average cost per SKU of $4,039, roughly double the earlier FDA estimate (without a PDP adjustment) of $2,070.

To validate its estimate, NDMA cited a cost model that had been developed by the Research Triangle Institute (RTI) to estimate the regulatory impact of the NLEA. The RTI model assumed that the cost of changing a food product label was a function of administrative, analytical, marketing, printing, and label inventory costs. Printing costs depended on the type of printing process, the frequency of redesign, the number of SKU's affected, the complexity of the label changes, and the length of the compliance period (Ref. 26). NDMA estimated, based on responses from 21 member firms, that about 50 percent of the industry's SKU's are printed using lithography, 47 percent by flexography, 1 percent by gravure, and the remaining by other methods. Applying these proportions to the RTI model for complex printing tasks with four or more color changes, NDMA derived a label printing cost of $3,458 per SKU for an average OTC drug product and concluded that this result verified its estimate of $4,039 per SKU (without scrap).

The agency agrees that the cost data used in FDA's economic analysis of the proposed rule were not drawn from a random sample, although they were supplied by sources familiar with the OTC drug industry, including smaller and private label manufacturers. FDA notes, however, that the survey underlying the NDMA cost estimates was likewise not based on a random sample of manufacturers. While NDMA member firms include a range of large, small, brand-label, and private-label manufacturers, many smaller firms do not belong to NDMA. Indeed, NDMA indicates that its 74 members (which may represent less than 20 percent of all OTC drug manufacturers), account for 90 to 95 percent of all OTC drug sales. A survey limited to this membership necessarily over-represents large manufacturers of nationally branded products and under-represents smaller manufacturers of regionally branded products.

Following review of the survey data provided by NDMA, FDA concludes that NDMA's figures overstate the industry average cost of redesigning OTC drug labels. For example, the survey reports unreasonably large differentials between branded and private label manufacturers, with survey costs for branded SKU's from 3 to 40 times greater than those for private label SKU's. For graphics development (directions for studio, draft/mock-ups, review, and concurrence), the average SKU cost reported was $6,215 for branded and $291 for private label products. Assuming an hourly wage rate of $40 for branded and private product personnel, manufacturers of branded products spend 155 hours per SKU on this function compared to 7 hours by private labelers. For separations (color mock-ups created and reviewed), the survey reported the per SKU cost for branded and private label companies at $3,210 and $82, respectively, almost a 40-fold difference. The agency acknowledges that large manufactures of nationally branded products involve more personnel in decision making and may use higher quality packaging materials. Nevertheless, in view of the substantial degree of market competition in this industry, private labelers typically package goods to resemble the competing national brand. Moreover, while questioning the size of the reported range, FDA could not review the basis for NDMA's estimates, because the supporting data, such as the number of labor hours or labor costs used in its calculations, were not submitted.

Furthermore, while the proposed rule required manufacturers to reformat the information panels, the NDMA survey instructed respondents to include the cost of changing all labeling, including certain promotional materials. Thus, some manufacturers may have reported costs for developing new product identities, advertising campaigns, etc. Also, survey respondents were asked to estimate the cost to redesign only one SKU, which ignores both learning curve and economy of scale effects. For the most part, the same industry personnel are responsible for copy and layout decisions for numerous product lines and SKU's. Moreover, FDA does not agree that the RTI model necessarily validates NDMA's redesign cost estimate. The portion of the RTI model used by NDMA was developed to estimate the cost of printing food labels, which are often considerably larger than OTC drug labels.

NDMA's recent estimate also differs from the average cost of $7,900 per SKU submitted by the Cosmetic, Toiletry, and Fragrance Association to change a drug-cosmetic label (Ref. 27). OTC drug-cosmetics are generally considered to have more expensive labeling than OTC drugs alone, because they compete with other elaborately packaged cosmetic products.

To finalize its estimate of the average cost of redesigning an OTC drug label, FDA considered several approaches. First, the agency maintained its initial estimating methodology, but adjusted the estimated unit cost per SKU. Based on all available information, FDA concludes that the cost of redesigning nationally branded products manufactured by large companies ranges from $5,000 to $15,000 per SKU. The cost to redesign regional or low sales volume brands of smaller manufacturers is considerably less, ranging from about $1,000 to $8,000 per SKU. The cost to redesign labels for private label brands is smaller still, but approximates FDA's original estimate of $1,000 and NDMA's survey estimate of $1,261 per SKU. Accordingly, to calculate a final estimate, the agency divided OTC drug products into three classes: (1) Branded products manufactured by large NDMA member companies, with a midpoint cost estimate of $10,000 per SKU; (2) branded products manufactured by smaller companies, with a mid-point cost estimate of $4,500 per SKU; and (3) private label products, assumed to cost $1,261 per SKU, as reported by NDMA.

The agency used its original estimate of the SKU distribution, which indicated that about 30 percent of all OTC drug SKU's are branded, and the NDMA member survey to determine costing weights to apply to each industry sector. Respondents to NDMA's survey reported that they account for about 4,000 branded SKU's, which amount to 15 percent of all branded SKU's. As these survey respondents comprise almost half of NDMA's membership, FDA assumed that branded products of all NDMA members may account for about 30 percent of all branded SKU's, or approximately 10 percent of all affected SKU's (30 percent branded x 30 percent NDMA members). The remaining branded products, therefore, account for 20 percent of all affected SKU's, and the private label products account for the remaining 70 percent. This calculation results in a weighted average cost of $2,783 (without scrap) to redesign a label (i.e., ($10,000 x 10 percent)+($4,500 x 20 percent)+($1,261 x 70 percent)), a figure higher than the prior FDA estimates but below the NDMA survey estimate of $4,039.

A second approach was developed by the Eastern Research Group, Inc. (ERG), a private economics consulting firm under contract to FDA. ERG developed its model based on data collected during site visits to several large and small drug

companies and through discussions with other industry consultants (Ref. 28). ERG assumed a more complex distribution of various types of SKU's among firms of different sizes and included specific cost variables for regulatory affairs, art/graphics, manufacturing changes, and inventory losses by firm size (by employment), firm type (branded or private label), and type of label changed (carton, container, etc.). Under ERG's model, the estimated weighted average cost of label redesign (without scrap) is $1,210 per SKU (Ref. 28).

Because the OTC industry is so diverse and the relevant cost data are so limited, no single model or single estimate can be viewed as definitive. Nevertheless, the agency continues to believe that its overall approach represents a rational basis for estimating the redesign costs associated with this rule. The agency in its proposed analysis arrived at an estimate of $2,070 per SKU (without a PDP adjustment). That figure, when revised to take into account certain data from the NDMA survey, is increased to $2,783 per SKU. ERG employed a more complex model and arrived at a figure of $1,210 (or half that of FDA), while NDMA arrived at a weighted average of $4,039 (or twice that of FDA). Given this spread, and given the agency's concerns about NDMA's methodology and input data, the agency is adopting the revised figure of $2,783 as its base average cost estimate. The agency acknowledges that it has adopted a conservative figure, relative to that derived by ERG. However, nothing in the ERG model, or in the NDMA model, suggests that FDA should discard its methodology or its assumptions for estimating unit costs.

ii. *Principal display panel.* In its original analysis, FDA assumed that the PDP need not be altered and therefore adjusted its unit cost estimate for branded products downward by 50 percent. NDMA argued that this correction was inappropriate as it failed to account for many commonly used labeling and packaging configurations. NDMA pointed out that, with the exception of labels with separate front and back panels, all PDP's must be reprinted when the information panel is changed. Based on a poll of 7-member companies, NDMA estimated that about 90 percent of all OTC drug SKU's require the PDP to be reprinted when changes are made to the information panel.

The fact that the PDP needs to be reprinted when the information panel is changed does not mean that it has to be redesigned. For the majority of labels, the PDP and information labeling are printed as a single label, with one printing plate required for each of the colors used. For many products, only one or two colors will be changed on the information panel to accommodate the new requirements; consequently, only those plates would need to be redesigned, the others could be reused or simply copied at significantly reduced cost. Nevertheless, the agency acknowledges that many manufacturers would, at the time of redesigning the information panel, also make incremental changes to the PDP. Therefore, the agency has adopted the NDMA position and eliminated any downward PDP adjustment from its calculation of the cost of the final rule.

iii. *Scrap.* NDMA also argued that the cost of scrapping unused inventory should be included as a regulatory cost. Based on its survey, it estimated that scrap labeling inventory adds about $1,000 to the weighted redesign cost per SKU ($2,968 per SKU for higher cost firms and $576 per SKU for lower cost firms), raising its average unit cost estimate to about $5,000. NDMA declared this a conservative estimate that would underestimate the cost of scrap label inventory if the implementation date were less than 2 years.

FDA agrees that some scrap label inventory loss is inevitable when label changes are made, but notes that the longer the implementation period the easier it is for manufacturers to minimize the cost. The final rule allows either a 2- or 3-year implementation phase (depending on sales volume), which is sufficient time to minimize inventory losses. Because the NDMA survey question failed to state the length of the phase-in period, the survey response cannot be considered reliable. Nonetheless, because a better estimate of the average scrap cost is not available, FDA accepts NDMA's figures, but adjusts the weighting to 10 percent for the higher cost firms and 90 percent for the lower cost firms, for a weighted average of $800. This weighting is based on the assumption that both small brand name manufacturers and private label manufacturers have less expensive labels and smaller inventories than large brand-name companies. The consideration of scrap, therefore, raises FDA's weighted average design cost estimate to approximately $3,600 per SKU.

iv. *Administrative costs.* NDMA suggested that the agency also include administrative costs in its calculation of the cost to redesign the label. NDMA provided no estimate of these costs, but noted that there would be a burden to manufacturers to manage the additional required redesign of labels.

FDA agrees that the rule will impose administrative costs, but concludes that these costs are adequately accounted for in the previous estimates. OTC drugs are highly regulated products and manufacturers are expected to have regulatory personnel on staff or consultants available to address compliance matters. The complexity of the rule is not unusual compared to other OTC drug regulations and the requirements will be clear to graphics design and regulatory personnel. Moreover, the rule is expected to receive widespread publicity when issued and most OTC drug firms belong to trade associations or have access to trade publications that provide additional sources of information. Because the rule permits a 2- to 3-year implementation period, FDA continues to believe that managing the label changes will not impose burdens beyond the costs included in the agency's estimate.

b. *Methodology for calculating economic impact.* NDMA disagreed with the methodology the agency used to calculate the economic impact of the proposed rule for two reasons: (1) FDA treated the cost to redesign as a financed rather than an expensed cost and calculated the impact using an amortized cost rather than a net present value, and (2) FDA treated label redesign as an accelerated change rather than an additional change.

i. *Economic versus accounting costs.* NDMA asserted that FDA used an incorrect valuation method to assess the economic impact of the rule, because the agency's valuation of amortized lost label life incorrectly implies that the costs of label redesign are financed costs, rather than sunk costs expensed in the year they incur. According to NDMA, the proper approach is not to amortize, but to calculate the net present value of the incremental costs of label redesign.

FDA does not agree that the amortization of lost label life is inappropriate. Executive Order 12866 charges Federal agencies to determine the economic cost of its rules, but such costs are not necessarily identical to financial costs, as interpreted by accounting convention. According to the U.S. Office of Management and Budget (Ref. 29), the preferred measure for economic analyses is ''the opportunity cost' of the resources used or the benefits forgone as a result of the regulatory action.'' Whether firms expense label design costs in the year they occur is largely irrelevant to the proper calculation of economic costs, i.e., the opportunity cost of the rule.

Moreover, FDA's calculation yields results that are identical to those obtained through a net present value approach. To derive its results, FDA estimated a net present value and then, for ease of exposition, converted this figure into an equivalent stream of annual costs.

ii. *Additive versus accelerated costs.* The primary reason that NDMA's methodology produces substantially higher costs than FDA's estimate is that NDMA's approach assumes a ''market driven'' label cycle that is independent of the design changes required by the rule. For example, if the average lifetime of a particular label type is 3 years and a design change costs $3,000 per SKU, both FDA and NDMA agree that a 2-year phase-in would allow two-thirds of the labels to be replaced under normal business conditions without additional costs (assuming no package size changes). FDA's methodology, however, also assumed that the remaining one-third of the labels lose only 1-year of their expected lifetime, so that the economic cost (ignoring any discounting adjustment) would be $1,000 per SKU (1/3 x $3,000) for one-third of these SKU's. This approach, however, implicitly assumes that the label design cycle would resume at a 3-year interval, so that the next voluntary label redesign, on average, would not occur until 3 years after the mandated change.

In contrast, NDMA argues that voluntary label redesign occurs in response to external ''market driven'' factors that would be independent of this mandated change. According to NDMA, such redesigns are to change product attribute copy; change graphics; add litigation-driven warnings; delete ''new'' flags after 6 months; add multilingual labeling; change labeling information, such as manufacturer, distributor, or inactive ingredient; or add or change SKU's in a product line. NDMA contends that, because the mandated changes required by this rule would not affect the underlying ''market driven'' design cycle, the full cost of the redesign, rather than just the value of the remaining life of the former label, measures the economic cost of the regulation.

With respect to the previous numerical example, NDMA's methodology implies that those labels that were redesigned in year 2 for regulatory reasons would, on average, be redesigned again in year 3 for ''market driven'' reasons. (FDA would assume that the labels that had to be redesigned in year 2 would not, on average, be redesigned again until year 5.) NDMA's methodology, therefore, would calculate the economic cost at about $3,000 per affected SKU, compared to FDA's estimate of about $1,000.

The agency does not dispute the theoretical possibility of NDMA's argument. If ''market driven'' reasons for label adjustments always compelled an immediate response, companies could not coordinate voluntary label updates with mandatory label redesign; the regulatory cost for each affected label, therefore, would be the full cost of the design change. However, FDA does not agree that such abrupt shifts in marketing strategies are the industry norm. Many of the examples of ''market driven'' label changes NDMA cited are for exactly the kind of incremental adjustments that would be deferred and consolidated in a major redesign effort. For example, the demand for most changes to product attribute copy or graphics mounts gradually in response to shifting advertising and marketing styles. Once changed, such modifications postpone the need for future change. Revisions for litigation-driven warnings are less common events that would be expected to have a small effect on industry averages. According to the RTI study (Ref. 26), line copy changes or changes affecting just one color are minor changes that, in most cases, are made without the assistance of a label artist and cost one-sixth the cost of a four-or-more color change. Such minor adjustments would not be expected to alter the underlying design cycle.

The agency finds it more likely that the demand for most major label changes is a steadily increasing function of the time that has elapsed since the last labeling revision and that manufacturers continually refine marketing techniques and strategies. As most companies will find it cost-effective to complete these incremental labeling changes concurrently with the mandatory redesign required by this rule, FDA's revised analysis maintains the assumption that the current labeling change cycle will continue unaltered. Moreover, it is important to note that the agency's decision not to exclude PDP design costs is based on its finding that incremental style modifications accompany mandated changes. If firms would not bundle incremental style changes with the mandated changes, the PDP design costs should be subtracted from the regulatory cost estimate.

c. *Cost of increasing size of packages and/or labels.* Several comments objected to FDA's assumption that the proposed rule would require few changes to the size or configuration of OTC drug packages or labels. NDMA reported that its survey indicated that 33 percent of branded and 95 percent of private label SKU's could not accommodate the proposed label format. NDMA estimated that exemption petitions would be filed for 33,500 SKU's, that 32,600 SKU's would alter package configuration at a cost of over $1 billion, and that about 15,500 SKU's would be removed from the market. While not including administrative costs for feasibility studies to determine cost-effective packaging and labeling configurations, NDMA stated that they would be large. One manufacturer suggested that a new packaging line to accommodate a label change for just one product line would result in a one-time equipment expenditure of about $2.5 million (including equipment, installation, validation, depreciation of old equipment, facility renovation, and inventory loss) and recurring costs of almost $500,000 for the more expensive labeling.

The previously mentioned projections greatly overestimate the percentage of SKU's that will not be able to accommodate the new format and the cost of increasing the size of the labeling, where necessary. In particular, the assertion that 95 percent of private label SKU's could not accommodate the proposal requirements is difficult to understand, as the vast majority of private label OTC drug products are packaged almost identically to the leading branded products for competitive reasons. Moreover, the agency carefully reviewed labels submitted as examples of those that would not fit the proposed format and found that many could, in fact, accommodate the final rule without a change in label or package size.

FDA also questions the methodology for calculating the costs of package size changes. Although details of these calculations were not submitted, it appears that NDMA estimated the cost of purchasing or modifying equipment by multiplying the unit costs by the number of affected SKU's, with no allowance for multiple SKU's packaged on a given production line, or for the widespread usage of contract packagers. Although agreeing that such factors should be considered when determining costs, NDMA nonetheless assumed substantial equipment requirements for each SKU. Moreover, NDMA does not differentiate between the costs of branded and private label manufacturers. Most private label products are manufactured by firms that produce hundreds of SKU's on the same equipment, as most packaging machines can accommodate a spectrum of changes with only minor modification or retooling. As firms will choose the most cost-effective means of implementing

package changes, only in rare cases, or when equipment is already obsolete, should the rule lead to the purchase of new equipment.

For some small SKU's, the impact of this rule will be moderated by the more flexible leading and formatting provisions in the final rule and the modified small package format allowed in 201.66(d)(10). FDA further believes that any reduced consumer choice, should a small package product not be able to meet the new requirements, will be relatively insignificant because most manufacturers offer products in more than one package size.

To respond fully to the estimates offered by NDMA, FDA asked its economics consultant, ERG, to survey (Ref. 28) all of the OTC drug products found on the shelves in three retail outlets in the Boston area. These outlets included: (1) A large pharmacy chain, (2) an independent pharmacy, and (3) a convenience store. ERG examined each of the 2,689 distinct SKU's found on the store shelves, and recorded data on the package size and type, the available labeling space, and the font size. ERG then compared these data to generic mock-ups of the revised monographs to estimate the percent of the SKU's that might need to increase the size of either the label or package. ERG also estimated the amount of the additional space needed to accommodate the new format for those SKU's that lacked sufficient labeling surface area, using an expansion factor to derive estimates for SKU's for which no adequate mock-ups were available.

The results of the survey are shown by type of package in Table 4 of this document. The vast majority of SKU's, 92 percent, have sufficient labeling space to accommodate the revised format. Of these, 16 percent will require some reconfiguration of the current information presentation, such as moving, reducing, or eliminating certain marketing information. Another 1.7 percent of the SKU's would increase the size of their label to accommodate the new format and 6.4 percent either would not fit or were indeterminate (too close to call) and, thus, might require a new packaging configuration. (SKU's were judged indeterminate when the available labeling area was within 5 square centimeters of the required area.)

TABLE 4.—FINDINGS FOR 6.0-POINT FONT, CONDENSED TYPE ALLOWED[1]

Labeling outcome	Percent of SKU's
Revised label can fit using existing area allotted for regulatory information	75.9
Revised label fits if area allotted for regulatory information is increased	16.0
Revised label fits if expanded on existing container	1.7
Revised label will not fit	4.5
Indeterminate	1.9
Total	100

[1] Horizontal width of the characters reduced by approximately 20 percent while the vertical height of the characters is unchanged.

To evaluate the estimate of reconfiguration costs (i.e., changes to the size of the labeling or packaging) presented in the comments, ERG considered several options for packaging changes, including adding a carton (if not already present), adding a fifth panel, increasing the size of the packaging, or switching to a nonstandard form of labeling such as peel-back or accordion labels (Ref. 28). Where applicable, the costs for changing a container size included container inventory loss, adjustment of the packaging line, and stability testing. The estimated packaging change costs varied with the option chosen (for example, adjustment or retooling of existing machinery versus the purchase of new equipment), although the lower cost options had a higher probability of selection. ERG also considered the recurring annual costs that would be associated with the need for larger labels or packages. A detailed description of ERG's assumptions, calculations, and unit costs is presented in the full report.

4. Total Incremental Costs

The costs of labeling redesign apply only to products covered by final OTC drug monographs or applications. Currently there are about 39,310 SKU's in this category (see Table 3 of this document). No redesign costs are assigned to the remaining 59,330 SKU's because the 6-year implementation period for these products will allow manufacturers to incorporate the design changes in their usual redesign cycle. Using a weighted average cost to redesign a label of $3,600 per SKU and assuming labels are redesigned voluntarily every 2, 3, or 6 years, the total incremental costs for redesigning labeling using the methodology discussed earlier is $19.4 million.

Reconfiguration costs apply to those products that cannot accommodate the small package format allowed in § 201.66(d)(10). These costs include the one-time cost to increase labeling size (the label or package, where applicable) to accommodate a minimum 6.0 condensed font, plus the recurring cost of producing larger labeling. Because these costs are applied to this rule regardless of the monograph status of the product, all 98,639 SKU's are potentially subject to label reconfiguration costs; 39,310 within 2 years of the effective date of this final rule, the remaining 59,330 within 6 years of the effective date of this final rule. The estimated reconfiguration costs amount to $38.1 million in one-time costs and $11.5 million in annual recurring costs. The latter reflects the incremental increases in labeling or packaging materials to accommodate the format requirements.

Table 5 of this document presents FDA's estimate of the one-time and annual recurring costs and the total annualized cost by compliance activity. The total one-time costs of $57.5 million include $19.4 million for label redesign and $38.1 million for packaging changes. The annual costs are $11.5 million. The total annualized cost to industry (using a 7 percent discount rate) is estimated at $18.4 million. The cost to individual firms will vary with the number of SKU's, the type of changes needed, and the timing of the changes.

TABLE 5.—TOTAL INDUSTRY COMPLIANCE COSTS

Activity	One-Time ($Million)	Annual ($Million)	Total Annualized
Label redesign	19.4	NA	1.4
Packaging	38.1	11.5	17.0
Total	57.5	11.5	18.4

These estimates may overstate the costs attributable to this rule. First, reconfiguration costs will be reduced to the extent that companies opt to eliminate some smaller packaging sizes within a product line. In these instances, however, consumers will bear some of the added costs. Second, the recent amendment to section 502(e) of the act under FDAMA requires that OTC drug manufacturers list the inactive ingredients in their labeling. The ERG retail outlet survey (Ref. 28) found that about 7 percent of the SKU's currently do not include inactive ingredients on their labels. Some of these products may need larger label or package sizes irrespective of this rule.

D. Small Business Impact

Manufacturers and those entities that engage in the relabeling of OTC drug products will be required to redesign the labeling of their products to comply with this rule. Census data provide aggregate industry statistics on the number of manufacturers for Standardized Industrial Classification Code 2834, Pharmaceutical Preparations, by establishment size, but do not distinguish between manufacturers of prescription and OTC drugs. Over 92 percent of the roughly 700 establishments and over 87 percent of the 650 firms in this sector have fewer than 500 employees. The Small Business Administration (SBA) considers firms with fewer than 750 employees in this industry to be small, but the U.S. Census size categories do not correspond to the SBA designation. An alternative data source, IMS, identified roughly 400 firms as manufacturers of OTC drug products. Using the SBA size designation of 750 employees, about 70 percent of the 400 affected manufacturing firms would be considered small.

This regulation will affect the information content and format associated with OTC drug product labeling. Firms that manufacture or relabel OTC drug products will need to change the information panel for each affected product and may need to increase the size of the packaging or labeling for a few SKU's. These costs will be mitigated, however, by the several year implementation period, which will permit many of these changes to be coordinated with those labeling changes conducted in the normal course of business. OTC drug products subject to new drug and ANDA's will need to submit revised labeling to the agency in accordance with § 314.70. This is a standard procedure that companies routinely follow for labeling changes. The final rule will not require new reporting and recordkeeping activities. Therefore, no additional professional skills are necessary.

The economic impact of this rule on small firms is particularly difficult to measure, because published financial data do not distinguish between firms manufacturing mostly OTC drugs and firms manufacturing mostly prescription drugs. ERG adopted Census data on firm size and revenue for SIC 2834, Pharmaceutical Preparations, and assumed 400 manufacturers of OTC drug products to derive the figures in Table 6 of this document. These data indicate that if 90 percent of the OTC drug product firms meet the SBA size criteria for small businesses, the annualized industry cost attributed to small businesses would amount to $12.3 million out of the total $18.4 million. If revenues of small OTC drug product manufacturers are similar to those of all small manufacturers in SIC 2834, these costs represent only 0.17 percent of small business OTC drug revenues.

TABLE 6.—SMALL BUSINESS IMPACT

	OTC Manufacturing Total	OTC Small Business Total
Firms	400	357
Establishments	478	374
Employees	86,849	18,942
Average employees per firm	217	53
Percentage of total small business employment	NA	100%
Receipts ($000)	$42,363,000	$7,411,000
Receipts per firm ($000)	$106,000	$21,000
Total SKU's affected	98,639	65,792
As percentage of all SKU's	100%	66.7%
Total annualized compliance costs ($ millions)	$18.4	$12.3
Total annualized compliance costs as percentage of annual revenues	0.0004	0.0017

These calculations, however, assume that small businesses can finance the one-time outlays over time. In fact, some small firms may have difficulty raising the funds. FDA finds that, on average, the incremental one-time cost per SKU is about $600 ($57.5 million ÷ 98,639 SKU's). If a small firm manufactures 10 or 20 SKU's, it might need to raise from $6,000 to $12,000 within the permitted implementation period. In view of the figures developed for Table 6 of this document, which imply that the annual revenue per SKU averages about $100,000 for small businesses, such one-time outlays should be manageable for most small firms.

The agency has taken a number of steps to minimize the impact on small entities, including: (1) A 2- to 6- year implementation period to allow the sale of existing product inventories and to permit coordination of required labeling changes with routine industry-initiated labeling changes, (2) a modified format for small packages, (3) an additional phase-in year for OTC drug products covered by a final monograph or an

approved drug application if yearly sales are less than $25,000, and (4) coordination of the FDAMA requirement for listing inactive ingredients with the implementation of this rule. These provisions will provide additional flexibility and cost savings for small entities.

E. Alternatives

The major regulatory alternatives considered included various implementation periods and graphics features, including font sizes and print types. As shown in Table 7 of this document, redesign costs for the 39,310 SKU's with a final monograph decrease substantially with longer implementation periods for products covered by final monographs or approved drug applications. One-time costs for a 1-year implementation period would be about $59.1 million. A 2-year implementation period reduces this figure to $27 million and a 3-year period to $11.9 million. The selected alternative, which includes the 2-year implementation period, but permits a third year for products with low volume sales, reduces these redesign costs to $19.4 million. The agency believes this implementation period will provide substantial relief to industry while achieving important consumer safety and use goals in a timely manner.

TABLE 7.—EFFECT OF IMPLEMENTATION PERIOD ON REDESIGN COSTS

Implementation Period for Final Monographs	Cost ($ Millions)	Redesign Cost With 1 Additional Year for Low Volume Products ($ Millions)
1 year	59.1	46.9
2 years	27.0	19.4
3 years	11.9	8.9

FDA also considered alternative requirements for minimum font sizes and print types. Table 8 of this document presents, for several alternatives, ERG's estimates of the percent of SKU's with current labels too small to fit, the one-time costs for labeling reconfiguration, and the recurring label, carton, and container costs, under varied font size and print requirements. The annualized cost for a minimum 6.0 font but not condensed type (i.e., the horizontal width of the characters reduced approximately 10 to 20 percent while the vertical height of the characters is unchanged) requirement would be $25 million. The final rule allows condensed print, which reduces this cost to $17 million. The agency considered but rejected labeling with smaller than 6-point type size because of the readability issues associated with such labeling.

TABLE 8.—EFFECT OF PRINT REQUIREMENTS ON LABELING RECONFIGURATION COSTS

Minimum Font Size, Print Type Required	Percent of SKU's That Cannot Fit or Are Indeterminate	One-Time Packaging Reconfiguration ($ Millions)	Recurring Incremental Label, Carton and Container Materials ($ Millions)	Total Annualized Packaging Cost ($ Millions)
6.0, not condensed	9.5	45.9	18.3	25.0
6.0, condensed allowed	6.4	38.1	11.5	17.0
4.5, not condensed	3.4	21.0	5.1	8.2
4.5, condensed allowed	2.3	14.0	3.4	5.4

This final rule has been determined to be a major rule for purposes of 5 U.S.C. 801 *et. seq.*, subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121). FDA is submitting the information and reports as required by the statute.

IX. References

The following references are on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Miller, G. A., ''The Magical Number Seven, Plus or Minus Two: Some limits on Our Capacity for Processing Information,'' *Psychological Review*, 101(2):343–352, 1994.

2. Shiffrin, R. M., and R. M. Nosofsky, ''Seven Plus or Minus Two: A Commentary On Capacity Limitations,'' *Psychological Review*, 101(2):357–361, 1994.

3. Allen, P. A., and L. C. Crozier, ''Age and Ideal Chunk Size,'' *Journal of Gerontology: Psychological Sciences*, 47(1):47–51, 1992.

4. Wood, R., and A. Bandura, ''Impact of Conceptions of Ability on Self-Regulatory Mechanisms and Complex Decision Making,'' *Journal of Personality and Social Psychology*, 56(3): 407–415, 1989.

5. Chandler, P., and J. Sweller, ''Cognitive Load Theory and the Format of Instruction,'' *Cognition and Instruction*, 8(4):293–332, 1991.

6. Food and Drug Administration, ''National Uniformity for Nonprescription Drugs—Ingredient Listing for OTC Drugs,'' April 1998, Docket No. 98D–0149, Dockets Management Branch.

7. Comment No. 718, Docket No. 96P–0318, Dockets Management Branch.

8. Comment No. 684, Docket No. 96P–0318, Dockets Management Branch.

9. *Webster's Ninth New Collegiate Dictionary*, p. 371, 1990.

10. Nonprescription Drug Manufacturers Association, ''Label Readability Guidelines,'' May 1996, in OTC vol. 28FR, Docket No. 96N–0420, Dockets Management Branch.

11. Watanabe, R. K., ''The Ability of the Geriatric Population to Read Labels on Over-the-Counter Medication Containers,'' *Journal of the American Optometric Association*, 65:32–37, 1994.

12. Comment No. CP1, Docket No. 96P–0318, Dockets Management Branch.

13. Letter from R. G. Chesemore, FDA, to B. Nakutin, dated April 22, 1997, coded PDN1, Docket No. 96P–0318, Dockets Management Branch.

14. Food and Drug Administration ''Consumer Comprehension and Preference for Variation in the Proposed Over-the-Counter Drug Labeling Format,'' in OTC vol. 28FR, Docket No. 96N–0420, Dockets Management Branch.

15. Levy, A. S., S. B. Fein, and R. E. Schucker, ''More Effective Nutrition Label Formats Are Not Necessarily More Preferred,'' *Journal of the American Dietetic Association*, 92(10):1230–1234, 1992.

16. Einarson, T. R., ''Drug-Related Hospital Admissions,'' *The Annals of Pharmacotherapy*, 27:832–840, 1993.

17. Ives, T. J., E. J. Bentz, and R. E. Gwyther, ''Drug-Related Admissions to a Family Medicine Inpatient Service,'' *Archives of Internal Medicine*, 147:1117–1120, 1987.

18. Caranasos, G. J., R. Stewart, and L. E. Cluff, ''Drug-induced Illness Leading to

Hospitalization,'' *Journal of the American Medical Association*, 228:713–7171, 1974.

19. Mitchell, A. A. et al., ''Adverse Drug Reactions in Children Leading to Hospital Admission,'' *Pediatrics*, 82:24–29, 1988.

20. Classen, D. C. et al., ''Adverse Drug Events in Hospitalized Patients,'' *Journal of the American Medical Association*, 277(4):301–306, 1997.

21. Agency for Health Care Policy and Research, ''National Medical Expenditure Survey: Annual Expenses and Sources of Payment for Health Care Services Research Findings 14,'' p. 7, 1995.

22. McKenney, J. M., and W. L. Harrison, ''Drug-related Hospital Admissions,'' *American Journal of Hospital Pharmacists*, 33:792–795, 1976.

23. U.S. Department of Commerce, ''Statistical Abstract of the United States 1998,'' *The National Data Book*, Table 683, 118:426, 1998.

24. U.S. Department of Commerce, ''1992 Census of Retail Trade; Establishment and Firm Size,'' Table 3, pp. 56, 57, and 68, 1992.

25. Comment No. 716, Supplement No. 2 (attachment 1, appendix G), Docket No. 96N–0420, Dockets Management Branch.

26. Research Triangle Institute, ''Compliance Cost of Food Labeling Regulations: Final Report (January, 1991),'' FDA contract number 223–87–2097, Docket Nos. 90N–0134 and 90N–0135, Dockets Management Branch.

27. Comment No. C717, Docket No. 96N–0420, Dockets Management Branch.

28. Eastern Research Group, Inc., ''Cost Impacts of the Over-the-Counter Pharmaceutical Labeling Rule,'' in OTC vol. 28FR, Docket No. 96N–0420, Dockets Management Branch.

29. Office of Management and Budget, ''Economic Analysis of Federal Regulations Under Executive Order 12866,'' 1996.

List of Subjects

21 CFR Part 201

Drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 330

Over-the-counter drugs.

21 CFR Parts 331, 341, 346, 355, and 358

Labeling, Over-the-counter drugs.

21 CFR Part 369

Labeling, Medical devices, Over-the-counter drugs.

21 CFR Part 701

Cosmetics, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 201, 330, 331, 341, 346, 355, 358, 369, and 701 are amended as follows:

PART 201—LABELING

1. The authority citation for 21 CFR part 201 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 358, 360, 360b, 360gg–360ss, 371, 374, 379e; 42 U.S.C. 216, 241, 262, 264.

2. Section 201.63 is amended by revising the section heading, the first sentence in paragraph (a), and paragraph (e) to read as follows:

§ 201.63 Pregnancy/breast-feeding warning.

(a) The labeling for all over-the-counter (OTC) drug products that are intended for systemic absorption, unless specifically exempted, shall contain a general warning under the heading ''Warning'' (or ''Warnings'' if it appears with additional warning statements) as follows: ''If pregnant or breast-feeding, ask a health professional before use.'' [first four words of this statement in bold type] * * *

* * * * *

(e) The labeling of orally or rectally administered OTC aspirin and aspirin-containing drug products must bear a warning that immediately follows the general warning identified in paragraph (a) of this section. The warning shall be as follows:

''It is especially important not to use'' (select ''aspirin'' or ''carbaspirin calcium,'' as appropriate) ''during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.''

3. Section 201.64 is amended by revising the last sentence in paragraph (b) to read as follows:

§ 201.64 Sodium labeling.

* * * * *

(b) * * * The sodium content per dosage unit shall follow the heading ''Other information'' as stated in § 201.66(c)(7).

* * * * *

4. Section 201.66 is added to subpart C to read as follows:

§ 201.66 Format and content requirements for over-the-counter (OTC) drug product labeling.

(a) *Scope*. This section sets forth the content and format requirements for the labeling of all OTC drug products. Where an OTC drug product is the subject of an applicable monograph or regulation that contains content and format requirements that conflict with this section, the content and format requirements in this section must be followed unless otherwise specifically provided in the applicable monograph or regulation.

(b) *Definitions*. The following definitions apply to this section:

(1) *Act* means the Federal Food, Drug, and Cosmetic Act (secs. 201 *et seq*. (21 U.S.C. 321 *et seq*.)).

(2) *Active ingredient* means any component 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 body of humans. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect.

(3) *Approved drug application* means a new drug (NDA) or abbreviated new drug (ANDA) application approved under section 505 of the act (21 U.S.C. 355).

(4) *Bullet* means a geometric symbol that precedes each statement in a list of statements. For purposes of this section, the bullet style is limited to solid squares or solid circles, in the format set forth in paragraph (d)(4) of this section.

(5) *Established name* of a drug or ingredient thereof means the applicable official name designated under section 508 of the act (21 U.S.C. 358), or, if there is no designated official name and the drug or ingredient is recognized in an official compendium, the official title of the drug or ingredient in such compendium, or, if there is no designated official name and the drug or ingredient is not recognized in an official compendium, the common or usual name of the drug or ingredient.

(6) *FDA* means the Food and Drug Administration.

(7) *Heading* means the required statements in quotation marks listed in paragraphs (c)(2) through (c)(9) of this section, excluding subheadings (as defined in paragraph (a)(9) of this section).

(8) *Inactive ingredient* means any component other than an active ingredient.

(9) *Subheading* means the required statements in quotation marks listed in paragraphs (c)(5)(ii) through (c)(5)(vii) of this section.

(10) *Drug facts labeling* means the title, headings, subheadings, and information required under or otherwise described in paragraph (c) of this section.

(11) *Title* means the heading listed at the top of the required OTC drug product labeling, as set forth in paragraph (c)(1) of this section.

(12) *Total surface area available to bear labeling* means all surfaces of the outside container of the retail package or, if there is no such outside container, all surfaces of the immediate container or container wrapper except for the flanges at the tops and bottoms of cans and the shoulders and necks of bottles and jars.

(c) *Content requirements.* The outside container or wrapper of the retail package, or the immediate container label if there is no outside container or wrapper, shall contain the title, headings, subheadings, and information set forth in paragraphs (c)(1) through (c)(8) of this section, and may contain the information under the heading in paragraph (c)(9) of this section, in the order listed.

(1) (Title) ''Drug Facts''. If the drug facts labeling appears on more than one panel, the title ''Drug Facts (continued)'' shall appear at the top of each subsequent panel containing such information.

(2) ''Active ingredient'' or ''Active ingredients'' ''(in each [insert the dosage unit stated in the directions for use (e.g., tablet, 5 mL teaspoonful) or in each gram as stated in §§ 333.110 and 333.120 of this chapter])'', followed by the established name of each active ingredient and the quantity of each active ingredient per dosage unit. Unless otherwise provided in an applicable OTC drug monograph or approved drug application, products marketed without discrete dosage units (e.g., topicals) shall state the proportion (rather than the quantity) of each active ingredient.

(3) ''Purpose'' or ''Purposes'', followed by the general pharmacological category(ies) or the principal intended action(s) of the drug or, where the drug consists of more than one ingredient, the general pharmacological categories or the principal intended actions of each active ingredient. When an OTC drug monograph contains a statement of identity, the pharmacological action described in the statement of identity shall also be stated as the purpose of the active ingredient.

(4) ''Use'' or ''Uses'', followed by the indication(s) for the specific drug product.

(5) ''Warning'' or ''Warnings'', followed by one or more of the following, if applicable:

(i) ''For external use only'' [in bold type] for topical drug products not intended for ingestion, or ''For'' (select one of the following, as appropriate: ''rectal'' or ''vaginal'') ''use only'' [in bold type].

(ii) All applicable warnings listed in paragraphs (c)(5)(ii)(A) through (c)(5)(ii)(G) of this section with the appropriate subheadings highlighted in bold type:

(A) Allergic reaction warnings set forth in any applicable OTC drug monograph or approved drug application for any product that requires a separate allergy warning. This warning shall follow the subheading ''Allergy alert:''

(B) Reye's syndrome warning for drug products containing salicylates set forth in § 201.314(h)(1). This warning shall follow the subheading ''Reye's syndrome:''

(C) Flammability warning, with appropriate flammability signal word (e.g., §§ 358.150(c) and 358.550(c) of this chapter). This warning shall follow a subheading containing the appropriate flammability signal word described in an applicable OTC drug monograph or approved drug application.

(D) Water soluble gums warning set forth in § 201.319. This warning shall follow the subheading ''Choking:''

(E) Alcohol warning set forth in § 201.322. This warning shall follow the subheading ''Alcohol warning:''

(F) Sore throat warning set forth in § 201.315. This warning shall follow the subheading ''Sore throat warning:''

(G) Warning for drug products containing sodium phosphates set forth in § 201.307(b)(2)(i) or (b)(2)(ii). This warning shall follow the subheading ''Dosage warning:''

(iii) ''Do not use'' [in bold type], followed by all contraindications for use with the product. These contraindications are absolute and are intended for situations in which consumers should not use the product unless a prior diagnosis has been established by a doctor or for situations in which certain consumers should not use the product under any circumstances regardless of whether a doctor or health professional is consulted.

(iv) ''Ask a doctor before use if you have'' [in bold type] or, for products labeled only for use in children under 12 years of age, ''Ask a doctor before use if the child has'' [in bold type], followed by all warnings for persons with certain preexisting conditions (excluding pregnancy) and all warnings for persons experiencing certain symptoms. The warnings under this heading are those intended only for situations in which consumers should not use the product until a doctor is consulted.

(v) ''Ask a doctor or pharmacist before use if you are'' [in bold type] or, for products labeled only for use in children under 12 years of age, ''Ask a doctor or pharmacist before use if the child is'' [in bold type], followed by all drug-drug and drug-food interaction warnings.

(vi) ''When using this product'' [in bold type], followed by the side effects that the consumer may experience, and the substances (e.g., alcohol) or activities (e.g., operating machinery, driving a car, warnings set forth in § 369.21 of this chapter for drugs in dispensers pressurized by gaseous propellants) to avoid while using the product.

(vii) ''Stop use and ask a doctor if'' [in bold type], followed by any signs of toxicity or other reactions that would necessitate immediately discontinuing use of the product.

(viii) Any required warnings in an applicable OTC drug monograph, other OTC drug regulations, or approved drug application that do not fit within one of the categories listed in paragraphs (c)(5)(i) through (c)(5)(vii), (c)(5)(ix), and (c)(5)(x) of this section.

(ix) The pregnancy/breast-feeding warning set forth in § 201.63(a); the third trimester warning set forth in § 201.63(e) for products containing aspirin or carbaspirin calcium; the third trimester warning set forth in approved drug applications for products containing ketoprofen, naproxen sodium, and ibuprofen (not intended exclusively for use in children).

(x) The ''Keep out of reach of children'' warning and the accidental overdose/ingestion warning set forth in § 330.1(g) of this chapter.

(6) ''Directions'', followed by the directions for use described in an applicable OTC drug monograph or approved drug application.

(7) ''Other information'', followed by additional information that is not included under paragraphs (c)(2) through (c)(6), (c)(8), and (c)(9) of this section, but which is required by or is made optional under an applicable OTC drug monograph, other OTC drug regulation, or is included in the labeling of an approved drug application.

(i) Required information about certain ingredients in OTC drug products (e.g., sodium in § 201.64(c)) shall appear as follows: ''each (insert appropriate dosage unit) contains:'' [in bold type] (insert name(s) of ingredient(s) and the quantity of each ingredient). This information shall be the first statement under this heading.

(ii) The phenylalanine/aspartame content required by § 201.21(b), if applicable, shall appear as the next item of information.

(iii) Additional information that is authorized to appear under this heading shall appear as the next item(s) of information. There is no required order for this subsequent information.

(8) ''Inactive ingredients'', followed by a listing of the established name of each inactive ingredient. If the product is an OTC drug product that is not also a cosmetic product, then the inactive ingredients shall be listed in alphabetical order. If the product is an OTC drug product that is also a cosmetic product, then the inactive ingredients shall be listed as set forth in § 701.3(a) or (f) of this chapter, the names of cosmetic ingredients shall be determined in accordance with § 701.3(c) of this chapter, and the provisions in § 701.3(e), (g), (h), (l), (m), (n), and (o) of this chapter and § 720.8 of this chapter may also apply, as appropriate. If there is a difference in the labeling provisions in this § 201.66 and §§ 701.3 and 720.8 of this chapter, the labeling provisions in this § 201.66 shall be used.

(9) ''Questions?'' or ''Questions or comments?'', followed by the telephone number of a source to answer questions about the product. It is recommended that the days of the week and times of the day when a person is available to respond to questions also be included. A graphic of a telephone or telephone receiver may appear before the heading. The telephone number must appear in a minimum 6-point bold type.

(d) *Format requirements*. The title, headings, subheadings, and information set forth in paragraphs (c)(1) through (c)(9) of this section shall be presented on OTC drug products in accordance with the following specifications. In the interest of uniformity of presentation, FDA strongly reccommends that the Drug Facts labeling be presented using the graphic specifications set forth in appendix A to part 201.

(1) The title ''Drug Facts'' or ''Drug Facts (continued)'' shall use uppercase letters for the first letter of the words ''Drug'' and ''Facts.'' All headings and subheadings in paragraphs (c)(2) through (c)(9) of this section shall use an uppercase letter for the first letter in the first word and lowercase letters for all other words. The title, headings, and subheadings in paragraphs (c)(1), (c)(2), and (c)(4) through (c)(9) of this section shall be left justified.

(2) The letter height or type size for the title ''Drug Facts'' shall appear in a type size larger than the largest type size used in the Drug Facts labeling. The letter height or type size for the title ''Drug Facts (continued)'' shall be no smaller than 8-point type. The letter height or type size for the headings in paragraphs (c)(2) through (c)(9) of this section shall be the larger of either 8-point or greater type, or 2-point sizes greater than the point size of the text. The letter height or type size for the subheadings and all other information described in paragraphs (c)(2) through (c)(9) of this section shall be no smaller than 6-point type.

(3) The title, headings, subheadings, and information in paragraphs (c)(1) through (c)(9) of this section shall be legible and clearly presented, shall not appear in reverse type, shall have at least 0.5-point leading (i.e., space between two lines of text), and shall not have letters that touch. The type style for the title, headings, subheadings, and all other required information described in paragraphs (c)(2) through (c)(9) of this section shall be any single, clear, easy-to-read type style, with no more than 39 characters per inch. The title and headings shall be in bold italic, and the subheadings shall be in bold type, except that the word ''(continued)'' in the title ''Drug Facts (continued)'' shall be regular type. The type shall be all black or one dark color, printed on a white or other light, neutral color, contrasting background, except that the title and the headings may be presented in a single, alternative, contrasting dark color unless otherwise provided in an approved drug application, OTC drug monograph (e.g., current requirements for bold print in §§ 341.76 and 341.80 of this chapter), or other OTC drug regulation (e.g., the requirement for a box and red letters in § 201.308(c)(1)).

(4) When there is more than one statement, each individual statement listed under the headings and subheadings in paragraphs (c)(4) through (c)(7) of this section shall be preceded by a solid square or solid circle bullet of 5-point type size. Bullets shall be presented in the same shape and color throughout the labeling. The first bulleted statement on each horizontal line of text shall be either left justified or separated from an appropriate heading or subheading by at least two square ''ems'' (i.e., two squares of the size of the letter ''M''). If more than one bulleted statement is placed on the same horizontal line, the end of one bulleted statement shall be separated from the beginning of the next bulleted statement by at least two square ''ems'' and the complete additional bulleted statement(s) shall not continue to the next line of text. Additional bulleted statements appearing on each subsequent horizontal line of text under a heading or subheading shall be vertically aligned with the bulleted statements appearing on the previous line.

(5) The title, headings, subheadings, and information set forth in paragraphs (c)(1) through (c)(9) of this section may appear on more than one panel on the outside container of the retail package, or the immediate container label if there is no outside container or wrapper. The continuation of the required content and format onto multiple panels must retain the required order and flow of headings, subheadings, and information. A visual graphic (e.g., an arrow) shall be used to signal the continuation of the Drug Facts labeling to the next adjacent panel.

(6) The heading and information required under paragraph (c)(2) of this section shall appear immediately adjacent and to the left of the heading and information required under paragraph (c)(3) of this section. The active ingredients and purposes shall be aligned under the appropriate headings such that the heading and information required under paragraph (c)(2) of this section shall be left justified and the heading and information required under paragraph (c)(3) of this section shall be right justified. If the OTC drug product contains more than one active ingredient, the active ingredients shall be listed in alphabetical order. If more than one active ingredient has the same purpose, the purpose need not be repeated for each active ingredient, provided the information is presented in a manner that readily associates each active ingredient with its purpose (i.e., through the use of brackets, dot leaders, or other graphical features). The information described in paragraphs (c)(4) and (c)(6) through (c)(9) of this section may start on the same line as the required headings. None of the information described in paragraph (c)(5) of this section shall appear on the same line as the ''Warning'' or ''Warnings'' heading.

(7) Graphical images (e.g., the UPC symbol) and information not described in paragraphs (c)(1) through (c)(9) of this section shall not appear in or in any way interrupt the required title, headings, subheadings, and information in paragraphs (c)(1) through (c)(9) of this section. Hyphens shall not be used except to punctuate compound words.

(8) The information described in paragraphs (c)(1) through (c)(9) of this section shall be set off in a box or similar enclosure by the use of a barline. A distinctive horizontal barline extending to each end of the ''Drug Facts'' box or similar enclosure shall provide separation between each of the headings listed in paragraphs (c)(2) through (c)(9) of this section. When a heading listed in paragraphs (c)(2) through (c)(9) of this section appears on a subsequent panel immediately after the ''Drug Facts (continued)'' title, a horizontal hairline shall follow the title and immediately precede the heading. A horizontal hairline extending within two spaces on either side of the ''Drug

Facts'' box or similar enclosure shall immediately follow the title and shall immediately precede each of the subheadings set forth in paragraph (c)(5) of this section, except the subheadings in paragraphs (c)(5)(ii)(A) through (c)(5)(ii)(G) of this section.

(9) The information set forth in paragraph (c)(6) of this section under the heading ''Directions'' shall appear in a table format when dosage directions are provided for three or more age groups or populations. The last line of the table may be the horizontal barline immediately preceding the heading of the next section of the labeling.

(10) If the title, headings, subheadings, and information in paragraphs (c)(1) through (c)(9) of this section, printed in accordance with the specifications in paragraphs (d)(1) through (d)(9) of this section, and any other FDA required information for drug products, and, as appropriate, cosmetic products, other than information required to appear on a principle display panel, requires more than 60 percent of the total surface area available to bear labeling, then the Drug Facts labeling shall be printed in accordance with the specifications set forth in paragraphs (d)(10)(i) through (d)(10)(v) of this section. In determining whether more than 60 percent of the total surface area available to bear labeling is required, the indications for use listed under the ''Use(s)'' heading, as set forth in paragraph (c)(4) of this section, shall be limited to the minimum required uses reflected in the applicable monograph, as provided in § 330.1(c)(2) of this chapter.

(i) Paragraphs (d)(1), (d)(5), (d)(6), and (d)(7) of this section shall apply.

(ii) Paragraph (d)(2) of this section shall apply except that the letter height or type size for the title ''Drug Facts (continued)'' shall be no smaller than 7-point type and the headings in paragraphs (c)(2) through (c)(9) of this section shall be the larger of either 7-point or greater type, or 1-point size greater than the point size of the text.

(iii) Paragraph (d)(3) of this section shall apply except that less than 0.5-point leading may be used, provided the ascenders and descenders do not touch.

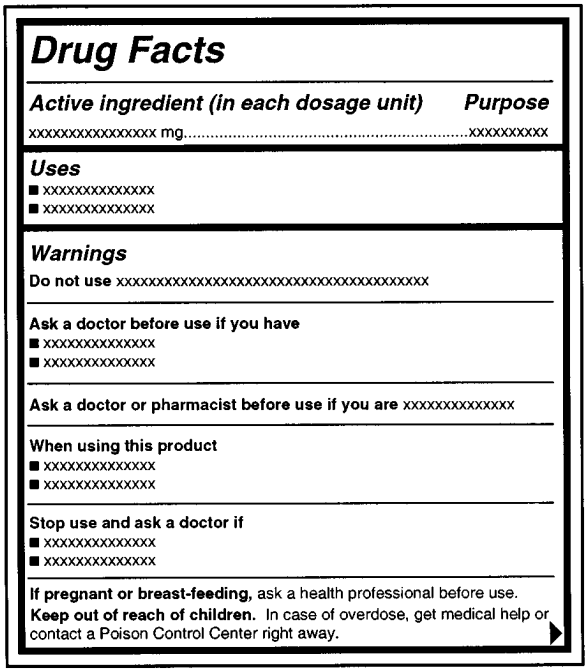
(iv) Paragraph (d)(4) of this section shall apply except that if more than one bulleted statement is placed on the same horizontal line, the additional bulleted statements may continue to the next line of text, and except that the bullets under each heading or subheading need not be vertically aligned.

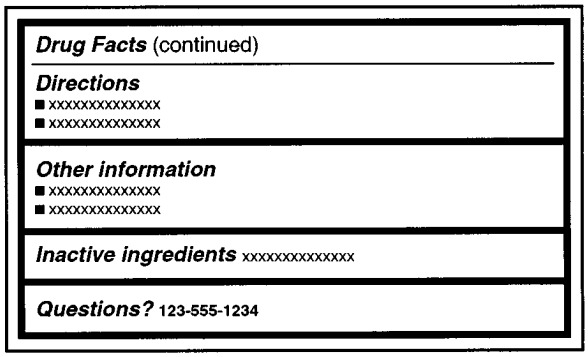
(v) Paragraph (d)(8) of this section shall apply except that the box or similar enclosure required in paragraph (d)(8) of this section may be omitted if the Drug Facts labeling is set off from the rest of the labeling by use of color contrast.

(11)(i) The following labeling outlines the various provisions in paragraphs (c) and (d) of this section:

BILLING CODE 4160–01–F

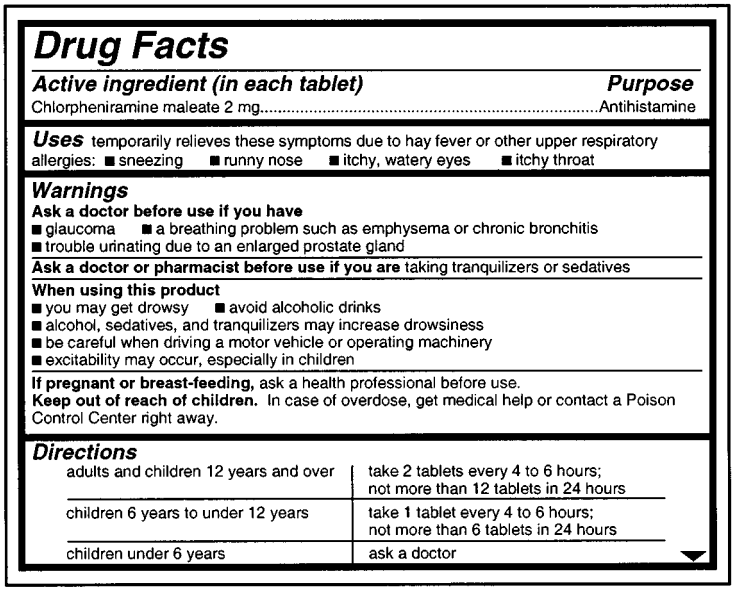
OTC Drug Product Labeling Outline





BILLING CODE 4160–01–C

(ii) The following sample label illustrates the provisions in paragraphs (c) and (d) of this section:



Drug Facts

Active ingredient (in each tablet) ***Purpose***

Chlorpheniramine maleate 2 mg ..... Antihistamine

Uses temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: ■ sneezing ■ runny nose ■ itchy, watery eyes ■ itchy throat

Warnings

Ask a doctor before use if you have
■ glaucoma ■ a breathing problem such as emphysema or chronic bronchitis
■ trouble urinating due to an enlarged prostate gland

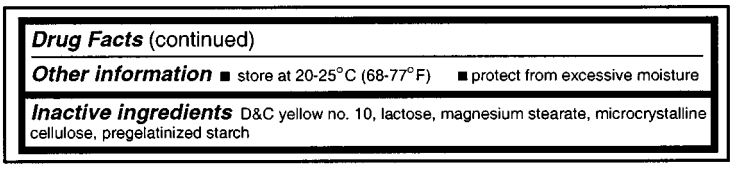
Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives

When using this product
■ you may get drowsy ■ avoid alcoholic drinks
■ alcohol, sedatives, and tranquilizers may increase drowsiness
■ be careful when driving a motor vehicle or operating machinery
■ excitability may occur, especially in children

If pregnant or breast-feeding, ask a health professional before use.
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

adults and children 12 years and over	take 2 tablets every 4 to 6 hours; not more than 12 tablets in 24 hours
children 6 years to under 12 years	take 1 tablet every 4 to 6 hours; not more than 6 tablets in 24 hours
children under 6 years	ask a doctor

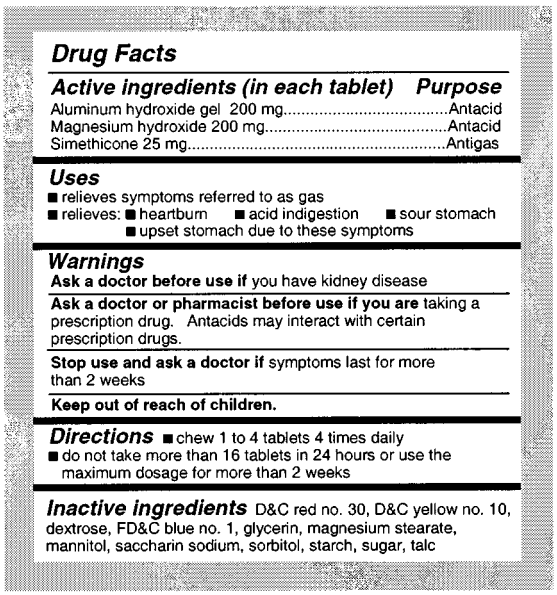


Drug Facts (continued)

Other information ■ store at 20-25°C (68-77°F) ■ protect from excessive moisture

Inactive ingredients D&C yellow no. 10, lactose, magnesium stearate, microcrystalline cellulose, pregelatinized starch

(iii) The following sample label illustrates the provisions in paragraphs (c) and (d) of this section, including paragraph (d)(10) of this section, which permits modifications for small packages:



Drug Facts

Active ingredients (in each tablet) ***Purpose***

Aluminum hydroxide gel 200 mg ..... Antacid
Magnesium hydroxide 200 mg ..... Antacid
Simethicone 25 mg ..... Antigas

Uses
■ relieves symptoms referred to as gas
■ relieves: ■ heartburn ■ acid indigestion ■ sour stomach ■ upset stomach due to these symptoms

Warnings

Ask a doctor before use if you have kidney disease

Ask a doctor or pharmacist before use if you are taking a prescription drug. Antacids may interact with certain prescription drugs.

Stop use and ask a doctor if symptoms last for more than 2 weeks

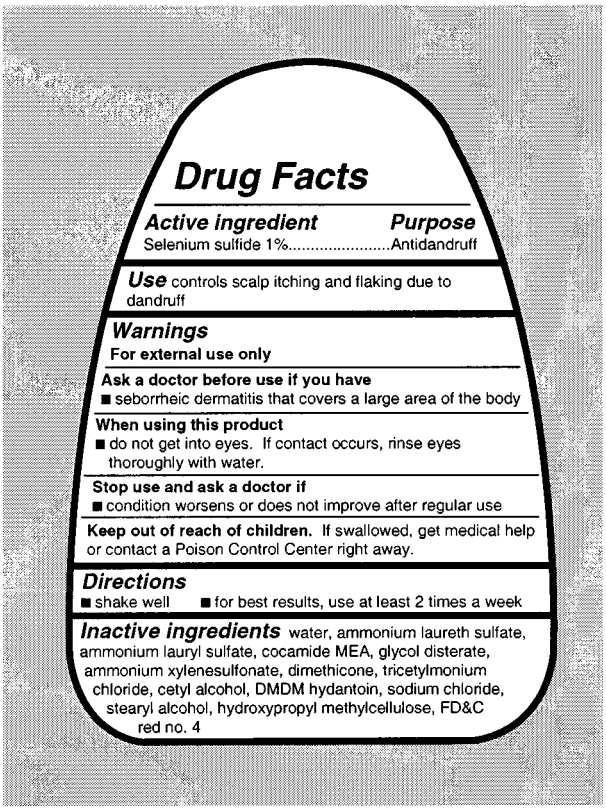
Keep out of reach of children.

Directions ■ chew 1 to 4 tablets 4 times daily
■ do not take more than 16 tablets in 24 hours or use the maximum dosage for more than 2 weeks

Inactive ingredients D&C red no. 30, D&C yellow no. 10, dextrose, FD&C blue no. 1, glycerin, magnesium stearate, mannitol, saccharin sodium, sorbitol, starch, sugar, talc

BILLING CODE 4160–01–C

(iv) The following sample label illustrates the provisions in paragraphs (c) and (d) of this section for a drug product marketed with cosmetic claims:



BILLING CODE 4160–01–C

(e) *Exemptions and deferrals.* FDA on its own initiative or in response to a written request from any manufacturer, packer, or distributor, may exempt or defer, based on the circumstances presented, one or more specific requirements set forth in this section on the basis that the requirement is inapplicable, impracticable, or contrary to public health or safety. Requests for exemptions shall be submitted in three copies in the form of an ''Application for Exemption'' to the Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. The request shall be clearly identified on the envelope as a ''Request for Exemption from 21 CFR 201.66 (OTC Labeling Format)'' and shall be directed to Docket No. 98N–0337. A separate request shall be submitted for each OTC drug product. Sponsors of a product marketed under an approved drug application shall also submit a single copy of the exemption request to their application. Decisions on exemptions and deferrals will be maintained in a permanent file in this docket for public review. Exemption and deferral requests shall:

(1) Document why a particular requirement is inapplicable, impracticable, or is contrary to public health or safety; and

(2) Include a representation of the proposed labeling, including any outserts, panel extensions, or other graphical or packaging techniques intended to be used with the product.

(f) *Interchangeable terms and connecting terms.* The terms listed in § 330.1(i) of this chapter may be used interchangeably in the labeling of OTC drug products, provided such use does not alter the meaning of the labeling that has been established and identified in an applicable OTC drug monograph or by regulation. The terms listed in § 330.1(j) of this chapter may be deleted from the labeling of OTC drug products when the labeling is revised to comply with this section, provided such deletion does not alter the meaning of the labeling that has been established and identified in an applicable OTC drug monograph or by regulation. The terms listed in § 330.1(i) and (j) of this chapter shall not be used to change in any way the specific title, headings, and subheadings required under paragraphs (c)(1) through (c)(9) of this section.

(g) *Regulatory action.* An OTC drug product that is not in compliance with the format and content requirements in this section is subject to regulatory action.

5. Section 201.314 is amended by revising the first two sentences in paragraph (a) and by revising paragraphs (g)(1) and (h)(1) to read as follows:

§ 201.314 Labeling of drug preparations containing salicylates.

(a) The label of any oral drug preparation intended for sale without prescription and which contains any salicylate ingredient (including aspirin, salicylamide, other salicylates, and combinations) must conspicuously bear, on a clearly contrasting background, the warning statement: ''Keep out of reach of children [highlighted in bold type]. In case of overdose, get medical help or contact a Poison Control Center right away,'' or ''Keep out of reach of children [highlighted in bold type],'' except that if the article is an aspirin preparation, it shall bear the first of these warning statements. * * *

* * * * *

(g)(1) The label of any drug containing more than 5 percent methyl salicylate

(wintergreen oil) should bear a conspicuous warning such as: ''Do not use otherwise than as directed.'' These drug products must also include the ''Keep out of reach of children'' warning and the accidental ingestion warning as required in § 330.1(g) of this chapter.

* * * * *

(h)(1) The labeling of orally or rectally administered over-the-counter aspirin and aspirin-containing drug products subject to this paragraph is required to prominently bear a warning. The warning shall be as follows: ''Children and teenagers should not use this medicine for chicken pox or flu symptoms before a doctor is consulted about Reye syndrome, a rare but serious illness reported to be associated with aspirin.''

* * * * *

6. Section 201.319 is amended by revising paragraph (b) to read as follows:

§ 201.319 Water-soluble gums, hydrophilic gums, and hydrophilic mucilloids (including, but not limited to agar, alginic acid, calcium polycarbophil, carboxymethylcellulose sodium, carrageenan, chondrus, glucomannan ((B-1,4, linked) polymannose acetate), guar gum, karaya gum, kelp, methylcellulose, plantago seed (psyllium), polycarbophil, tragacanth, and xanthan gum) as active ingredients; required warnings and directions.

* * * * *

(b) Any drug products for human use containing a water-soluble gum, hydrophilic gum, or hydrophilic mucilloid as an active ingredient in an oral dosage form when marketed in a dry or incompletely hydrated form as described in paragraph (a) of this section are misbranded within the meaning of section 502 of the Federal Food, Drug, and Cosmetic Act unless their labeling bears the following warnings (under the subheading ''Choking'') and directions:

'''Choking' [highlighted in bold type]: Taking this product without adequate fluid may cause it to swell and block your throat or esophagus and may cause choking. Do not take this product if you have difficulty in swallowing. If you experience chest pain, vomiting, or difficulty in swallowing or breathing after taking this product, seek immediate medical attention;'' and

'''Directions' [highlighted in bold type]:'' (Select one of the following, as appropriate: ''Take'' or ''Mix'') ''this product (child or adult dose) with at least 8 ounces (a full glass) of water or other fluid. Taking this product without enough liquid may cause choking. See choking warning.''

* * * * *

7. Appendix A is added to part 201 to read as follows:

Appendix A to Part 201—Examples of Graphic Enhancements Used by FDA

I. Section 201.66 Standard Labeling Format

A. Overall

1. The ''Drug Facts'' labeling is set off in a box or similar enclosure by the use of a barline with all black type printed on a white, color contrasting background.

B. Typeface and size

1. ''Drug Facts'' is set in 14 point Helvetica Bold Italic, left justified.

2. ''Drug Facts (continued)'' is set in 8 point Helvetica Bold Italic for the words ''Drug Facts'' and 8 point Helvetica Regular for the word ''(continued)'' and is left justified.

3. The headings (e.g., ''Directions'') are set in 8 point Helvetica Bold Italic, left justified.

4. The subheadings (e.g., ''Ask a doctor or pharmacist before use if you are'') are set in 6 point Helvetica Bold, left justified.

5. The information is set in 6 point Helvetica Regular with 6.5 point leading, left justified.

6. The heading ''Purpose'' is right justified.

7. The bullet is a 5 point solid square.

8. Two em spacing separates bullets when more than one bullet is on the same line.

9. A table format is used for 3 or more dosage directions.

10. A graphic appears at the bottom of the first panel leading the reader to the next panel.

C. Barlines and hairlines

1. A 2.5-point horizontal barline extends to each end of the ''Drug Facts'' box (or similar enclosure), providing separation between each of the headings.

2. A 0.5-point horizontal hairline extends within 2 spaces on either side of the ''Drug Facts'' box (or similar enclosure), immediately following the title and immediately preceding the subheadings.

3. A 0.5-point horizontal hairline follows the title, immediately preceding the heading, when a heading appears on a subsequent panel immediately after the ''Drug Facts (continued)'' title.

D. Box or Enclosure

1. All information is enclosed by a 2.5-point barline.

II. Section 201.66 Modified Labeling Format

A. Overall

1. The ''Drug Facts'' labeling is presented in all black type printed on a white color contrasting background.

B. Typeface and size

1. ''Drug Facts'' is set in 9 point Helvetica Bold Italic, left justified.

2. The headings (e.g., ''Directions'') are set in 8 point Helvetica Bold Italic, left justified.

3. The subheadings (e.g., ''Ask a doctor or pharmacist before use if you are'') are set in 6 point Helvetica Bold, left justified.

4. The information is set in 6 point Helvetica Regular with 6.5 point leading, left justified.

5. The heading ''Purpose'' is right justified.

6. The bullet is a 5 point solid square.

7. Bulleted information may start on same line as headings (except for the ''Warnings'' heading) and subheadings, with 2 em spacing separating bullets, and need not be vertically aligned.

C. Barlines and hairlines

1. A 2.5-point horizontal barline extends to each end of the ''Drug Facts'' box (or similar enclosure), providing separation between each of the headings.

2. A 0.5-point horizontal hairline extends within 2 spaces on either side of the ''Drug Facts'' box (or similar enclosure), immediately following the title and immediately preceding the subheadings.

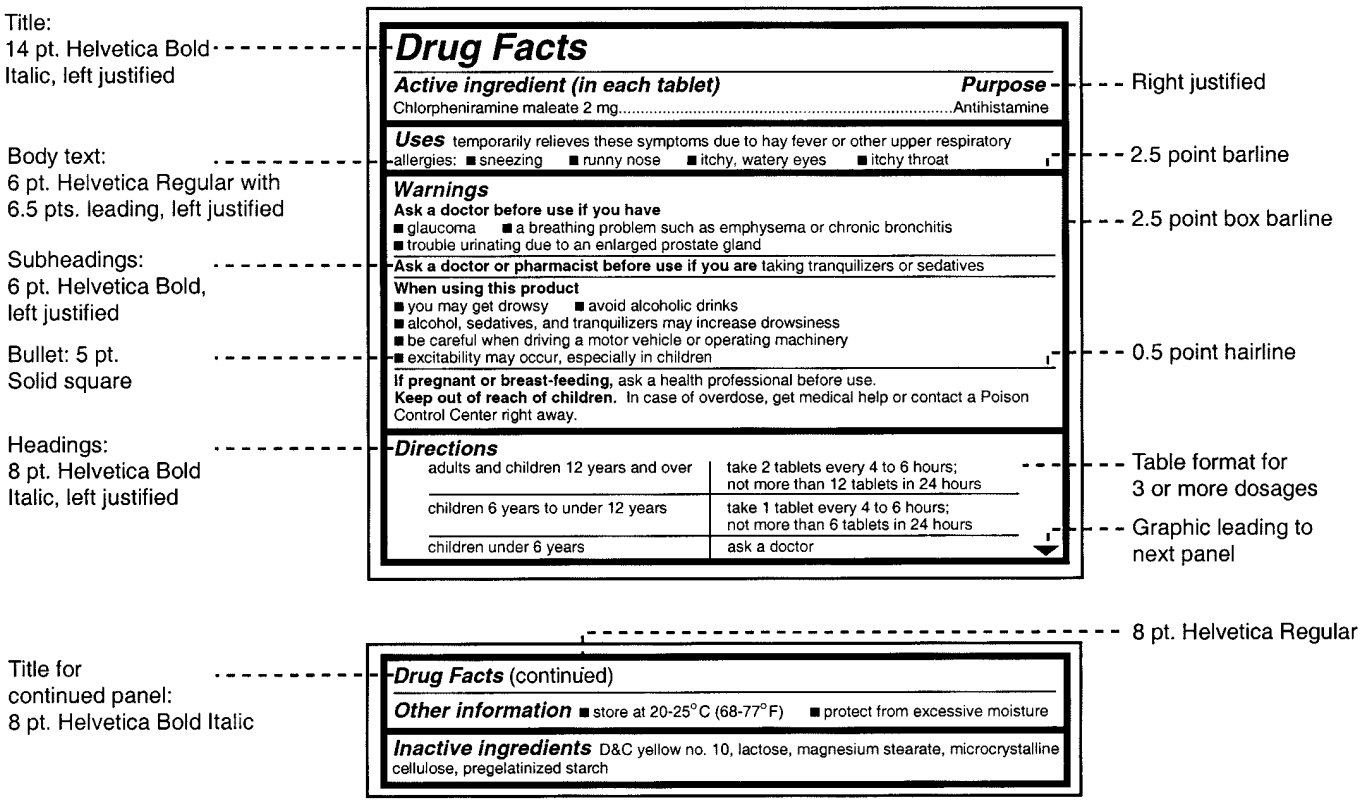
D. Box or Enclosure

1. All information is set off by color contrast. No barline is used.

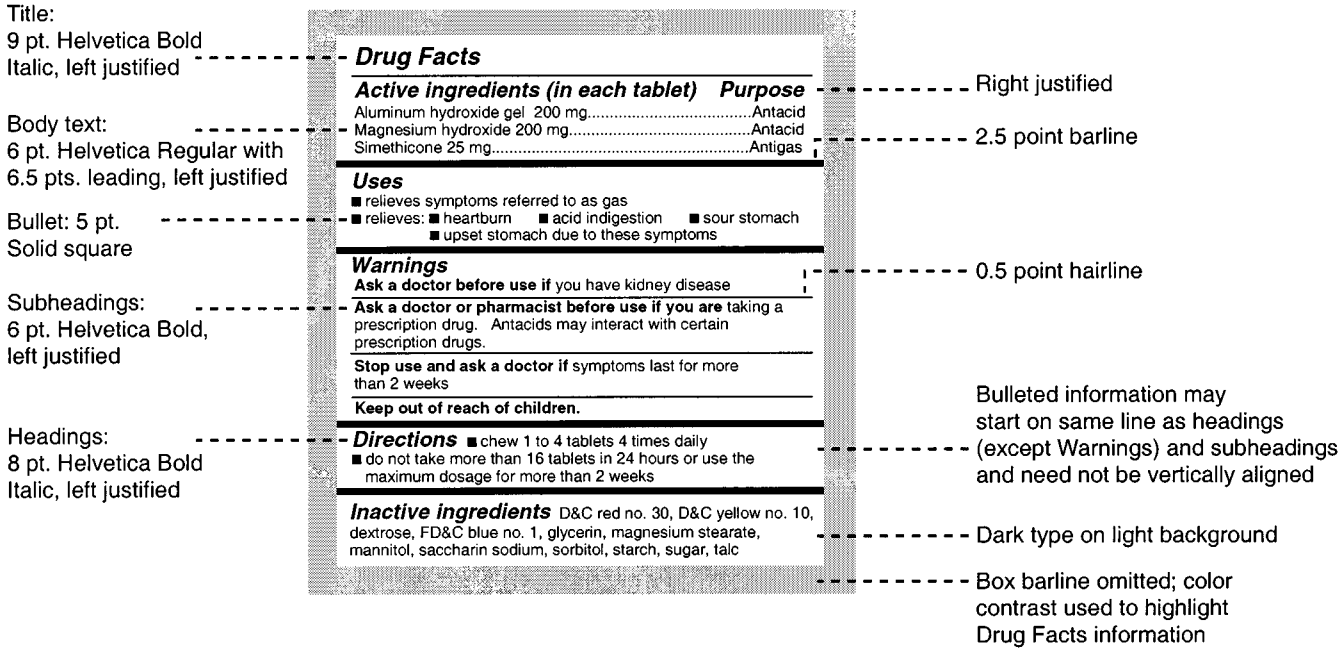
BILLING CODE 4160–01–F

III. Examples of § 201.66 Standard Labeling and Modified Labeling Formats

A. Section 201.66 Standard Labeling Format



B. Section 201.66 Modified Labeling Format



BILLING CODE 4160–01–C

PART 330—OVER–THE–COUNTER (OTC) HUMAN DRUGS WHICH ARE GENERALLY RECOGNIZED AS SAFE AND EFFECTIVE AND NOT MISBRANDED

8. The authority citation for 21 CFR part 330 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

9. Section 330.1 is amended by revising paragraphs (c)(1), (c)(2), (i), and (j), and by removing the first three sentences in paragraph (g) and adding two sentences in their place to read as follows:

§ 330.1 General conditions for general recognition as safe, effective, and not misbranded.

* * * * *

(c)(1) The product is labeled in compliance with chapter V of the Federal Food, Drug, and Cosmetic Act (the act) and subchapter C *et seq.* of this chapter, including the format and content requirements in § 201.66 of this chapter. An OTC drug product that is not in compliance with chapter V and subchapter C, including § 201.66 of this chapter, is subject to regulatory action. For purposes of § 201.61(b) of this chapter, the statement of identity of the product shall be the term or phrase used in the applicable OTC drug monograph established in this part.

(2) The ''Uses'' section of the label and labeling of the product shall contain the labeling describing the ''Indications'' that have been established in an applicable OTC drug monograph or alternative truthful and nonmisleading statements describing only those indications for use that have been established in an applicable monograph, subject to the provisions of section 502 of the act relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act. Any other labeling under this subchapter and subchapter C *et seq.* of this chapter shall be stated in the exact language where exact language has been established and identified by quotation marks in an applicable OTC drug monograph or by regulation (e.g., § 201.63 of this chapter), except as provided in paragraphs (i) and (j) of this section.

* * * * *

(g) The labeling for all drugs contains the general warning: ''Keep out of reach of children.'' [highlighted in bold type]. The labeling of drugs shall also state as follows: For drugs used by oral administration, ''In case of overdose, get medical help or contact a Poison Control Center right away''; for drugs used topically, rectally, or vaginally and not intended for oral ingestion, ''If swallowed, get medical help or contact a Poison Control Center right away''; and for drugs used topically and intended for oral use, ''If more than used for'' (insert intended use, e.g., pain) ''is accidentally swallowed, get medical help or contact a Poison Control Center right away.'' * * *

* * * * *

(i) The following terms may be used interchangeably in the labeling of OTC drug products, provided such use does not alter the meaning of the labeling that has been established and identified in an applicable monograph or by regulation. The following terms shall not be used to change in any way the title, headings, and subheadings required under § 201.66(c)(1) through (c)(9) of this chapter:

(1) ''Abdominal'' or ''stomach'' (in context only).

(2) ''Administer'' or ''give''.

(3) ''Aggravate(s)'' or ''make(s) worse''.

(4) ''Application of this product'' or ''applying''.

(5) ''Are uncertain'' or ''do not know''.

(6) ''Ask'' or ''consult'' or ''contact''.

(7) ''Asking'' or ''consulting''.

(8) ''Assistance'' or ''help'' or ''aid''.

(9) ''Associated with'' or ''due to'' or ''caused by''.

(10) ''Avoid contact with eyes'' or ''do not get into eyes''.

(11) ''Avoid inhaling'' or ''do not inhale''.

(12) ''Before a doctor is consulted'' or ''without first consulting your doctor'' or ''consult your doctor before''.

(13) ''Beverages'' or ''drinks''.

(14) ''Clean'' or ''cleanse''.

(15) ''Consulting'' or ''advising''.

(16) ''Continue(s)'' or ''persist(s)'' or ''is persistent'' or ''do(es) not go away'' or ''last(s)''.

(17) ''Daily'' or ''every day''.

(18) ''Develop(s)'' or ''begin(s)'' or ''occur(s)''.

(19) ''Difficulty'' or ''trouble''.

(20) ''Difficulty in urination'' or ''trouble urinating''.

(21) ''Discard'' or ''throw away''.

(22) ''Discontinue'' or ''stop'' or ''quit''.

(23) ''Doctor'' or ''physician''.

(24) ''Drowsiness'' or ''the drowsiness effect''.

(25) ''Drowsiness may occur'' or ''you may get drowsy''.

(26) ''Enlargement of the'' or ''an enlarged''.

(27) ''Especially in children'' or especially children''.

(28) ''Exceed'' or ''use more than'' or ''go beyond''.

(29) ''Exceed recommended dosage'' or ''use more than directed''.

(30) ''Excessive'' or ''too much''.

(31) ''Excitability may occur'' or ''you may get excited''.

(32) ''Experience'' or ''feel''.

(33) ''For relief of'' or ''relieves''.

(34) ''For temporary reduction of'' or ''temporarily reduces''.

(35) ''For the temporary relief of'' or ''temporarily relieves''.

(36) ''For the treatment of'' or ''treats''.

(37) ''Frequently'' or ''often''.

(38) ''Give to'' or ''use in''.

(39) ''Immediately'' or ''right away'' or ''directly''.

(40) ''Immediately'' or ''as soon as''.

(41) ''Immediately following'' or ''right after''.

(42) ''Improve(s)'' or ''get(s) better'' or ''make(s) better''.

(43) ''Increased'' or ''more''.

(44) ''Increase your risk of'' or ''cause''.

(45) ''Indication(s)'' or ''Use(s)''.

(46) ''Inhalation'' or ''puff''.

(47) ''In persons who'' or ''if you'' or ''if the child''.

(48) ''Instill'' or ''put''.

(49) ''Is (are) accompanied by'' or ''you also have'' (in context only) or ''(optional: that) occur(s) with''.

(50) ''Longer'' or ''more''.

(51) ''Lung'' or ''pulmonary''.

(52) ''Medication(s)'' or ''medicine(s)'' or ''drug(s)''.

(53) ''Nervousness, dizziness, or sleeplessness occurs'' or ''you get nervous, dizzy, or sleepless''.

(54) ''Not to exceed'' or ''do not exceed'' or ''not more than''.

(55) ''Obtain(s)'' or ''get(s)''.

(56) ''Passages'' or ''passageways'' or ''tubes''.

(57) ''Perforation of'' or ''hole in''.

(58) ''Persistent'' or ''that does not go away'' or ''that continues'' or ''that lasts''.

(59) ''Per day'' or ''daily''.

(60) ''Presently'' or ''now''.

(61) ''Produce(s)'' or ''cause(s)''.

(62) ''Prompt(ly)'' or ''quick(ly)'' or ''right away''.

(63) ''Reduce'' or ''minimize''.

(64) ''Referred to as'' or ''of''.

(65) ''Sensation'' or ''feeling''.

(66) ''Solution'' or ''liquid''.

(67) ''Specifically'' or ''definitely''.

(68) ''Take'' or ''use'' or ''give''.

(69) ''Tend(s) to recur'' or ''reoccur(s)'' or ''return(s)'' or ''come(s) back''.

(70) ''To avoid contamination'' or ''avoid contamination'' or ''do not contaminate''.

(71) ''To help'' or ''helps''.

(72) ''Unless directed by a doctor'' or ''except under the advice of a doctor'' or ''unless told to do so by a doctor''.

(73) ''Use caution'' or ''be careful''.
(74) ''Usually'' or ''generally'' (in context only).
(75) ''You'' (''Your'') or ''the child'' (''the child's'').
(76) ''You also have'' or ''occurs with''.
(77) ''When practical'' or ''if possible''.
(78) ''Whether'' or ''if''.
(79) ''Worsen(s)'' or ''get(s) worse'' or ''make(s) worse''.

(j) The following connecting terms may be deleted from the labeling of OTC drug products, provided such deletion does not alter the meaning of the labeling that has been established and identified in an applicable monograph or by regulation. The following terms shall not be used to change in any way the specific title, headings, and subheadings required under § 201.66(c)(1) through (c)(9) of this chapter:
(l) ''And''.
(2) ''As may occur with''.
(3) ''Associated'' or ''to be associated''.
(4) ''Consult a doctor''.
(5) ''Discontinue use''.
(6) ''Drug Interaction Precaution''.
(7) ''Due to''.
(8) ''Except under the advice and supervision of a physician''.
(9) ''If this occurs''.
(10) ''In case of''.
(11) ''Notice''.
(12) ''Or''.
(13) ''Occurring with''.
(14) ''Or as directed by a doctor''.
(15) ''Such as''.
(16) ''Such as occurs with''.
(17) ''Tends to''.
(18) ''This product''.
(19) ''Unless directed by a doctor''.
(20) ''While taking this product'' or ''before taking this product''.
(21) ''Within''.

* * * * *

PART 331—ANTACID PRODUCTS FOR OVER–THE–COUNTER (OTC) HUMAN USE

10. The authority citation for 21 CFR part 331 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

11. Section 331.30 is amended by revising paragraph (d) to read as follows:

§ 331.30 Labeling of antacid products.

* * * * *

(d) *Drug interaction precaution*. The labeling of the product contains the following statement ''Ask a doctor or pharmacist before use if you are [bullet][1] presently taking a prescription drug. Antacids may interact with certain prescription drugs.''

* * * * *

PART 341—COLD, COUGH, ALLERGY, BRONCHODILATOR, AND ANTIASTHMATIC DRUG PRODUCTS FOR OVER–THE–COUNTER HUMAN USE

12. The authority citation for 21 CFR part 341 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

13. Section 341.74 is amended by revising paragraphs (c)(4)(v) and (c)(4)(vi) to read as follows:

§ 341.74 Labeling of antitussive drug products.

* * * * *

(c) * * *
(4) * * *
(v) *For products containing dextromethorphan or dextromethorphan hydrobromide as identified in § 341.14(a)(3) and (a)(4) when labeled for adults or for adults and children under 12 years of age. Drug interaction precaution*. ''Do not use if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.''
(vi) *For products containing dextromethorphan or dextromethorphan hydrobromide as identified in § 341.14(a)(3) and (a)(4) when labeled only for children under 12 years of age. Drug interaction precaution*. ''Do not give to a child who is taking a prescription monoamine oxidase inhibitor MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your child's prescription drug contains an MAOI, ask a doctor or pharmacist before giving this product.''

* * * * *

14. Section 341.76 is amended by revising paragraph (c)(4) to read as follows:

§ 341.76 Labeling of bronchodilator drug products.

* * * * *

(c) * * *
(4) *Drug interaction precaution*. ''Do not use if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.''

* * * * *

15. Section 341.80 is amended by revising paragraphs (c)(1)(i)(D) and (c)(1)(ii)(D) to read as follows:

§ 341.80 Labeling of nasal decongestant drug products.

* * * * *

(c) * * *
(1) * * *
(i) * * *
(D) *Drug interaction precaution*. ''Do not use if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.''
(ii) * * *
(D) *Drug interaction precaution*. ''Do not give to a child who is taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your child's prescription drug contains an MAOI, ask a doctor or pharmacist before giving this product.''

* * * * *

PART 346—ANORECTAL DRUG PRODUCTS FOR OVER–THE–COUNTER HUMAN USE

16. The authority citation for 21 CFR part 346 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

17. Section 346.50 is amended by revising paragraph (c)(7)(ii) to read as follows:

§ 346.50 Labeling of anorectal drug products.

* * * * *

(c) * * *
(7) * * *
(ii) ''Ask a doctor or pharmacist before use if you are [bullet][1] presently taking a prescription drug for high blood pressure or depression.''

* * * * *

[1] See § 201.66(b)(4) of this chapter.

[1] See § 201.66(b)(4) of this chapter.

PART 355—ANTICARIES DRUG PRODUCTS FOR OVER–THE–COUNTER HUMAN USE

18. The authority citation for 21 CFR part 355 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

19. Section 355.50 is amended by revising paragraphs (c)(1) and (c)(2) to read as follows:

§ 355.50 Labeling of anticaries drug products.

* * * * *

(c) * * *

(1) *For all fluoride dentifrice (gel, paste, and powder) products.* ''Keep out of reach of children under 6 years of age. [highlighted in bold type] If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.'' These warnings shall be used in place of the general warning statements required by § 330.1(g) of this chapter.

(2) *For all fluoride rinse and preventive treatment gel products.* ''Keep out of reach of children. [highlighted in bold type] If more than used for'' (select appropriate word: ''brushing'' or ''rinsing'') ''is accidentally swallowed, get medical help or contact a Poison Control Center right away.'' These warnings shall be used in place of the general warning statements required by § 330.1(g) of this chapter.

* * * * *

PART 358—MISCELLANEOUS EXTERNAL DRUG PRODUCTS FOR OVER–THE–COUNTER HUMAN USE

20. The authority citation for 21 CFR part 358 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

21. Section 358.650 is amended in paragraph (d)(1) by revising the information in the brackets to read as follows:

§ 358.650 Labeling of pediculicide drug products.

* * * * *

(d) * * *

(1) * * * [statement in boldface type].

* * * * *

PART 369—INTERPRETATIVE STATEMENTS RE WARNINGS ON DRUGS AND DEVICES FOR OVER–THE–COUNTER SALE

22. The authority citation for 21 CFR part 369 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 371.

23. Section 369.9 is revised to read as follows:

§ 369.9 General warnings re accidental ingestion by children.

Section 369.20 includes under certain items, but not all medicines, the statement: ''Keep this and all medicines out of children's reach. In case of overdose, get medical help or contact a Poison Control Center right away,'' or ''Keep out of reach of children.'' However, in view of the possibility of accidental ingestion of drugs, it is not only suggested but is recommended that one of these statements be used on the label of all drug products.

§ 369.20 Drugs; recommended warning and caution statements. [Amended]

24. Section 369.20 is amended as follows:

a. The entry ''NUX VOMICA AND STRYCHNINE PREPARATIONS.'' is revised to read as follows:

NUX VOMICA AND STRYCHNINE PREPARATIONS.

''Do not use more than the recommended dosage. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.''

b. The entry beginning ''SALICYLATES, INCLUDING ASPIRIN'' is revised to read as follows:

SALICYLATES, INCLUDING ASPIRIN AND SALICYLAMIDE (EXCEPT METHYL SALICYLATE, EFFERVESCENT SALICYLATE PREPARATIONS, AND PREPARATIONS OF AMINOSALICYLIC ACID AND ITS SALTS). (See also § 201.314 of this chapter.)

''Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away;'' or ''Keep out of reach of children.''

If the article is an aspirin preparation, it should bear the first of the above two warning statements. In either case, the above information should appear on the label.

Caution—For children under 3 years of age, consult your physician; or

Caution—For younger children, consult your physician.

One of the two immediately preceding caution statements is required on the label of all aspirin tablets, but such a statement is not required on the labels of other salicylates clearly offered for administration to adults only.

If offered for use in arthritis or rheumatism, in juxtaposition therewith, the statement:

Caution—If pain persists for more than 10 days, or redness is present, or in conditions affecting children under 12 years of age, consult a physician immediately.

c. The entry ''SALICYLATES: METHYL SALICYLATE (WINTERGREEN OIL).'' is revised to read as follows:

SALICYLATES: METHYL SALICYLATE (WINTERGREEN OIL). (See also §§ 201.303 and 201.314 of this chapter.)

''Do not use otherwise than as directed. Keep out of reach of children to avoid accidental poisoning. If swallowed, get medical help or contact a Poison Control Center right away.''

If the preparation is a counter-irritant or rubefacient the statement:

Caution—Discontinue use if excessive irritation of the skin develops. Avoid getting into the eyes or on mucous membranes.

If offered for use in arthritis or rheumatism, in juxtaposition therewith, the statement:

Caution—If pain persists for more than 10 days, or redness is present, or in conditions affecting children under 12 years of age consult a physician immediately.

d. The entry ''ZINC STEARATE DUSTING POWDERS.'' is revised to read as follows:

ZINC STEARATE DUSTING POWDERS.

''Keep out of reach of children; avoid inhaling. If swallowed, get medical help or contact a Poison Control Center right away.''

§ 369.21 Drugs; warning and caution statements required by regulations. [Amended]

25. Section 369.21 is amended as follows:

a. The entry '''COUGH–DUE–TO–COLD' PREPARATIONS (CARBETAPENTANE CITRATE).'' is revised to read as follows:

''COUGH–DUE–TO–COLD'' PREPARATIONS (CARBETAPENTANE CITRATE). (See § 310.201(a)(20) of this chapter.)

''Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.''

b. The entry ''SODIUM GENTISATE.'' is revised to read as follows:

SODIUM GENTISATE. (See §§ 201.314 and 310.301(a)(2) of this chapter.)

Warning—Do not give to children under 6 years of age or use for prolonged period unless directed by physician.

''Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.''

If offered for use in arthritis or rheumatism, in juxtaposition therewith, the statement:

Caution—If pain persists for more than 10 days, or redness is present, or

in conditions affecting children under 12 years of age, consult a physician immediately.

PART 701—COSMETIC LABELING

26. The authority citation for 21 CFR part 701 continues to read as follows:

Authority: 21 U.S.C. 321, 352, 361, 362, 363, 371, 374; 15 U.S.C. 1454, 1455.

27. Section 701.3 is amended by revising paragraph (d) to read as follows:

§ 701.3 Designation of ingredients.

* * * * *

(d) Where a cosmetic product is also an over-the-counter drug product, the declaration shall declare the active drug ingredients as set forth in § 201.66(c)(2) and (d) of this chapter, and the declaration shall declare the cosmetic ingredients as set forth in § 201.66(c)(8) and (d) of this chapter.

* * * * *

Dated: January 4, 1999.

Jane E. Henney

Commissioner of Food and Drugs.

Donna E. Shalala,

Secretary of Health and Human Services.

Note: The following Appendix A to the preamble will not appear in the Code of Federal Regulations.

BILLING CODE 4160–01–F

Appendix A to Preamble—Examples of Prototype OTC Drug Product Labeling

Example 1

Single Ingredient Product Using Standard Labeling Format*

Drug Facts

Active ingredient (in each tablet) — ***Purpose***

Chlorpheniramine maleate 2 mg ..... Antihistamine

Uses temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: ■ sneezing ■ runny nose ■ itchy, watery eyes ■ itchy throat

Warnings

Ask a doctor before use if you have

■ glaucoma ■ a breathing problem such as emphysema or chronic bronchitis
■ trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives

When using this product

■ you may get drowsy ■ avoid alcoholic drinks
■ alcohol, sedatives, and tranquilizers may increase drowsiness
■ be careful when driving a motor vehicle or operating machinery
■ excitability may occur, especially in children

If pregnant or breast-feeding, ask a health professional before use.
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

adults and children 12 years and over	take 2 tablets every 4 to 6 hours; not more than 12 tablets in 24 hours
children 6 years to under 12 years	take 1 tablet every 4 to 6 hours; not more than 6 tablets in 24 hours
children under 6 years	ask a doctor

Drug Facts (continued)

Other information ■ store at 20-25°C (68-77°F) ■ protect from excessive moisture

Inactive ingredients D&C yellow no. 10, lactose, magnesium stearate, microcrystalline cellulose, pregelatinized starch

* Note: 14 point Helvetica Bold Italic Title
8 point Helvetica Bold Italic Headings
6 point Helvetica Bold Subheadings
6 point Helvetica Regular Text
6.5 point Leading

Example 2

Combination Product Using Standard Labeling Format*
[Outer Carton]

Drug Facts

Active ingredients (in each 5 mL) ***Purpose***

Brompheniramine maleate 2 mg.....Antihistamine
Dextromethorphan HBr 10 mg.....Cough suppressant
Pseudoephedrine HCl 30 mg.....Nasal decongestant

Use temporarily relieves:
- sneezing
- runny nose
- nasal congestion
- cough

Warnings

Do not use if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson s disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have
- heart disease
- glaucoma
- diabetes
- thyroid disease
- high blood pressure
- cough that occurs with too much phlegm (mucus)
- trouble urinating due to an enlarged prostate gland
- a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis, or emphysema

Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers

When using this product
- **do not use more than directed**
- excitability may occur, especially in children
- drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery

Stop use and ask a doctor if
- you get nervous, dizzy, or sleepless
- cough lasts more than 7 days, comes back, or occurs with fever, rash, or headache that lasts. These could be signs of a serious condition.
- symptoms do not get better within 7 days or occur with a fever

If pregnant or breast-feeding, ask a health professional before use.
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Drug Facts (continued)

Directions
- take every 4 to 6 hours
- do not take more than 4 doses in 24 hours

adults and children 12 years and over	10 mL
children 6 years to under 12 years	5 mL
children under 6 years	ask a doctor

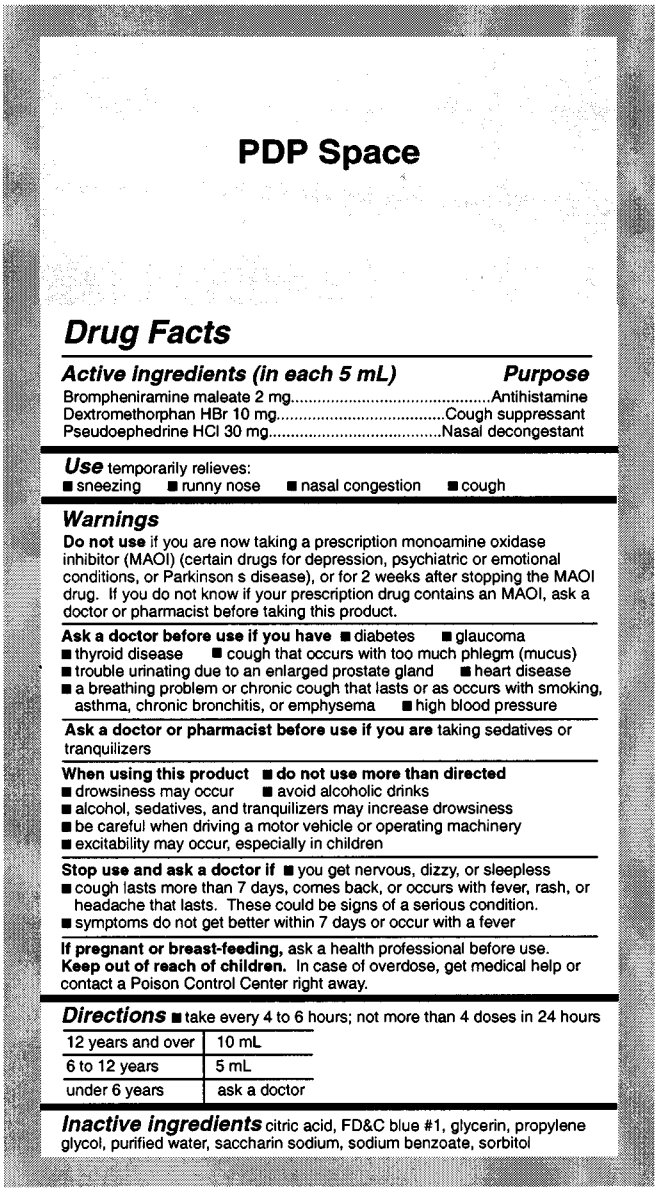
Inactive ingredients citric acid, FD&C blue #1, glycerin, propylene glycol, purified water, saccharin sodium, sodium benzoate, sorbitol

Questions? **123-555-1234**

* Note: 14 point Helvetica Bold Italic Title
8 point Helvetica Bold Italic Headings
6 point Helvetica Bold Subheadings
6 point Helvetica Regular Text
8 point Helvetica Bold Telephone Number
7 point Leading

Example 3

Combination Product Using Section 201.66(d)(10) Modified Format*
[Bottle with Wraparound Label, No Outer Carton]



PDP Space

Drug Facts

Active Ingredients (in each 5 mL)	***Purpose***
Brompheniramine maleate 2 mg	Antihistamine
Dextromethorphan HBr 10 mg	Cough suppressant
Pseudoephedrine HCl 30 mg	Nasal decongestant

Use temporarily relieves:
■ sneezing ■ runny nose ■ nasal congestion ■ cough

Warnings

Do not use if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson s disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have ■ diabetes ■ glaucoma ■ thyroid disease ■ cough that occurs with too much phlegm (mucus) ■ trouble urinating due to an enlarged prostate gland ■ heart disease ■ a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis, or emphysema ■ high blood pressure

Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers

When using this product ■ **do not use more than directed** ■ drowsiness may occur ■ avoid alcoholic drinks ■ alcohol, sedatives, and tranquilizers may increase drowsiness ■ be careful when driving a motor vehicle or operating machinery ■ excitability may occur, especially in children

Stop use and ask a doctor if ■ you get nervous, dizzy, or sleepless ■ cough lasts more than 7 days, comes back, or occurs with fever, rash, or headache that lasts. These could be signs of a serious condition. ■ symptoms do not get better within 7 days or occur with a fever

If pregnant or breast-feeding, ask a health professional before use. **Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

Directions ■ take every 4 to 6 hours; not more than 4 doses in 24 hours

12 years and over	10 mL
6 to 12 years	5 mL
under 6 years	ask a doctor

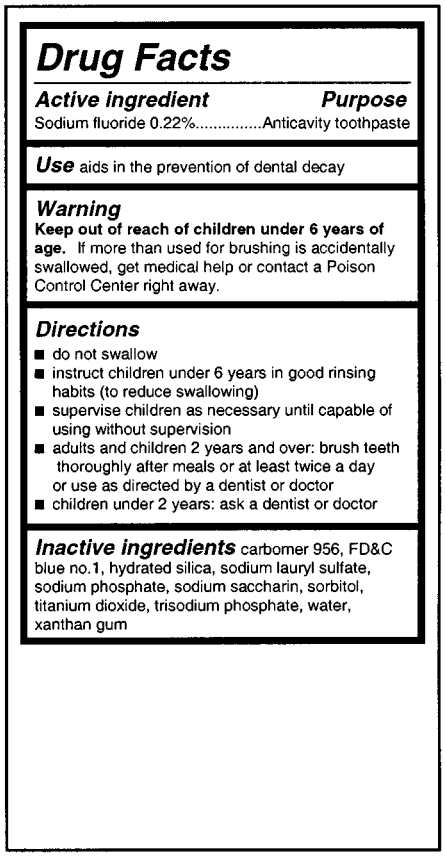
Inactive ingredients citric acid, FD&C blue #1, glycerin, propylene glycol, purified water, saccharin sodium, sodium benzoate, sorbitol

* Note: 12 point Helvetica Bold Italic Title
8 point Helvetica Bold Italic Headings
6 point Helvetica Bold Subheadings
6 point Helvetica Regular Text
6.5 point Leading

Box barline omitted; color contrast used to highlight Drug Facts information

Example 4

Product Using Standard Labeling Format*
[Stand Alone Tube, No Outer Carton]



Drug Facts

Active ingredient ***Purpose***
Sodium fluoride 0.22%.....Anticavity toothpaste

Use aids in the prevention of dental decay

Warning
Keep out of reach of children under 6 years of age. If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

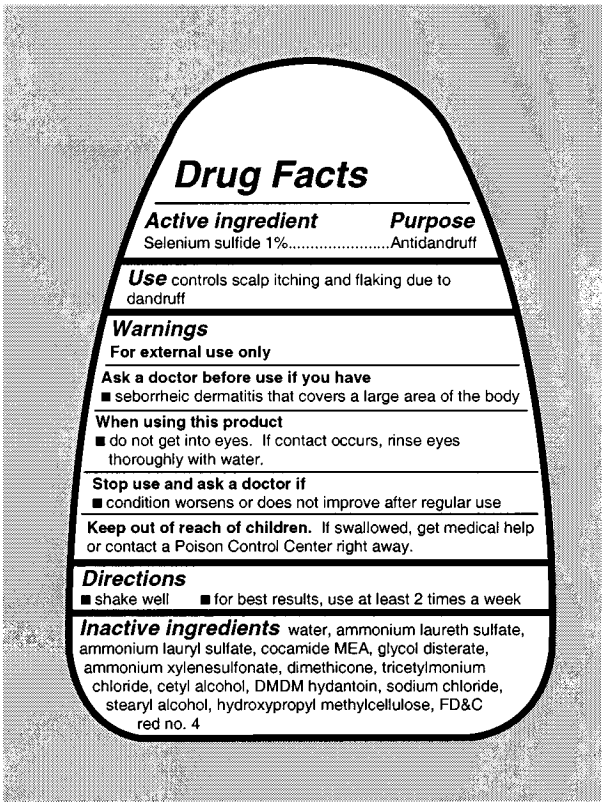
Directions
- do not swallow
- instruct children under 6 years in good rinsing habits (to reduce swallowing)
- supervise children as necessary until capable of using without supervision
- adults and children 2 years and over: brush teeth thoroughly after meals or at least twice a day or use as directed by a dentist or doctor
- children under 2 years: ask a dentist or doctor

Inactive ingredients carbomer 956, FD&C blue no.1, hydrated silica, sodium lauryl sulfate, sodium phosphate, sodium saccharin, sorbitol, titanium dioxide, trisodium phosphate, water, xanthan gum

* Note: 14 point Helvetica Bold Italic Title
8 point Helvetica Bold Italic Headings
6 point Helvetica Bold Italic Subheadings
6 point Helvetica Regular Text
7 point Leading

Example 5

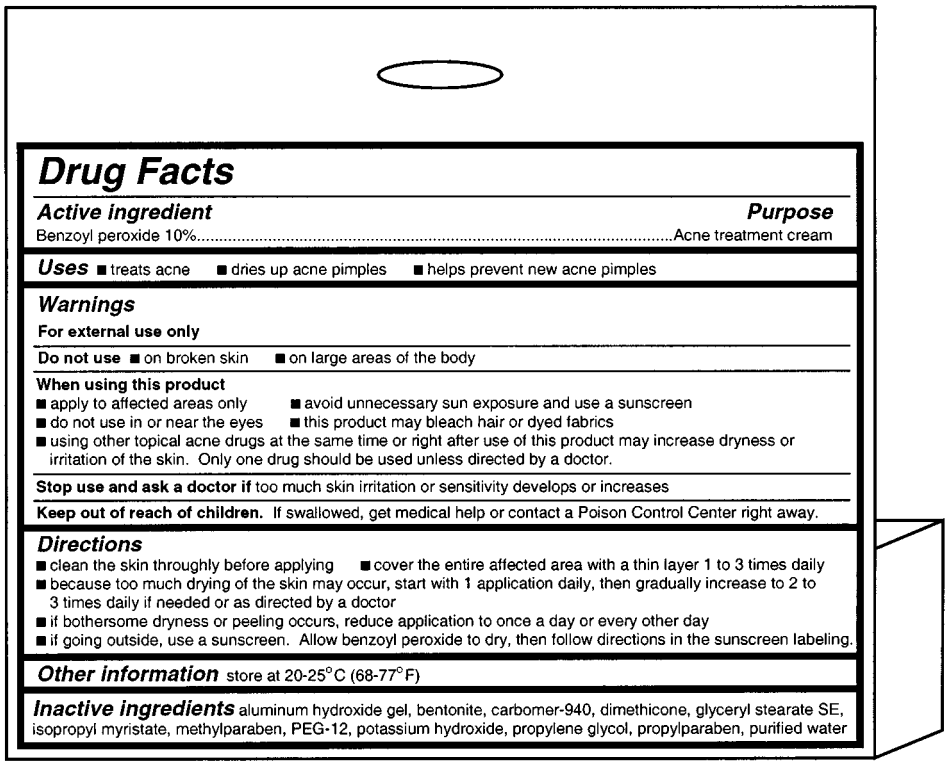
Drug-Cosmetic Product Using Standard Labeling Format*
[Irregular Shape Bottle Label, No Outer Carton]



* Note: 14 point Helvetica Bold Italic Title
8 point Helvetica Bold Italic Headings
6 point Helvetica Bold Subheadings
6 point Helvetica Regular Text
7 point Leading

Example 6

Product Marketed In A Tube Using Standard Labeling Format*
[Packaged In A Carton Riser]



Drug Facts

Active ingredient ***Purpose***

Benzoyl peroxide 10%.....Acne treatment cream

Uses ■ treats acne ■ dries up acne pimples ■ helps prevent new acne pimples

Warnings

For external use only

Do not use ■ on broken skin ■ on large areas of the body

When using this product

■ apply to affected areas only ■ avoid unnecessary sun exposure and use a sunscreen
■ do not use in or near the eyes ■ this product may bleach hair or dyed fabrics
■ using other topical acne drugs at the same time or right after use of this product may increase dryness or irritation of the skin. Only one drug should be used unless directed by a doctor.

Stop use and ask a doctor if too much skin irritation or sensitivity develops or increases

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

■ clean the skin throughly before applying ■ cover the entire affected area with a thin layer 1 to 3 times daily
■ because too much drying of the skin may occur, start with 1 application daily, then gradually increase to 2 to 3 times daily if needed or as directed by a doctor
■ if bothersome dryness or peeling occurs, reduce application to once a day or every other day
■ if going outside, use a sunscreen. Allow benzoyl peroxide to dry, then follow directions in the sunscreen labeling.

Other information store at 20-25°C (68-77°F)

Inactive ingredients aluminum hydroxide gel, bentonite, carbomer-940, dimethicone, glyceryl stearate SE, isopropyl myristate, methylparaben, PEG-12, potassium hydroxide, propylene glycol, propylparaben, purified water

* Note: 14 point Helvetica Bold Italic Title
8 point Helvetica Bold Italic Headings
6 point Helvetica Bold Subheadings
6 point Helvetica Regular Text
7 point Leading

Example 7

Product Using Section 201.66(d)(10) Modified Format*
[Tube With Wraparound Label]

Drug Facts

Active ingredient (in each tablet) ***Purpose***
Calcium carbonate 500 mg.....Antacid

Use relieves: ■ sour stomach ■ acid indigestion ■ heartburn ■ upset stomach due to these symptoms

Warnings

Ask a doctor or pharmacist before use if you are taking a prescription drug. Antacids may interact with certain prescription drugs.

Stop use and ask a doctor if symptoms last more than 2 weeks

Keep out of reach of children.

Directions ■ chew 2 to 4 tablets. Repeat hourly if symptoms return. ■ do not take more than 16 tablets in 24 hours or use the maximum dosage more than 2 weeks

Other information

■ **each tablet contains:** calcium 200 mg

Inactive ingredients cornstarch, mineral oil, sucrose, talc

* Note: 9 point Helvetica Narrow Bold Italic Title
8 point Helvetica Narrow Bold Italic Headings
6 point Helvetica Narrow Bold Subheadings
6 point Helvetica Narrow Text
6 point Leading

[FR Doc. 99–6296 Filed 3–11–99; 11:59 am]
BILLING CODE 4160–01–C

Federal Register

Wednesday
March 17, 1999

Part III

Department of Agriculture

Cooperative State Research, Education, and Extension Service

Food and Agricultural Sciences National Needs Graduate Fellowship Grants Program for Fiscal Year 1999: Request for Proposals and Request for Input; Notice

DEPARTMENT OF AGRICULTURE

Cooperative State Research, Education, and Extension Service

Food and Agricultural Sciences National Needs Graduate Fellowship Grants Program for Fiscal Year 1999: Request for Proposals and Request for Input

AGENCY: Cooperative State Research, Education, and Extension Service.

ACTION: Notice of request for proposals and Request for Input.

SUMMARY: The Cooperative State Research, Education, and Extension Service (CSREES) announces the availability of grant funds and requests proposals for the Food and Agricultural Sciences National Needs Graduate Fellowship Grants Program for Fiscal Years (FY's) 1999 and 2000, and for FY 1999 Supplemental Grants for Special International Study or Thesis/Dissertation Research Travel Allowances. Proposals are hereby requested from eligible institutions as identified herein for competitive consideration of National Needs Graduate Fellowship Grant awards. Additionally, CSREES seeks proposals from recipients of currently active Food and Agricultural Sciences National Needs Fellowship Grants for supplemental grants to support special international study or thesis/dissertation research experiences for current Fellows. By this notice CSREES additionally solicits stakeholder input from any interested party regarding the FY 1999 request for proposals for this program.

DATES: Proposals for Food and Agricultural Sciences National Needs Graduate Fellowship Grants must be received on or before June 7, 1999. Proposals received after the closing date will not be considered for funding. Proposals for supplemental grants to support special international study or thesis/dissertation research experiences for current Fellows must be received by February 16, 2000. Comments regarding this request for proposals are requested within six months from the issuance of this notice. Comments received after that date will be considered to the extent practicable.

ADDRESSES: Written stakeholder comments should be submitted by first-class mail to: Office of Extramural Programs; Competitive Research Grants and Awards Management; USDA-CSREES; STOP 2299; 1400 Independence Avenue, S.W.; Washington, D.C. 20250–2299, or via e-mail to: RFP-OEP@reeusda.gov. In your comments, please include the name of the program and the fiscal year solicitation of applications to which you are responding.

FOR FURTHER INFORMATION CONTACT: Howard E. Sandberg, Ph.D., Higher Education Programs; Cooperative State Research, Education, and Extension Service; U.S. Department of Agriculture; STOP 2251; 1400 Independence Avenue, S.W.; Washington, D.C. 20250–2251; telephone: (202) 720–2193; e-mail: hsandberg@reeusda.gov.

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Stakeholder Input

CSREES is soliciting comments regarding this request for proposals from any interested party. These comments will be considered in the development of the next request for proposals for this program. Such comments will be forwarded to the Secretary or his designee for use in meeting the requirements of section 103(c)(2) of the Agricultural Research, Extension, and Education Reform Act of 1998 (Pub. L. 105–185). This section requires the Secretary to solicit and consider input on a current request for proposals from persons who conduct or use agricultural research, education, or extension for use in formulating the next year's request for proposals.

In your comments, please include the name of the program and the fiscal year request for proposals to which you are responding. Comments are requested within six months from the issuance of the request for proposals. Comments received after that date will be considered to the extent practicable.

Part I. Food and Agricultural Sciences National Needs Graduate Fellowship Grants

Section A—General Information

1. Administrative Provisions

This Program is subject to the provisions found at 7 CFR Part 3402 for the Food and Agricultural Sciences National Needs Graduate Fellowship Grants Program. These provisions set forth procedures to be followed when submitting grant proposals, rules governing the evaluation of proposals and the awarding of grants, and regulations relating to the post-award administration of grant projects.

2. Legislative Authority

The authority for this program is contained in Section 1417(b)(6) of the National Agricultural Research, Extension, and Teaching Policy Act of 1977, as amended (NARETPA) (7 U.S.C. 3152(b)(6)). This program is subject to the provisions found at 7 CFR Part 3402.

In accordance with the statutory authority, subject to the availability of funds, the Secretary of Agriculture, who has delegated the authority to the Administrator of CSREES, may make competitive grants, for periods not to exceed five years, to land-grant colleges and universities, to colleges and universities having significant minority enrollments and a demonstrable capacity to carry out the teaching of food and agricultural sciences, and to other colleges and universities having a demonstrable capacity to carry out the teaching of food and agricultural sciences, to administer and conduct graduate fellowship programs to help meet the Nation's needs for development of scientific and professional expertise in the food and agricultural sciences. For this program, the term ''food and agricultural sciences'' means basic, applied, and

developmental research, extension, and teaching activities in food and fiber, agricultural, renewable natural resources, forestry, and physical and social sciences, including activities related to subject areas defined in section 1404(8) of NARETPA, 7 U.S.C. 3103(8).

3. Catalog of Federal Domestic Assistance

This program is listed in the Catalog of Federal Domestic Assistance under No. 10.210, Food and Agricultural Sciences National Needs Graduate Fellowship Grants.

4. Eligibility

Proposals may be submitted by institutions that confer a graduate degree in at least one area of the food and agricultural sciences targeted for national needs fellowships. For proposals involving more than one institution, all institutions must meet the eligibility requirement. Proposals may also be submitted by a research foundation maintained by an eligible college or university.

Section B—Program Description

1. Purpose of the Program

This program seeks to award grants to colleges and universities which have notable teaching and research competencies in the food and agricultural sciences. The grants are specifically intended to support fellowship programs that encourage outstanding students to pursue and complete a Ph.D. degree at such institutions in an area of the food and agricultural sciences for which there is a national need for the development of scientific and professional expertise.

2. Targeted National Need Areas

Food and agricultural sciences areas appropriate for fellowship grant applications are those in which shortages of expertise have been determined and targeted by CSREES for national needs graduate fellowship support. Beginning with FY 1997, CSREES supports six national need areas on a biennial basis and combines appropriations from two fiscal years into one competition to be held during odd-numbered years. The targeted national need areas to be supported for the combined FY 1999/2000 competition are: (1) Biotechnology—Animal; (2) Biotechnology—Plant; (3) Engineering—Food, Forest Products, or Agricultural; (4) Human Nutrition and/or Food Science; (5) Marketing or Management—Food, Forest Products, or Agribusiness; and (6) Water Science.

3. Degree Level Supported

In FY 1999/2000, only the doctoral level of study will be supported.

4. Proposal Submission Limitations

A doctoral degree-granting institution may only submit a maximum of six proposals, and no more than one proposal may be submitted in any one national need area.

5. Limitations on Number of Fellowships

For the FY 1999/2000 program, a proposal may request funding in only one national need area. A proposal may request a minimum of two fellowships and a maximum of four fellowships in the national need area for which funding is requested. While proposals must document institution willingness to recruit and train at least two, but not more than four, fellows in a national need area, CSREES may fund fewer fellows than requested in a proposal.

6. Available Funding

CSREES anticipates that approximately $5,600,000 will be available for fellowship grants for the FY 1999/2000 combined competition, including $2.8 million from FY 1999 appropriations and $2.8 million in anticipated FY 2000 appropriations. Contingent on the availability of these funds, approximately $933,000 will be allocated to each of the six national needs areas. This program is highly competitive, and it is anticipated that available funding will support approximately 81 doctoral fellows through approximately seven grants in each of the six targeted areas. No-year funds drawn from expired fellowship grants with unspent funds remaining may be used to fund additional fellows. Please note that Congress has not yet enacted a Fiscal Year 2000 appropriations bill for the Department. Therefore, the $5.6 million cited for FY 1999/2000 grants is only tentative and USDA is not bound by this estimate. If Congress appropriates other than the anticipated amount, the combined appropriated FYs 1999 and 2000 funds will be allocated equally among all six national need areas.

7. Stipend Level

Each institution funded will receive $69,000 for each doctoral fellowship awarded. However, it is anticipated that total program funds available will not be evenly divisible by $69,000. Therefore, one fellowship may be supported on a partial basis with a lesser amount of funds, or one fellowship may be supported fully by a combination of FY 1999/2000 funds and unspent funds remaining from expired fellowship grants. Except in the case of a partially funded fellowship, fellowship monies must be used to: (1) support the same doctoral fellow for three years at $22,000 per year; and (2) provide for an institution annual cost-of-education allowance of $1,000, not to exceed a total of $3,000 over the duration of the grant. Total funds awarded to an institution under the program in FY 1999/2000 shall not exceed $648,000.

Section C—How to Obtain Application Materials

An Application Kit containing program application materials will be made available to eligible institutions upon request. These materials include the Administrative Provisions, Solicitation, forms, instructions, and other relevant information needed to prepare and submit grant proposals. Copies of the application kit may be requested from the Proposal Services Unit; Office of Extramural Programs; Cooperative State Research, Education, and Extension Service; U.S. Department of Agriculture; STOP 2245; 1400 Independence Avenue, S.W.; Washington, D.C. 20250–2245. The telephone number is 202–401–5048. When contacting the Proposal Services Unit, please indicate that you are requesting forms for the FY 1999 National Needs Graduate Fellowship Grants Program.

Application materials may also be requested via Internet by sending a message with your name, mailing address (not e-mail) and phone number to psb@reeusda.gov which states that you want to receive a copy of the application materials for the Fiscal Year 1999/2000 Food and Agricultural Sciences National Needs Graduate Fellowship Grants Program. The materials will then be mailed to you (not e-mailed) as quickly as possible.

Section D—Submission of a Proposal

1. What to Submit

An original and seven (7) copies of a proposal must be submitted. Proposals should contain all requested information when submitted. Each proposal should be typed on 8½'' x 11'' white paper, double-spaced, and on one side of the page only. Please note that the text of the proposal should be prepared using a font no smaller than 12 point and one-inch margins. All copies of the proposal must be submitted in one package. Each copy of the proposal must be stapled securely in the upper left-hand corner (DO NOT BIND).

The proposal should be paginated and a Table of Contents should be included

preceding the proposal narrative. Applicants are cautioned to comply with the 20-page limitation for the narrative section of the proposal. Applicants also are cautioned to include summary faculty vitae through the use of Form CSREES–708.

2. Where and When to Submit

Hand-delivered proposals (brought in person by the applicant or through a courier service) must be received on or before June 7, 1999, at the following address: National Needs Graduate Fellowship Grants Program; c/o Proposal Services Unit; Office of Extramural Programs; Cooperative State Research, Education, and Extension Service; U.S. Department of Agriculture; Room 303, Aerospace Center; 901 D Street, S.W.; Washington, D.C. 20024. The telephone number is (202) 401–5048. Proposals transmitted via facsimile (fax) machine will not be accepted.

Proposals submitted through the U.S. mail must be received on or before June 7, 1999. Proposals submitted through the U.S. mail should be sent to the following address: National Needs Graduate Fellowship Grants Program; c/o Proposal Services Unit; Office of Extramural Programs; Cooperative State Research, Education, and Extension Service; U.S. Department of Agriculture; STOP 2245; 1400 Independence Avenue, S.W.; Washington, D.C. 20250–2245.

3. Acknowledgment of Proposals

The receipt of all proposals will be acknowledged in writing and via the Internet (e-mail). Therefore it is important to include your e-mail address on Form CSREES–712 when applicable. This acknowledgment will contain a proposal identification number. Once your proposal has been assigned a proposal number, please cite that number in future correspondence.

4. Intent to Submit a Proposal

Submission of an Intent to Submit a Proposal form (Form CSREES–706) is neither required nor requested for the FY 1999/2000 competition.

Section E—Selection Process and Evaluation Criteria

Section 223(2) of the Agricultural Research, Extension, and Education Reform Act of 1998, Public Law 105–185, amended section 1417 of NARETPA to require that certain priorities be given in awarding grants for teaching enhancement projects under section 1417(b) of NARETPA. This program is authorized under section 1417(b). CSREES considers all applications received in response to this solicitation as teaching enhancement project applications. To implement the new priorities for proposals submitted for the FY 1999/2000 competition, the evaluation criteria used to evaluate proposals, as provided in the Administrative Provisions for this program (7 CFR 3402.19), have been modified to include new criteria for proposals demonstrating enhanced coordination among eligible institutions and focusing on innovative, multidisciplinary education programs, material, or curricula. The following criteria and weights will be used to evaluate proposals submitted for funding to the FY 1999/2000 competition:

(A) 30 points—The degree to which the proposal establishes clearly that the proposed program of graduate study will result in the development of outstanding scientific/professional expertise related to the national need area and will do so in a reasonable period of time.

(B) 10 points—The degree to which the proposal contains any special features such as a focus on innovative, multidisciplinary education programs, material, or curricula; enhanced coordination among institutions eligible for grants under the Food and Agricultural National Needs Fellowship Grant Program; an inter-disciplinary, multi-disciplinary, or cross-disciplinary approach, an unusual collateral specialization in a related discipline, experiential learning opportunities, unique mentoring programs, seminars, or a multi-university collaborative approach.

(C) 20 points—The degree to which the proposal substantiates clearly that the institution's faculty, facilities and equipment, instructional support resources, and other academic attributes are excellent for providing outstanding graduate study and research at the forefront of science and technology related to the chosen area of national need.

(D) 20 points—The degree to which the institution's plans and procedures for recruiting and selecting academically outstanding Fellows and for advising and guiding Fellows through a program of study reflect excellence as documented in the proposal.

(E) 10 points—The degree to which supplementary summary data substantiate program quality in the targeted need area.

(F) 10 points—The quality of the proposal as reflected by its substantive content, organization, clarity, and accuracy.

Part II. 1999 Special International Study or Thesis/Dissertation Research Travel Allowances

Section A—General Information

1. Administrative Provisions

This Program is subject to the provisions found at 7 CFR Part 3402. These provisions set forth procedures to be followed when submitting grant proposals, rules governing the evaluation of proposals, the awarding of grants, and regulations relating to the post-award administration of such grants.

The Administrative Provisions (7 CFR part 3402) for this program specify that, based on the amount of funds appropriated in any fiscal year, CSREES will determine whether a new competition for special international study or thesis/dissertation research travel allowances will be held during that fiscal year, and publish that determination as part of the annual program announcement.

2. Legislative Authority

The authority for this program is contained in Section 1417(b)(6) of the National Agricultural Research, Extension, and Teaching Policy Act of 1977, as amended (NARETPA) (7 U.S.C. § 3152(b)(6)).

3. Catalog of Federal Domestic Assistance

This program is listed in the Catalog of Federal Domestic Assistance under No. 10.210.

4. Announcement of Availability of Supplemental Grants

CSREES has determined that a new competition for special international study or thesis/dissertation research travel allowances will be held during FY 1999, and hereby solicits proposals for competitive supplemental grants. In accordance with the Administrative Provisions for the Food and Agricultural Sciences National Needs Graduate Fellowship Grants Program (7 CFR 3402.5(e)), CSREES will award supplemental grants, on a competitive basis, for special international study or thesis/dissertation research travel allowances.

5. Eligibility

Institutions eligible to receive supplemental grants are those that have active National Needs Graduate Fellowship Grants (awarded in FY 1998 or earlier). Eligibility for this opportunity is limited to any current Fellow with sufficient time to complete the international experience before the termination date of the fellowship grant under which he/she is supported.

Before the international study or thesis/dissertation research travel may commence, a Fellow must have completed one academic year of full-time study, as defined by the institution, under the fellowship appointment and arrangements must have been formalized for the Fellow to study and/or conduct research in the foreign location(s). All national need areas previously supported under the Food and Agricultural Sciences National Needs Graduate Fellowships Grants Program are eligible for the supplementary grants for special international study or thesis/dissertation research travel allowances.

Section B—Program Description

1. Purpose of the Program

These supplementary grants provide support for a fellow to conduct special international study thesis/dissertation research or to undertake studies at a site outside of the United States primarily for the pursuit of activities that are not generally available within the United States.

2. Available Funding

Estimated funds for supplemental grants in FY 1999 are approximately $60,000. These funds are obtained from no-year funds drawn from expired fellowship grants with unspent funds remaining. CSREES has determined that no FY 1999 appropriations will be targeted to supplemental grants supporting special international study or thesis/dissertation research travel allowances.

3. Travel Allowance

For each travel allowance, the institution may request up to $5,000. Travel allowance monies may be used only to pay travel and living expenses for the Fellow while the Fellow is on the specific international assignment as proposed in the application for the special international study or thesis/dissertation research travel allowance. No limitation is placed on the number of applications an institution may submit. Awards will be made to the extent possible based on availability of funds. To the extent possible, all applications associated with one CSREES grant number should be submitted at the same time in order to facilitate the award of these supplemental grants and minimize accounting activity at the grantee institution.

Section C—How to Obtain Application Materials

An Application Kit containing program application materials will be made available to eligible institutions upon request. These materials include the Administrative Provisions, Solicitation, forms, instructions, and other relevant information needed to prepare and submit a proposal. Copies of the Application Kit may be requested from the Proposal Services Unit; Office of Extramural Programs; Cooperative State Research, Education, and Extension Service; U.S. Department of Agriculture; STOP 2245; 1400 Independence Avenue, S.W.; Washington, D.C. 20250–2245. The telephone number is 202–401–5048. When contacting the Proposal Services Unit, please indicate that you are requesting an Application Kit for the FY 1999 Special International Study or Thesis/Dissertation Research Supplemental Grant.

Application Kits may also be requested via Internet by sending a message with your name, mailing address (not e-mail) and telephone number to psb@reeusda.gov which states that you wish to receive a copy of the Application Kit for the FY 1999 Special International Study or Thesis/Dissertation Research Supplemental Grant. The materials will then be mailed to you (not e-mailed) as quickly as possible.

Section D—Submission of a Proposal

1. What to Submit

An original plus six copies of each application must be submitted. Proposals should contain all requested information when submitted. Each proposal should be typed on 8½″ x 11″ white paper, double-spaced, and on one side of the page only. Please note that the text of the proposal should be prepared using a font no smaller than 12 point and one-inch margins. Each copy of the application should be stapled securely in the upper left-hand corner (DO NOT BIND). All copies of the application must be submitted in one package. Applications transmitted via a facsimile (FAX) machine will not be accepted.

A separate application must be submitted by a fellowship grant project director at an eligible institution on behalf of each Fellow for which a special international study or thesis/dissertation research travel allowance is requested.

Each application must include an ''Application for Funding,'' Form CSREES–661, and a ''Budget,'' Form CSREES–55. To provide the office of Higher Education Programs (HEP) with sufficient information upon which to evaluate the merits of the requests for a special international study or thesis/dissertation research travel allowance, each application for a supplemental grant must contain a narrative which provides the following: (1) the specific destination(s) and duration of the travel; (2) the specific study or thesis/dissertation research activities in which the Fellow will be engaged; (3) how the international experience will contribute to the Fellow's program of study; (4) a budget narrative specifying and justifying the dollar amount requested for the travel; (5) summary credentials of both the U.S. and international faculty or other professionals with whom the Fellow will be working during the international experience (summary credentials must not exceed three pages per person; ''Summary Vita—Teaching Proposal,'' Form CSREES–708, may be used for this purpose); (6) a letter from the dean of the Fellow's college or equivalent administrative unit supporting the Fellow's travel request and certifying that the travel experience will not jeopardize the Fellow's satisfactory progress toward degree completion; and (7) a letter from the fellowship grant project director certifying the Fellow's eligibility, the accuracy of the Fellow's travel request, and the relevance of the travel to the Fellow's advanced degree objectives.

The narrative portion of the application must not exceed 10 pages, excluding the summary vita/vitae.

2. Where and When to Submit

Applications for the special international study or thesis/dissertation research travel allowance supplemental grants may be submitted at any time prior to February 16, 2000. However, to allow time for CSREES to process the applications, proposals should be submitted at least three months prior to the proposed beginning date of the international research project. Applicants are urged to submit their proposals early.

(**Note:** Proposals for these special supplemental awards should not be submitted as part of the application for a FY 1999/2000 Graduate Fellowship grant.)

Hand-delivered proposals (brought in person by the applicant or through a courier service) must be received on or before February 16, 2000, at the following address: Special International Study or Thesis/Dissertation Research Supplemental Grant; c/o Proposal Services Unit; Office of Extramural Programs; Cooperative State Research, Education, and Extension Service; U.S. Department of Agriculture; Room 303, Aerospace Center; 901 D Street, S.W.; Washington, D.C. 20024. The phone

number is 202–401–5048. Proposals transmitted via a facsimile (fax) machine will not be accepted.

Proposals submitted through the U.S. mail must be received on or before February 16, 2000. Proposals submitted through the U.S. mail should be sent to the following address: Special International Study or Thesis/Dissertation Research Supplemental Grant; c/o Proposal Services Unit; Office of Extramural Programs; Cooperative State Research, Education, and Extension Service; U.S. Department of Agriculture; STOP 2245; 1400 Independence Avenue, S.W.; Washington, D.C. 20250–2245.

3. Acknowledgment of Proposals

The receipt of all proposals will be acknowledged in writing and via the Internet (e-mail). Therefore it is important to include your e-mail address on Form CSREES–712 when applicable. This acknowledgment will contain a proposal identification number. Once your proposal has been assigned a proposal number, please cite that number in future correspondence.

Section E—Selection Process and Evaluation Criteria

Applications for the special international travel allowances will be evaluated as they are received until available funds for the supplemental grants are exhausted. Upon receipt of an application, CSREES staff will first determine the eligibility of the Fellow for whom the application was submitted for an international travel experience. Eligible and complete requests then will be reviewed, using the criteria and weights indicated below, by professional staff from USDA or other Federal agencies, as appropriate. Proposals judged to be worthy of funding will be eligible for supplemental awards. Since awards for supplemental grants will be made as reviews are completed, there is no assurance funds will be available late in the application period for every acceptable proposal.

The evaluation criteria for special international study or thesis/dissertation research travel allowance applications are indicated below. The points are provided as a guide to the relative importance of each criterion, but all criteria must be addressed satisfactorily.

a. Destination and duration—the degree to which the destination and duration of the travel experience is appropriate for enhancing the Fellow's academic program—10 points.

b. Travel experience activities—the degree to which the specific international experiences contribute to the Fellow's program of study—30 points.

c. Advance preparations—the degree to which the proposed study or research activities are well-planned, including the likelihood that these activities will come to fruition and that the participation of identified personnel will materialize—20 points.

d. Budget—the degree to which the budget for the international experience is justified—10 points.

e. Personnel—the degree to which the personnel, both U.S. and international, involved with the travel experience have the appropriate credentials and experience to direct the Fellow's international experience, and the likelihood that their participation as mentors, trainers, advisors, or teachers will contribute to the educational value of the travel experiences—20 points.

f. Supporting documentation—the degree to which letters from the dean of the college (or equivalent administrative unit) and the fellowship grant project director support the application—10 points.

Done at Washington, D.C., this 11th day of March 1999.

Colien Hefferan,

Acting Administrator, Cooperative State Research, Education, and Extension Service.

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LIST OF PUBLIC LAWS

This is a continuing list of public bills from the current session of Congress which have become Federal laws. It may be used in conjunction with ''P L U S'' (Public Laws Update Service) on 202–523–6641. This list is also available online at http://www.nara.gov/fedreg.

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.R. 882/P.L. 106–2

To nullify any reservation of funds during fiscal year 1999 for guaranteed loans under the Consolidated Farm and Rural Development Act for qualified beginning farmers or ranchers, and for other purposes (Mar. 15, 1999; 113 Stat. 5)

Last List March 11, 1998

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